The National Working Group on Evidence-Based Health Care

Consumer *forum* summary

"Nothing About Us Without Us:
Patient / Consumer Participation in Evidence-Based Health Care"
Consumer Forum Summary

On April 19, 2007, the National Working Group on Evidence-Based Health Care (the Working Group) hosted a consumer forum on the central role patients should play in evidence-based health care (EBH). The forum featured patient and expert panelists who discussed approaches to including patient insight and preferences in health care decision making.

The panels included the following:

Panel 1: The Value of Patient Perspectives

- Moderator: Bill Murphy/ Epilepsy Foundation & National Working Group on Evidence-Based Health Care
- Chris Ward/ Patient Participant
- Robert Ratchford/ Patient Participant
- Kay Wissmann/ Y-ME
- Perry Cohen/ Parkinson Pipeline Project

Panel 11: National Institute for Health and Clinical Excellence's Efforts to Engage Patients and the Public

- Andrea Sutcliffe/ National Institute for Health and Clinical Excellence (NICE)
- John Bridges/ Johns Hopkins Bloomberg School of Public Health

Panel 111: U.S. Food and Drug Administration's Patient Representative and Patient Consultant Programs

- JoAnn Minor/ Food and Drug Administration (FDA)
- Theresa Toigo/ FDA
- Musa Mayer, patient participant

Panel IV: Communicating the Science Correctly: Agency for Healthcare Research and Quality's John M. Eisenberg Center

- Jean R. Slutsky, Agency for Healthcare Research and Quality (AHRQ)
- Sandra Robinson/ John M. Eisenberg Clinical Decisions and Communications Science Center
- Linda Golodner/ National Consumers League

The Forum highlighted key points of consensus:

- Scientific evidence is one component in the equation for better health care. This equation balances science with clinical experience and patient values.
- Patient/ consumer involvement is imperative in the development, review and dissemination of evidence-based knowledge on health treatments, technologies and services.
- Adequate investment in including patients/ consumers in these processes is crucial.
- The organization conducting evidence-based research and subsequently developing and implementing decisions based upon that research are responsible for ensuring that patients/ consumers are prepared to fully participate in its process, and should respect and value patient/consumer input.
- Government, private and public-private entities should draw lessons and approaches from existing models from other nations, as well as in the U.S., of patient/ consumer involvement in evidence-based health care.
- Evidence is valuable in informing better communication and decision-making between the patient/ consumer and the treating provider.

As a result of this forum, the Working Group is developing guiding principles on roles and specific methods for patient/consumer involvement. This forthcoming paper will be disseminated and posted on the Working Group website at

www.evidencebasedhealthcare.org.

Welcome and Introductions

Speaker: Jennifer L. Bright/ Mental Health America & National Working Group on Evidence-Based Health Care

In her opening remarks, Ms. Bright offered an overview of the National Working Group on Evidence-Based Health Care and provided context around why patient and consumer participation in evidence-based health care is essential. She also outlined the goals of the Consumer Forum.

Ms. Bright defined evidence-based health care as balancing the best research evidence from clinical science, expertise of clinician and patient preferences and values (i.e., goals for treatment). This definition is the driving force behind the Working Group. Putting patients in the center of evidence-based health care decision making is a top priority for the Working Group, as illustrated by the Working Group's logo. Patients and consumers must be a part of evidence-based health care decisions. Patients/ consumers provide an essential and fundamental value to decision making processes. Clinical evidence is important; however it is just one piece of the puzzle. Patients / consumers need to be at the table to raise the important questions that cannot be answered by science alone. Health care decisions should be based on quality first; cost, while a factor in decision-making, should not be the primary factor in determining patients' and providers' choices.

Ms. Bright raised these key questions for participants to consider:

- Who is making decisions about your health care?
- Are research and science measuring what patients/ consumers care about?
- If the science is limited in its scope and applicability, what policy decisions can be made based on this?
- Are patients/ consumers involved in research design?
- How do we empower patients/ consumers to ask the right questions?

