

Testimony from SMDM President, Mark Roberts, MD, MPP

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My name is Mark Roberts and I am an internist and professor of Medicine at the University of Pittsburgh, and am speaking here in my role as the President of the Society for Medical Decision Making, an academic society concerned with making better healthcare decisions. I appreciate the Coordinating Council's invitation to speak on behalf of our society's members, many of whom have developed the methodologies that are used in comparative effectiveness research, both here in the US and abroad. Today, I will emphasize several points regarding the prioritization of comparative effectiveness research.

First, we support continuing investment in the development and advancement of comparative effectiveness methods themselves, and the rigorous training in their use. Comparative effectiveness research requires the application of multiple methodologies, including advanced clinical trial design, data synthesis methods, observational methods, mathematical modeling and many others. We cannot rely solely on randomized controlled trials to answer complex questions, such as what is the optimal time to initiate HIV therapy or what set of complex patient characteristics make one therapy superior to another. We support ongoing research in the development and evaluation of the methods used to conduct comparative effectiveness so that the most appropriate methods for the specific task can be used with surety.

Second, we believe that costs are an important outcome – in addition to effectiveness. We believe that comparative effectiveness analyses are enhanced by the inclusion of costs so that patients, doctors and society have a measure of value for the decisions they face. However, costs should never be used in isolation without consideration of the health effects. As Alan Garber, a member of our society has explained, conducting comparative effectiveness without the inclusion of costs is like “choosing from a menu without prices”. Patients and their doctors can and do understand these tradeoffs.

Third, comparative effectiveness research must also account for the individual nature of patient characteristics, including their specific preferences and personal values. The best treatment for an individual patient with a specific disease simply cannot be determined from knowledge of the average effect of a treatment in a narrowly defined randomized controlled trial. While this is obvious for biological variability such as the choice of chemotherapy in breast cancers patients who carry specific genetic markers, it is also true for the values that patients have for the possible outcomes of their disease and the treatments they face. *That a particular therapy has a higher 5-year survival may be irrelevant to an ailing grandmother who wants the therapy that maximizes her ability to be alive at her granddaughter's wedding next month.* CER must develop the ability to account for the important individual differences in physiology and risk faced by patients making decisions about their care, and it must also account for individual patient preferences, values and fears. Tools and methods to help patients and their doctors include these important characteristics are necessary so that patients can become partners with their caregivers in their search for the best therapy, and that the practice of evidence-based medicine can become more personalized and patient centered.

If conducted with well validated methods that incorporate individual characteristics of patients and their values, Comparative effectiveness has tremendous opportunity to improve the quality and efficiency of healthcare in the United States. Thank you.