



THE NATIONAL WORKING GROUP ON EVIDENCE-BASED HEALTH CARE

Advancing the Evidence of Experience:

Practical Issues for Patient/Consumer Inclusion

Forum Proceedings | June 2008 | Washington, DC

The Working Group

The Working Group is a collaboration of patient/consumer organizations, professional societies, providers, researchers, and other interested stakeholders that want to stay abreast of the developments and initiatives in evidence-based healthcare. Since January 2006, the Working Group has sought to educate and engage patient/consumer groups, as well as other stakeholders, and to advance the dialogue about meaningful participation by patient/consumer stakeholders in such efforts.



On March 6 and 7, The National Working Group on Evidence-Based Health Care (the Working Group) convened more than 80 patient/consumer advocates, decision-makers, regulators, and other stakeholders to discuss the importance of, and methods for, patient/consumer involvement in evidence-based healthcare (EBH).

One goal of the forum was to evaluate aspects of current patient engagement in the research continuum, which includes designing, prioritizing, conducting, translating/disseminating, and implementing research. In addition, the forum sought to facilitate the sharing of strategies and tactics to incorporate the patient/consumer perspective into EBH. The forum consisted of a series of expert panels featuring brief presentations by illustrious speakers and interactive discussions among meeting attendees.

Establishing a Common Language for Evidence-Based Healthcare

A common language should be established to facilitate effective communication among Working Group members, policymakers, patient/consumer advocates, patients/consumers, and other stakeholders around EBH. Specifically, meeting attendees struggled with the definitions of patient versus consumer; quality versus value; and EBH. Panelists at the meeting agreed that EBH should be defined by three equally weighted components: patient/consumer values and goals; physician expertise and values; and scientific evidence.

Communicating the Value of the Patient/Consumer Perspective

A commonly cited barrier to patient/consumer engagement in the research continuum is a lack of understanding of their benefit to the research process. Attendees and stakeholders noted the importance of patient-reported outcomes or “any aspect of a patient’s health status that comes directly from the patient”¹ as an important piece of evidence necessary for decision-making. Researchers, policymakers, and others need to be aware of the unique and important perspective, partnership, and “people power” patients/consumers can offer researchers, policymakers, and physicians.

Sending the Right Messages About EBH, CER

An important role of the Working Group moving forward will be to act as a resource for informing patients/consumers and legislators about the policy issues most relevant to patients/consumers surrounding EBH. Given the continued policy discussions around comparative effectiveness research (CER), it will be particularly important for the Working Group to ensure that CER legislation includes a strong role for patients, specifically in identifying areas for research and in translating, disseminating, and implementing CER into practice.

Creating Avenues for Engagement

Identifying the various ways Working Group members can engage in EBH is important. Working Group members should encourage patients/consumers to engage in discussions about their healthcare with their physician. In addition, patients/consumers can serve as resources to those conducting research and take action in the EBH policy debate by writing letters and speaking to legislators.

1. FDA. The Importance of Patient-Reported Outcomes ...It's All About the Patients. http://www.fda.gov/fdac/features/2006/606_patients.html. December 2006.

Including the Voice of the Patient/Consumer: A Broad Overview of Current Efforts

10:30 a.m. – 12:00 p.m.

Panelists: Jean Slutsky, Director, Effective Health Care Program (EHCP), Agency for Healthcare Research and Quality (AHRQ); Richard Klein, HIV/AIDS Program Director, Office of Special Health Issues, Food and Drug Administration (FDA); and Abby Block, Director, Center for Beneficiary Choices, Centers for Medicare & Medicaid Services (CMS)

“Inclusion of patients/consumers is no longer a question; it is a fact. The key question is how best to do it.”

Jean Slutsky, AHRQ

The session focused on the efforts of government programs to engage patients/consumers in research activities. Featured programs included: AHRQ, FDA, and CMS

- All of the program representatives noted the importance of including patients/consumers and recognizing their unique and valuable perspective; all have undertaken multi-pronged efforts to include patients/consumers in their research paradigms.
- Klein noted that patient/consumer involvement in FDA activities facilitates mutual learning such that the FDA is able to better understand the issues facing patients, while patients are able to better understand the demands on the agency. For example, FDA’s Patient Representative and Patient Consultant Programs help patients/consumers contribute to FDA product reviews in the areas of trial design, entry criteria, endpoints, drug toxicity issues, quality of life issues, study recruitment, informed consent, expanded access, product labeling, and reading and commenting on guidance.