Panel 1: The Value of Patient Perspectives

Moderator: Bill Murphy/ Epilepsy Foundation & National Working Group on Evidence-based Health Care. Speakers: Chris Ward; Robert Ratchford; Kay Wissmann/ Y-ME; Perry Cohen/ Parkinson Pipeline Project

Patient representatives drew from their own experiences to define the importance of patient/consumer inclusion in the development, translation and dissemination of evidence for health care decision-making.

The following are key highlights from the patient/ consumer panel:

- Patient choice is imperative so that individuals with chronic, complex conditions can access treatments that may be most effective for them.
- Patients need complete information about benefits, risks and unknown information about treatment technologies.
- Patient participation in clinical research design is crucial to generating more functionally, as well as clinically, relevant information/ knowledge.
- Patients/ consumers must understand the important questions to ask their treating provider so that they can demand the best possible care.

Panel 11: NICE's Efforts to Engage Patients and the Public

Andrea Sutcliffe/ NICE; John Bridges/ Johns Hopkins Bloomberg School of Public Health

The following are key highlights from the panel:

- NICE views patient involvement as a valuable investment in their work on investigating benefit/risk and cost effectiveness of treatment approaches.
- NICE's work on this program is creates a learning environment for patients, physicians and decision makers involved with NICE, as well as observers across the world.
- The fundamental goal is patient empowerment.

Ms. Sutcliffe discussed the different ways in which the NICE involves both patients and the general public in developing its health guidances. Established as a part of the British National Health Service (NHS) in 1999, NICE conducts technology appraisals (including clinical and cost effectiveness), provides guidance to the NHS on the use of new and existing technologies and develops clinical practice and public health guidelines. NHS staff develops NICE guidance by incorporating input from other health care stakeholders including health care professionals, patients, caregivers, industry, and academics.

Patient and public involvement is essential to the NICE's work. NICE's Patient and Public Involvement Programme (PPIP) helps to identify patient and caregiver organizations and members of the general public interested in providing input to NICE on guidance documents. PPIP also provides training and support to those patient/ consumer representatives who contribute to the guidance development process. NICE's Citizens Council integrates broad social value judgments of the general public into NICE guidance. Ms. Sutcliffe stated that patients offer insights on the personal impact of treatments, identify relevant treatment outcomes, and inform the impact of health technology on a whole range of issues that are not demonstrated in research. More information about NICE is available at http://www.nice.org.uk.

Dr. Bridges responded to Ms. Sutcliffe's presentation with his commentary on how patient-based Health Technology Assessment (HTA) should be used to promote patient empowerment and patient-centered care. He discussed the societal barriers to patient-based HTA and the core principles for realizing patient-based

HTA which included:

- focusing on the patient's problems;
- taking a patient's perspective;
- accommodating to the patient's preference;
- allowing patient participation;
- building upon the patient/ physician partnership; and
- empowering the patient to improve their health.

Panel 111: U.S. FDA's Patient Representative and Patient Consultant Programs

JoAnn Minor/ FDA; Theresa Toigo/ FDA; Musa Mayer, patient participant

The following are key highlights from the panel:

- Patient involvement in defining research in pre-approval stages spurs innovation and partnership with regulatory and patient communities.
- Investing in educating patients/ consumers about how to participate in patient involvement programs, and giving them knowledge to succeed in that interaction is important.
- Finding balance between evidence and access is an important focus – when patients are involved, the process is whole and better decision-making results.

Ms. Minor and Ms. Toigo provided information about the FDA's Patient Representative and Patient Consultant Programs which informs the FDA on issues, problems, and/or questions pertinent to the viewpoint of patients and family members living with a certain serious or life-threatening diseases. Ms. Toigo expressed the important role that patients play in influencing change in PDA policy and related how HIV/AIDS activists were instrumental in changing the FDA process for incorporating patients in its work.

FDA's Patient Representative Program provides the FDA with the perspective of patients on therapies for their disease during the final review of that therapy at an FDA Advisory Committee meeting. Patient Representatives sit as both voting and non-voting participants on the FDA advisory committees that make recommendations to FDA concerning new drugs and medical devices approval for marketing. The FDA's Drug Development Patient Consultant Program incorporates the perspective of patients into the drug development process through involvement in the drug regulatory review process. The Patient Consultants have active roles in meetings between the FDA and drug companies. Both the Patient Representatives and Patient Consultants must be experienced patient advocates who are knowledgeable about their disease and officially associated with a patient advocacy organization. Anyone can nominate a candidate to serve as a Patient Representative or a Patient Consultant and self-nominations are also accepted.

