



THE NATIONAL WORKING GROUP ON  
EVIDENCE-BASED HEALTH CARE

Members of the Federal Coordinating Council for Comparative Effectiveness Research, I would like to thank you for the opportunity to provide public comment on CER and the Council's activities.

My name is Hazel Moran, and I am from Mental Health America, America's oldest and largest advocacy organization concerned with all aspects of America's mental health. In fact we celebrate our Centennial this year. Given our longstanding interest in the public's health we are the founder of the National Working Group on Evidence-Based Health Care (The Working Group), which is a collaboration of approximately 40 patient and consumer organizations, professional societies, providers and other interested stakeholders that want to help shape the initiatives in evidence-based healthcare (EBH) in order to close the gap between our knowledge and ordinary practice. As such, I am pleased to speak on behalf of consumers and patients in support of comparative effectiveness research.

Since 2005, we have worked to broaden participation of patient groups in all aspects of EBH to improve the usefulness of this information for consumers and clinicians as well as to assure that the locus of decision making remain with the patient and his/her clinician. We focused principally on comparative effectiveness reviews and evidence dissemination as two key components of the EBH movement.

Through information exchange and engagement in public dialogue, the Working Group has emphasized the importance of balancing an understanding of scientific research with real-world clinician expertise, each individual patient's needs and history as well as their perspectives and preferences. The Working Group strives to empower patients and consumers by involving them in designing and prioritizing research, as well as reviewing evidence and contributing to its translation, dissemination and implementation. For example, Mental Health America participated in the review and dissemination of several publications including AHRQ's Summary Guides on the Off-Label Use of Atypical Antipsychotic medication and the treatment of Depression. Our involvement has been viewed as constructive and helpful we would like to continue to engage in the growing federal CER effort by helping to deepen patient involvement in CER. To generate the balanced and practical clinical evidence that the legislation envisions, it will be critical for the Council to ensure that all those conducting federal CER incorporate the patient and clinician perspective into the direction and design of CER.

The creation of new evidence and new decision support techniques to inform patient's treatment decisions offer great potential to improve care. To help realize this progress, patients and consumers can provide important support to federal CER research in three principal ways.

First, they can advise on topic selection. Second, by specifying the information they need to make decisions about their care, patients can help determine what data should be captured in CER. Third, patients can provide valuable public support for the CER dissemination and implementation.

In the Federal Register Notice for this meeting, you specifically asked for individuals making comments to respond to six questions. We would like to respond to those questions with three recommendations:

- **Create a national citizens' advisory board to help HHS** better understand the perspectives and values of the general public when designing and disseminating CER. This is critically important to make sure that the full continuum of issues are considered when making policy recommendations regarding the implementation of CER findings. A good model for this is the Citizens Council that the UK's NICE convenes.<sup>2</sup> NICE charges the Council with conveying the views of the public both to the Institute and to the groups that NICE commissions for appraisals and clinical guidelines.
- **Establish an explicit channel for patients to advise HHS on CER.** The FDA's Patient Representative Program is an excellent model for this kind of participation.<sup>1</sup> The program educates patients to be effective advisors, and then includes them on advisory boards that correspond to their particular medical experience. HHS could similarly inform patients on some basic scientific and methodological concerns of CER and then solicit their input. Additionally, these patients must be trained and supported to effectively engage in this process. HHS should, as part of the patient advisory function, design and implement a systematic program to educate and support the patients so that they can effectively engage in these technical discussions. The establishment of an HHS Office of Patient Values and Inclusion can ensure that patients assist in all aspects of developing the systems to deliver therapies for the major medical problems we face as a nation, managing chronic disease in an era of discovery. More recognition of these patient assets is needed along with support for training and development. The establishment of such an Office can assure this.
- **Sponsor research that is designed to improve clinical decision making by both clinicians and patients.** Research that considers the individuality of health conditions and factors such as family history, individual experience in treatment and patient values and preferences is needed. Designing CER trials that mine the heterogeneity of response for identifiable sub-groups and that include outcome variables that are aligned

with patient preferences should improve the clinical applicability of the work. Patient involvement in trial design would assist in improving the relevance of their findings. Integration with the developing HIT architecture should ensure that decision support tools informed by CER and systematic reviews are included in this new technology – moving knowledge to the bedside in order to craft individual treatment plans for individual patients.

Greater roles for patient advocates are essential to advance medicine in collaboration with scientists and physicians to interpret the effectiveness of therapies. Understanding the experiences of patients and the public is important to helping organizations work more effectively to evaluate and improve services. People should have the opportunity to be actively involved in shaping the organization and the delivery of health and social care services for their communities. Changes that are made to the delivery of services should be based on their experiences and views.

The National Working Group on Evidence-Based Health Care appreciates the opportunity to provide the Federal Coordinating Council on Comparative Effectiveness Research with specific comments on its activities as it relates to comparative effectiveness research. The Working Group plans to submit formal comments to the Council with further detail on our recommendations.