

Supporting Patient and Consumer Involvement in Patient Centered Outcomes Research Meeting Summary

Agency for Healthcare Research and Quality
Community Forum
Wednesday, July 13, 2011

On July 13, 2011, the Agency for Healthcare Research and Quality's (AHRQ) Community Forum project convened an advisory panel to discuss how best to involve patients and consumers in its Effective Health Care (EHC) Program. The purpose of the meeting was to guide the Community Forum team in developing tools and resources to support and expand patient and consumer contributions to patient-centered outcomes research. AHRQ's EHC Program, which conducts and supports comparative effectiveness research (CER), funds individual researchers, research centers, and academic organizations who collaborate with the Agency to develop and disseminate evidence-based information to patients, clinicians, and other decision-makers. Input from patients and consumers throughout the EHC Program's research processes can improve research quality and assure that research is relevant, important, and responsive to patients' and consumers' needs.

AHRQ's Community Forum, initiated in 2010, seeks to improve and expand public and stakeholder engagement in the Agency's Effective Health Care (EHC) Program.

The AHRQ panel consisted of patients and consumers who have had the experience of representing the patient perspective on research projects, as well as people who have worked with existing training programs to facilitate patient and consumer collaboration in research and regulatory activities. The names, titles and affiliations of the panelists are listed in Appendix A. The discussion provided insight on techniques and resources to effectively and efficiently identify appropriate patient and consumer representatives; mechanisms to best support and train patient and consumer representatives; managing patient and consumer relationships with researchers; and strategies for partnering with patients and consumers in the translation and dissemination of research products.

Patient and Consumer Involvement in Research. Patient and consumer representatives bring an important perspective to the research team. When involved early in the research process, they can assist the research team by articulating the questions that are most important to facilitate patients' decisions, the outcomes of

greatest interest to them, and how patients access and apply evidence to decision-making. Collaborating with patient and consumer representatives at each stage in the research process improves the relevance and applicability of research findings.

Expanding Patient and Consumer Involvement in Patient-Centered Outcomes Research. Programs such as AHRQ's EHC Program must address four broad tasks to effectively engage patients and consumers in their work. These are:

1. Outreach to Patient and Consumer Representatives
2. Support for Patient and Consumer Representatives
3. Managing the Patient and Consumer Relationship with Researchers
4. Partnering with Patients to Disseminate Research Products.

This report describes the major ideas and themes emerging from panel discussions at the July 13th meeting on each of these topics in turn, followed by overarching themes. We conclude with a summary of concrete suggestions for involving patients and consumers in AHRQ's EHC program.

Outreach to Patient and Consumer Representatives

Patient Role & Characteristics. Patient and consumer representatives include patients, patient advocates, community advocacy group members, family members and patients' primary caregivers. These individuals should be recognized as having a specific expertise (personal experience with a condition) that is a valuable contribution to the research team – no different from other experts, e.g., statisticians, who bring a specific expertise to the process.

Patients and consumers can bring a range of perspectives. Identifying the "right" patient/consumer representative is largely dependent on the goals of the particular project or meeting. Toward that end, the expected role and required training of representatives should be clearly established prior to recruitment efforts. This includes clearly articulating the purpose of the meeting or activity, and the objectives both of the meeting as a whole and for patient/consumer participation. Based on these objectives, meeting conveners should create a description of the type of patient perspective they will seek to match the activity's purpose.

Panelists identified a number of characteristics that they believe are important for an effective patient/consumer representative. By definition, the individual must have personal experience with the disease in question. They should be objective and able to move beyond their own personal experience to represent others. Researchers should be cognizant of where a patient is in his or her journey with the condition they are experiencing. Patients who have been recently diagnosed or are at a particularly intense or acute point may not be ready or available to collaborate on research activities.

Patient/consumer representatives should be knowledgeable about a range of treatment options, or about important treatment options. It is helpful if they have prior experience that has brought them in contact with other patients, as this gives them the ability to represent a broader patient/consumer perspective. They may be (or may have been) involved or affiliated with a patient or consumer advocacy organization or they may simply have contact with other patients through networking or through online communities. Individuals who are comfortable speaking extemporaneously in public will be most easily able to express their views in a group setting, but those initially reluctant to speak can learn how to do so more effectively with guidance.

A final consideration is that patient/consumer representatives have no conflicts of interest that would significantly affect the research process. This includes financial conflicts such as from receiving an honorarium for participation in a similar research effort, or non-financial conflicts such as involvement in advocacy activities that limit the individual's ability to maintain objectivity. Conflict of interest is a broadly recognized concern; however, panelists acknowledged that the complete absence of conflicts may not be a realistic goal. At a minimum, though, all participants should fully disclose their interests in advance. Panelists stressed the importance of talking with patient/consumer representatives during the recruitment process to uncover personal agendas and conflicts of interest, as well as to assess their ability to represent others.