- The sophistication and extent of patient/consumer involvement in the programs the speakers presented varied based on the activities of the program and the strategies and tactics employed.
 - > For instance, the AHRQ EHCP employs targeted efforts, like selecting patient/consumer representatives to serve on its Stakeholder Group as well as broad inclusion efforts through its calls for public comment. In addition, the John M. Eisenberg Clinical Decisions and Communications Science Center translates complex scientific information into short, plain language materials that can be used by patients, clinicians, and policymakers to assess treatments, medications, and technologies. The materials are field and focus-group tested prior to public release.
- The speakers noted that each program is continuing to take steps to increase the level of meaningful patient/consumer engagement.
 - > Block mentioned that CMS uses a number of tools, including Medicare’s Prescription Drug Plan Finder, to inform beneficiaries about consumer service, access to prescriptions, and drug pricing information.

A question and answer session followed the panel presentations. A participant asked if patient advocates really have the ability to play a role in determining patient-reported outcomes. Klein responded by stating that quality of life issues are difficult to quantify because they are not typically viewed as data that can be standardized or validated; therefore, it is difficult to compare data. There are efforts within the National Institutes of Health (NIH) to develop protocols and tools to assist in translating quality of life issues into standardized data sets that are useful.

Keynote Address

12:00 p.m. – 1:00 p.m.

Beverly Parker of the Y-ME National Breast Cancer Organization is a three-time breast cancer survivor. As the keynote, she described her experience over the past 23 years as a patient navigating the U.S. healthcare system. Parker researched her disease, treatment options, and side effects so that she was an equal partner with her practitioners in making treatment decisions that were the best for her. Her presentation underscored the need for patients to make their voice heard and to make values, perspectives, and goals part of their treatment decisions.

Clear Messages: Importance of Information Sharing, Translation, and Dissemination

1:00 p.m. – 2:30 p.m.

Panelists: Cheryl Matheis, Director Health Strategies, AARP Public Policy Institute; and Kay Dickerson, Director, U.S. Cochrane Center

Communicating valuable information to patients/consumers is an extremely difficult task. Panelists discussed efforts to communicate both directly with patients/consumers and advocates, and noted challenges in understanding which education strategies work. More research is needed to identify effective outreach efforts.

- AARP employs very sophisticated communication methods, including a variety of written publications and even a television program, *My Generation*, which covers issues from health and money to relationships and volunteering. Despite these efforts, AARP has been challenged in understanding which method works best. In order to evaluate the effectiveness of

various approaches, AARP has estimated that the cost of an evaluation would approximate the price of the communication effort itself and noted that only the federal government has the resources to conduct such an assessment.

- Dickerson presented an online tool designed to educate consumer advocates in understanding EBH basics, such as generating research questions, study design issues, statistical methods, and critical appraisals for making better decisions. The tool was created by the U.S. Cochrane Center to support Consumers United for Evidence-Based Healthcare (CUE), a membership organization that partners health and consumer advocacy organizations and EBH researchers.

A question and answer session followed the panel presentations. A participant asked how the concept of EBH is being translated to legislators. A panelist noted that payers were driving the conversation. Policymakers, in discussions about EBH, often focus on comparative effectiveness and cost-effectiveness. The panelist also spoke of the importance of the patient perspective when discussing EBH to ensure appropriate decisions are made with information collected through EBH.

Building Patient Preference into Research Agendas

2:45 p.m. – 4:30 p.m.

Panelists: Simon Whitney, Assistant Professor of Family and Community Medicine, Baylor College of Medicine; Sean Tunis, Director, Center for Medical Technology Policy (CMTP); William Riley, Program Chief, National Institutes of Mental Health (NIMH); and Mark Gorman, Director of Online Advocacy Programs, The National Coalition for Cancer Survivorship

Panelists noted that despite the value added by patients/consumers when they are engaged in research there remain obstacles to their participation.

- Whitney identified two significant barriers to patient involvement, including the habit of researchers to narrowly focus on the interesting scientific questions and the highly burdensome protocols required by Internal Review Boards to conduct research around patient perspectives and experiences.

In addition, panelists noted that patient values are often not considered throughout the research continuum, and the information garnered for patient decision-making is difficult to quantify and use within the confines of strict research protocols.

- Tunis pointed out the inability of the current research enterprise to answer questions important to healthcare decision-makers (including patients), arguing that research should be dictated by “decision-based evidence making.”
 - > Lack of guidance for manufacturers around the type of evidence decision-makers are seeking is an

issue CMTP is currently working to address. CMTP created a Patient Consumer Advisory Panel to inform its activities.

“Current clinical research enterprise is not producing all needed evidence; therefore, we need to expand capacity for decision-based evidence making.”