Ms. Minor, a Patient Consultant herself, explained the process of empowering and supporting patients to participate in the FDA program, including FDA sponsored training conferences. She stated, "Patient involvement is possible and beneficial to all, in any successful patient program knowledge is power both for the advocate and the organization."

Ms. Mayer discussed her personal experience as a participant in FDA efforts as well as her experience with other patient programs. Eighteen years ago, Ms. Mayer learned she had stage II breast cancer. She said that serving on advisory committees, consulting with FDA staff and in participating in the FDA training conferences every month profoundly influenced her work as a patient/ research advocate. Learning to balance issues of access and evidence has framed her experience in working with FDA. Ms. Mayer sees herself as a translator of patient experiences to experts around the table and conversely to advocates in the community. Ms. Mayer quoted a colleague who stated about the FDA Patient Consultant program, "There is more of a

human approach to the review process than a cut and dry clinical and statistical one, things become less black and white. The process becomes whole. The doctor, the patient, and clinical experts are all represented." Ms. Mayer later added, "When the process is whole, better decisions are made."

Panel IV: Communicating the Science Correctly: AHRQ's John M. Eisenberg Center

Jean R. Slutsky, Director/ AHRQ; Sandra Robinson/ John M. Eisenberg Clinical Decisions and Communications Science Center; Linda Golodner/ National Consumers League

The following are key highlights from the panel:

- Dissemination of research is a crucial step in evidence-based health care – patient stakeholder involvement is fundamental to ensuring effective communication.
- AHRQ's emphasis on focus groups and other outreach to gain patient/consumer input to their guides has been an important and valued process.
- Information for patients/ consumers must be accessible in terms of literacy, numeracy, language/culture and technology.

Ms. Slutsky provided an overview of the AHRQ's Effective Health Care Program. The program conducts research that focuses on the outcomes and effectiveness of health care services and treatments. AHRQ works with research centers across the country to compile existing data, conduct original research, and help the public learn about current available research. AHRQ's John M. Eisenberg Center at Oregon Health and Science University puts research into short, consumer-friendly guides that can be used by patients, consumers, clinicians, and policymakers. AHRQ also established a Stakeholder Group representing consumers, clinicians, academia, health plans, and medical technology manufacturers to provide input on Effective Health Care Program research questions, methodologies, and dissemination strategies. The Effective Health Care Program also provides many opportunities for the public to provide comments on research questions, draft documents, and research topics that they post online at http://effectivehealthcare.ahrq.gov.

Ms. Robinson presented about the role of the John M. Eisenberg Clinical Decisions and Communications Science Center which compiles the research results of different treatments / interventions into a variety of useful formats. The guides convey findings about effectiveness, safety, and drug costs. The Eisenberg Center convenes consumer focus groups for input into these guides. She described the various stages in which patients / consumers are included in the development of translational materials for consumers, clinicians and policymakers.

Ms. Golodner, a consumer representative on the Effective Health Care Program Stakeholder Group, discussed the role of the National Consumers League in supporting AHRQ's efforts to including patients/ consumers. Ms. Golodner discussed how to effectively reach out to patients/ consumers. She emphasized the need for information to be written in a way that

is comprehensible to patients of all reading levels and recognizing cultural and linguistic differences. She also discussed the use of technology to convey information.

Additional Information

The National Working Group on Evidence-Based Health Care represents consumers, caregivers, practitioners and researchers committed to promoting accurate and appropriate evidence-based policies and practices to improve the quality of health care in the United States. We are dedicated to health care that relies on the most up-to-date research, clinician expertise and patient values.

The Core Values of the Working Group:

- Communicate the importance of and appropriate use of evidence in public policy decisions.
- Establish a forum for information on federal and state initiatives to review policy trends around EBH.
- Advocate for transparency and inclusion of all stakeholders in evidence-based policies and decisions.
- Develop consensus for common principles on EBH.

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