Panelists suggested a series of recruitment approaches to determine if an individual would be an appropriate patient/consumer representative for a given project. First, as noted above, the researcher should clearly outline the intent for involving the patient/consumer representative by establishing objectives, roles and expectations before beginning the recruitment process. Based on this exercise, the researcher can develop a specific description of the experience needed and request résumés from

potential participants. Résumés requested should be specific to the representative's experience with a health condition, including advocacy activities and previous involvement in research activities (involvement in peer-review of research, IRB review experience, etc).

Conducting telephone interviews is a useful part of the recruitment process, as it provides an opportunity to learn more about the patient/consumer representative while also allowing the researcher to elaborate on the details of the upcoming project. As noted above, interviews and conversations with potential representatives are also important for determining their ability to objectively represent the patient experience devoid of any personal agendas or conflicts. Finally, panelists noted that the recruitment process should be bi-directional in nature. Patient/consumer representatives should be encouraged to ask questions up front about what will be expected of them so that they can make an informed decision about participating.

Locating Patient/Consumer Representatives. Identifying patient/consumer representatives for involvement in research activities requires dedicated resources and should be adequately accounted for in project timelines. When possible, networking with known patient and consumer organizations is an efficient approach to identifying experienced representatives. Centralized patient advocate groups (e.g., Patient Advocates In Research, Consumers United for Evidence-based Health Care, and the Research Advocacy Network), government agencies (e.g., FDA Patient Representative Program, Congressionally Directed Medical Research Programs), and disease-specific organizations (e.g., National Breast Cancer Coalition Project LEAD®, and Ovarian Cancer National Alliance (OCNA)) provide research training opportunities for patient/consumer advocates and have an existing infrastructure for transparent and fair recruitment practices. They are valuable sources for recommending and identifying trained patient/consumer representatives.

Panelists also noted that patient/consumer representatives themselves are valuable resources for identifying other representatives. Through their participation in research projects and their networks with other patient/consumer representatives, they can serve as a resource both for identifying and recommending other individuals based on a project's need. Networking with patient/consumer representatives and including them on selection committees is an effective means for identifying new representatives for research collaboration.

Many patients and consumers may want to become involved in research but not be aware of how to do so. Creating pathways for patient/consumer representatives to identify opportunities will facilitate their involvement. Existing networks of patient/consumer representatives— e.g., the FDA Patient Advocacy Network, NBCCs ProjectLEAD®, or Cochrane Consumers Network – offer researchers an avenue for providing regular information on opportunities for involvement, for example through newsletters, listserv updates, or Facebook® pages that these networks regularly use for communicating with members. Panelists recognized the challenges in identifying patient/consumer representatives from ethnically diverse and underserved populations. The panel recommended using multiple recruitment methods to identify a broader demographic including older patients, minorities, and the underserved. Organizations successful at recruiting minority and underserved populations were noted to do so by developing relationships and networks with faith-based and other special interest community organizations. Other approaches discussed for recruiting patient/ consumer representatives from underrepresented populations included working with social workers and local patient advocacy organizations, getting advice from support group leads, and publicizing opportunities through online groups.

Once patient/consumer representatives become involved in research activities, maintaining the relationship becomes equally important both to assure continuity for the duration of the immediate project and to facilitate future collaborations. Maintaining regular contact with representatives and providing updates through newsletters or listservs about current activities and new opportunities for involvement provides a meaningful way for researchers to develop a network of patient/consumer representatives.

Support for Patient and Consumer Representatives

The Importance of Training Activities. Panelists strongly emphasized the importance of training patient/consumer representatives with respect to research participation in general, as well as providing targeted training for specific projects and roles. Training should meet the appropriate level for the specific task or activity and take into account existing levels of knowledge and experience. For example, if the need is for the individual to share his or her personal experience with a condition or treatment as part of a key informant interview, extensive research training may not be necessary. However, if the representative is being asked to participate in formal efforts to prioritize

research, training will need to include information on the project background, purpose of the activity, the nature of the prioritization process, other participants, etc. The information should be provided well in advance and ideally, the representative should have an opportunity to ask clarifying or follow-up questions prior to the activity commencing.

Providing mentors to new patient/consumer representatives was also recommended to facilitate peer-to-peer training to prepare representatives for their involvement in providing input into research. For example, new patient/consumer representatives taking part in the CDMRP peer-review program are paired with an experienced consumer reviewer for mentoring on what to expect in the way of the pre-meeting work, how meetings are run, and how they can expect to contribute. Project LEAD® also employs mentorship as part of its training process. Groups of new ProjectLEAD® advocates are assigned a mentor who is responsible for checking in with them to ensure they have the information they need to effectively participate in the research process. In addition, the mentor can help the advocate with networking and identifying new opportunities for getting involved.