Sean Tunis, CMTP

- Riley discussed the NIH’s Patient-Reported Outcomes Measurement Information System (PROMIS), which seeks to develop new patient-reported outcome tools for use in research. The PROMIS tools measure patient-reported symptoms, such as pain and fatigue, and aspects of health-related quality of life.
- Gorman talked about the successes and challenges of being a patient advocate. He emphasized patient participation in research engagement opportunities, like the FDA’s Patient Consultant and Representative Programs, which allow patients to influence the type of research conducted. Patient participation in research evaluation helps to make evidence-based treatment a reality. In addition, robust information technology that delivers this evidence to the point-of-care will assist physicians in making better treatment decisions, according to Gorman and others. Further, electronic medical records will allow researchers to gather more data at the subpopulation level, which will result in the capture of more data on a variety of patients in a “real-world” setting.

A question and answer session followed the panel’s presentations. A participant highlighted the issue of

distinguishing subpopulations in research. A panelist discussed the inherent problem associated with making decisions regarding the individual based on information collected and averaged from a large data set. The panelist highlighted that one solution to this problem could be improved by health information technology.

Comparative Effectiveness Policy Debate: Opportunities for Patient and Consumer Involvement

4:30 p.m. – 5:15 p.m.

Panelists: Stuart Guterman, Senior Program Director, Medicare's Future, The Commonwealth Fund; Tanisha Carino, Vice President, Center on Evidence-Based Medicine, Avalere Health; and Bill Murphy, Director, Epilepsy Foundation

Generating more comparative information on drugs, devices, procedures, and healthcare systems has emerged as a means to “bend” the escalating U.S. healthcare-spending curve and encourage the provision of higher quality care for each healthcare dollar spent. Attendees and panelists emphasized the need for patients/consumers to have their voice heard in a united manner in the current CER debate, especially given the patient/consumer inclusion model articulated in recent CER legislation.

- Carino walked through the latest CER legislation and noted the importance of opportunities for patient and consumer engagement, highlighting Avalere’s recently conducted research to identify best practices for successful patient and consumer programs in EBH. They include:
 - > Establishing a champion to provide credible leadership; ensuring dedicated staff and funding are

available; seeking out willing and motivated volunteers; training patient and clinician participants; and measuring program success.

- Guterman presented a policy overview on the growing demand for CER, articulating the perspectives of various stakeholders.
- Murphy noted the challenge in identifying opportunities for patient/consumer engagement. Once opportunities are identified, it is important to ensure that the appropriate groups and/or persons are notified, positing the idea that the Working Group could possibly serve as a “matchmaking service.”

A question and answer session followed the panel’s presentations. The discussion focused on the importance of bringing the patient/consumer perspectives to bear on policy issues. Patient and consumer advocacy groups are a key voice in shaping policy and panelists challenged these groups to find ways to insert their perspectives into the policy process.

From Information to Implementation: Putting Individuals Back into Healthcare Decision-making

9:00 a.m. – 10:30 a.m.

Panelists: Carolyn Clancy, Director, AHRQ; Linda Harpole, Vice President, Global Health Outcomes, GlaxoSmithKline (GSK); Margaret C. Kirk, Chief Executive Officer, Y-ME National Breast Cancer Organization; Armin Ernst, Chief, Interventional Pulmonology, Director, Clinical Sponsored and Translational Research, Beth Israel Deaconess Medical Center; Brian Sweet, Chief Clinical Pharmacy Officer, Wellpoint, Inc.; Barry Straube, Director, Office of Clinical Standards and Quality, CMS; and Kristin Carmen Principal Research Scientist, American Institutes for Research

The panelists, representing a broad range of perspectives in healthcare, highlighted the various ways in which patients/consumers influence their respective healthcare decision-making processes.

- The federal government often involves patients/consumers through public comment, among other methods of engagement.
 - > Clancy noted AHRQ's EHCP which involves patients/consumers in setting research priorities and presents draft reports for public comment.
 - > Straube highlighted Medicare's Coverage and Analysis Group that solicits public comments to inform the national coverage decision-making processes.
- As a manufacturer, GSK incorporates patients into the research and development processes through a variety of mechanisms, such as Patient Insight Seminars. As part of the program, patients/consumers share, with scientists, the difficulties of living with a specific disease. Scientists then identify gaps and/or improvements that can be made in treatment options to better serve patients.
- A patient/consumer group, Y-ME National Breast Cancer Organization, stressed the importance of advocating for the patient/consumer when they do not have the means to translate information regarding their health. For example, Y-ME National Breast Cancer Organization provides a hotline to support breast cancer patients and their families in understanding and evaluating treatment options.
- Ernst, a provider at Beth Israel Deaconess Medical Center, encouraged providers to balance scientific evidence with the patient/consumer's goals and values.
 - > Ernst also recommended that providers consider the context in which a study is conducted when making treatment decisions. For instance, some studies are designed specifically to obtain FDA approval.
- Payers, like WellPoint, Inc., use high-grade evidence to ensure that coverage decisions meet the needs of patients and consumers. WellPoint is also increasingly using health outcomes data to capture the real-world experience of patients, while monitoring treatment and prescribing trends. This data is becoming a greater factor in coverage decision-making and ultimately ensuring that coverage decisions reflect the most effective treatment decisions.
- As a researcher, Carmen assessed current patient/consumer involvement and expressed the need for a starting point for patients/consumers to begin the engagement process building on their existing knowledge. Carmen and her colleagues developed a collection of tools patients/consumers can use to engage in healthcare decision-making.

“The concepts underlying evidence-based healthcare are complex...patients and consumers need the appropriate tools to support their decision-making.”

Kristin Carmen, American Institutes for Research

During the discussion, panelists debated the importance of health information in expanding patient literacy.

- Some panelists believe patients do not need or want to know all of the intricacies of EBH while others insisted on the importance of having a basic understanding of EBH concepts.
 - > Patients/consumers do not have the tools to weigh evidence and often rely on providers and patient/consumer groups to assist in the translation of evidence.
- Some panelists believe health literacy remains an obstacle to patient/consumer involvement. Patients and providers often do not have the same values, goals, and perceptions of high-quality care. Physicians have the training and tools to interpret evidence within the context of clinical expertise; patients have knowledge of experience. Better communication between physicians and patients helps to form a mutual understanding of the evidence and ensures that both parties make the appropriate treatment decisions.

A question and answer session followed the panel’s presentations. A participant asked about CMS’ strategy for determining coverage of orphan drugs. Straub noted that CMS’ coverage strategy is similar to that of drugs in broader categories, which includes weighing the evidence surrounding the treatment and determining whether the

treatment meets the needs of the Medicare population. In the future, CMS could potentially make coverage decisions in a more personalized fashion to meet the needs of individual patients.

Evidence-Based Healthcare Panel: Linking Comparative Effectiveness to Quality Improvement

10:45 a.m. – 12:00 p.m.

Panelists: Same as previous session

Continuing the discussion, panelists elaborated on how comparative effectiveness information can be used to improve healthcare quality. Specifically, they emphasized the importance of increasing transparency of clinical data, disseminating data in a meaningful way for patients/consumers, and utilizing patient/consumer groups to translate data based on patient values and goals.

- Panelists agreed that data transparency is an important step toward improving healthcare quality. With access to all available information, providers, payers, and patients/consumers can make informed decisions about their health.
 - > Health information technology can improve transparency, as well as support reducing medical errors, increasing care coordination, and facilitating more research.
- Appropriate evidence translation is crucial to improve health literacy. Tools and other resources suggesting actionable tasks for patients/consumers will allow for smooth initial engagement. For example, the AHRQ EHCP provides consumer summary guides to assist patients/consumers in healthcare decision-making.

- Patient/consumer groups serve as a resource in bridging the information gap between provider/policymaker/researcher and patient.

A question and answer session followed the panel presentations. A participant noted the importance of considering quality of life issues when discussing EBH. Payers and providers should take into account the reality of the patient's situation when making health-care decisions. For example, a patient is not concerned about the latest coverage decision when they are in the emergency room for pain; they are worried about what the physician is going to do to relieve that pain.

The forum was supported in part by Mental Health America, The National Working Group on Evidence-Based Health Care, and GlaxoSmithKline.

View Our Webcast

Advancing the Evidence of Experience: Practical Issues for Patient/Consumer Inclusion

View our webcast at: www.evidencebasedhealthcare.org

Next Steps

Educate Yourself

Patients/consumers need to take an active role in learning about their health. On an individual level, patients/consumers can start with one-on-one discussions with their physician. They should ask questions about their health-care and more importantly, leave with answers. Using online tools and other resources from AHRQ, patient/consumer groups will facilitate the learning process. Patients/consumers can ask the right questions when better informed. This will enable patients/consumers to influence the care they receive from their provider.

Engage to Shape EBH

Patient/consumer groups should partner with organizations throughout the research continuum to make sure patients/consumers have a voice. Moving forward, the Working Group will seek to work with these organizations to increase the effectiveness of the patient/consumer inclusion efforts and facilitate sharing of best practices among public and private entities. It is vital for patients/consumers to engage in this discussion to promote the production of evidence that is useful to patients/consumers and other healthcare decision-makers.

Continue to Make Your Voices Heard

Patient/consumer advocacy groups need to educate policymakers, researchers, and physicians on the valuable patient perspective and its ability to improve quality of evidence generation, translation, implementation, and, moreover the quality of care. Such advocacy efforts are particularly timely, given the ongoing CER debate. Patient/consumer groups should build coalitions with other stakeholder organizations and write letters to Congress to engage in the current CER debate.



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