Training Programs for Participating in Research. Formal research training programs, such as those developed by organizations such as NBCC ProjectLEAD® and the Research Advocacy Network focus on teaching patient/consumer representatives a multitude of skills necessary for effective involvement. This includes training on technical aspects such as research processes and terminology as well as the training on interpersonal skills and assertiveness training that is necessary to work as an effective member of interdisciplinary teams. Training programs developed for collaboration in research activities should be on-going and multimodal. They should be based on adult learning models and move past theory to involve case-studies and applied practice. Training materials should be provided in plain language and in small quantities to avoid overwhelming the patient/consumer representative.

Panelists encouraged the use of existing resources for training patient/consumer representatives. For example, Consumers United for Evidence-based Healthcare has developed an excellent online training module “Understanding evidence-based healthcare: A foundation for action” that is publically available. This resource was developed to teach patient/consumer representatives about critical appraisal of scientific evidence as well as how evidence can be used in health care decisions. Other

examples of available resources are presented in Appendix B. These resources have been thoughtfully developed and are available publically to support successful patient/consumer involvement in research and related activities.

Other Means of Supporting Patient/Consumer Representatives. In addition to training activities, panelists discussed other ways in which researchers can support patient/consumer representatives' involvement throughout the research process. Patient/consumer representatives often become involved in research activities as volunteers. Identifying roadblocks to their participation (e.g., financial or time constraints) is important. When possible, providing honoraria or support for travel can offset financial burdens. Planning activities such as teleconferences outside of normal work hours can reduce the burden of taking time off from paid employment or other responsibilities in order to participate. Involving more than one patient/consumer representative in research activities is another approach to supporting involvement. Not only does this allow for a greater representation of the patient experience and perspective, it provides a sense of camaraderie and peer support for those representing the patient perspective.

Panelists indicated that formal and informal opportunities researchers can provide for patient/consumer representatives to meet others are valued experiences. Networking allows representatives to learn from each other about their experiences and identify new opportunities for getting involved in research-related activities. Examples of networking opportunities include participation in annual meetings (FDA holds an annual patient representative meeting), social media connections, listserv participation, and mentorship programs.

Panelists emphasized that patient and consumer representatives who participate in research desire ongoing engagement and information. Closing the information loop by providing feedback at all stages of the research process is vital. Feedback demonstrates to representatives how their input is being used, further supporting their understanding of the process. In addition, it affirms that the time and effort representatives spend engaging with researchers has an impact.

Finally, panelists noted the importance of providing support and training to researchers and science managers to understand the role patient/consumer representatives have in the process. The research team should respect patient/consumer representatives as an equal and important part of the team.

Recognizing that patient/consumer involvement throughout research activities is an evolving practice within healthcare research, research teams should ensure they have the necessary understanding to facilitate and support meaningful involvement.

Techniques to Manage the Relationship Between Patient/Consumer Representatives and Researchers

Articulate Expectations. Often, patient/consumer representatives are invited to attend activities but not meaningfully engaged, resulting in patients' perception that the involvement is merely "window dressing." Panelists agreed that an important aspect of maintaining productive working relationships between researchers and patient/consumer representatives is developing shared goals and understanding at the outset about what the role of all participants – researchers and others as well as patient/consumer representatives will be. Equally important is an understanding of roles each will *not* play. For example, patient representatives' role in the research process will be different from roles they may have played in other activities, such as direct patient support, fundraising, or even political action with an organization.

Providing adequate project materials in advance of any activity is important to support the patient/consumer in effectively fulfilling their expected role. Presenting a clear timeline and anticipated time commitment at each stage of the project is also helpful. Finally, throughout the activity, researchers should facilitate opportunities for patient/consumer representatives to voice their thoughts and allow them time to comment and participate.

A key point to successful collaborations was making the experience "personal." Efforts to develop a team dynamic, such as by providing opportunities to meet in person or interact outside of working sessions, is important for fostering successful working relationships. Efforts towards developing a sense of equality and partnership with patient/consumer representatives also facilitate effective collaborations. These can include steps such as eliminating degrees from nametags, offering equal honoraria to all participants, providing an opportunity for participants to connect outside of the research setting, providing patient/consumer representatives with plain language descriptions of key concepts (i.e., a glossary of terms), and ensuring that a designated individual recaps the conversation during meetings or telephone calls at a level all stakeholders can understand.

Additional considerations for effective collaborations include establishing clear rules and expectations for engagement among all participants, clear processes for resolving conflict, and formal processes for voting. Developing transparent processes for all participants engaged in an activity creates mutual understanding of expectations. Most importantly, evaluating the process is instrumental for future planning. Evaluations should capture the perspective of patient/consumer representatives, as well as those of researchers and others involved. Evaluation results should be provided to participants, as well as an indication of how the results have or will be used to modify the process.

Partnering with Patients to Disseminate Research Products

Disseminating research findings to patients and consumers is a critical step in the research process. Ideally, when research is intended to address important health information needs of patients and consumers, patient/consumer representatives or organizations should be involved early in the planning process. Developing ongoing relationships with well known and trusted patient and consumer organizations creates channels for disseminating findings, as well as for obtaining early input that will assure such findings will be relevant to the needs of patients. Patient/consumer representatives provide critical insight on how information is accessed and used. Specific points they can inform include determining the key message and making it easy to remember, producing information in a way that is readily accessible to consumers (e.g., including visuals), clarifying messages (e.g., “this does not work,” or “this can hurt you”). When messaging and products are developed, researchers should provide organizations and individuals with easy mechanisms for disseminating the information. For example, a short blurb that can be placed in a newsletter, or information for blogs or other social media outlets can be supplied.

Finally, panelists discussed the goal of getting beyond just distribution and dissemination of research products to measuring the impact of research products on changes in clinical practice and health outcomes. This step is necessary for understanding the effectiveness of research dissemination efforts. Including measures for evaluating how research dissemination efforts modify health practices and, where possible, how they affect health outcomes should be an integral part of research strategies.

Summary

Themes. Key themes for supporting patient and consumer involvement throughout research activities emerged from the day-long discussion including: the importance of relationship building and networks, creating transparent processes, building on current efforts that support research collaborations, ensuring the research team is accountable for recognizing the importance of patient/consumer representative involvement in research processes, and ensuring patient/ consumer representatives have the opportunity to evaluate their experience.

Recommendations. Panelists provided specific recommendations for activities and resources to support collaboration between patient/consumer representatives and researchers in the EHC Program. Recommendations made for consideration include:

- Create a centralized resource (database or website) where researchers can go to identify patient/consumer representatives
- Create a resource for patient and consumer representatives with information on research participation and networking opportunities, such as meeting other patients or learning about other patient/consumer experiences in research collaboration
- Foster relationships with key organizations representing patients and consumers whom AHRQ would like to involve in EHC Program Research activities
- Develop partnerships with known organizations to disseminate information
- Develop a glossary and lexicon of plain-language terms relevant to CER (including defining CER in clear terms) to facilitate patient/consumer involvement in EHC Program research
- Use the web to provide a portal of shared information on best practices in patient/consumer involvement
- Compile examples (cases studies) of the impact patient/consumer involvement has had on research activities (e.g., changed research priorities, modified key questions research has addressed, changed the outcomes measures used in a study)
- Explore existing training resources that can be accessed for supporting patient and consumer involvement and make EHC Program researchers aware of them
- Develop a process for providing feedback to patient/consumer representatives who have participated in research activities about the results of meetings and how their involvement informed the research process or outcomes

APPENDIX A:
Panelist Names and Affiliations

Technical Expert Panel (TEP) Members	Affiliation
Amy Bonoff	Patient Advocate, National Breast Cancer Coalition Project LEAD®
Carolyn Branson	Consumer Reviewer Administration Manager, SRA International
Deborah Collyar	President, Patient Advocates in Research (PAIR)
Virna Elly	Patient Advocate, Mid-Atlantic Renal Coalition
Nancy Fitton	Program Coordinator, Consumers United for Evidence-Based Healthcare (CUE)
Peg A. Ford	Research Patient Advocate, Ovarian Cancer Advocacy Alliance
Andrea Furia-Helms	Director, FDA Patient Representative Program
Lawrence Sadwin	Patient Advocate, American Heart Association
John Santa	Director Health Ratings Center, Consumers Union
Jennifer Sweeney	Director of Quality Health Care, National Partnership for Women

Appendix B

Examples of Training Resources

- Consumers United for Evidence-Based Healthcare (CUE)
 - Online Course: Understanding Evidence-based Healthcare: A foundation for action (<http://us.cochrane.org/evidence-based-healthcare-resources>)

- Cochrane Consumer Network : <http://consumers.cochrane.org/resources>
 - Consumer guides to commenting on Systematic reviews
 - Consumer guides to writing Plain Language summaries
 - Glossary of terms

- Research Advocacy Network: www.researchadvocacy.org
 - Roadmap to Research Advocacy
 - Advocate Institute

- Food and Drug Administration Patient Advocacy Program:
<http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/PatientInvolvement/ucm123858.htm>
 - Role of Patient Advocates in FDA Advisory Committees
 - Overview of the FDA process