

March 16, 2012

Carolyn M. Clancy, MD
Office of the Director
Agency for Healthcare Research and Quality
540 Gaither Road, Suite 2000
Rockville, MD 20850

Re: Use of Deliberative Methods to Enhance Public Engagement in the Agency for Healthcare Research and Quality's Effective Healthcare Program and Comparative Effectiveness Research Enterprise

Dear Dr. Clancy:

On behalf of the American Society of Nephrology (ASN) and the 13,500 physicians, scientists, and other healthcare professionals the society represents, thank you for the opportunity to provide comments on the Agency for Healthcare Research and Quality's proposed information collection project on "Use of Deliberative Methods to Enhance Public Engagement in AHRQ's Effective Healthcare Program and Comparative Effectiveness Research Enterprise." ASN, which leads the fight against kidney disease through education, advocacy, and research, supports use of public input to inform and guide broad strategies related to the use of evidence to inform decisions. ASN believes patients with chronic kidney disease (CKD) represent a model group for patient-oriented research given the size, complexity, and diversity of the CKD population, and the broad applicability to other chronic disease patient populations with multiple co-morbidities. ASN submits the following comments to AHRQ for consideration.

The care of pediatric and adult patients with CKD provides a model for care of patients with common diseases who have complex medical histories, multiple co-morbidities, and are cared for in a variety of settings at a high cost.

Care of patients with CKD represents 27.6 percent of Medicare expenditures. Approximately 26 million Americans have some evidence of kidney disease and may develop a wide range of complications, including acute kidney injury, cardiovascular disease, and kidney failure {also known as end-stage renal disease (ESRD)}. Every year, more than 300,000 Americans are diagnosed with acute kidney injury, which is associated with increased mortality, healthcare costs, and progression to ESRD.

Currently, more than 570,000 patients have ESRD, and ESRD alone will cost Medicare an estimated \$29 billion this year. After three decades of exponential increase, adjusted rates of ESRD have finally plateaued in the past decade—suggesting improved care can work. But the combination of an aging population and epidemic increases in obesity and diabetes means the number of Americans with ESRD will continue to rise. Current projections estimate 774,000 Americans will have ESRD by 2020.

The same forces are increasing the population burden of CKD, and global consortia are confirming the wide-ranging consequences of all stages of kidney disease. Despite recent and dramatic improvements in the standardized diagnosis and staging of CKD, patients with CKD are often excluded from clinical trials. Strategies for optimizing their care in the face of multiple co-morbidities (e.g. diabetes, hypertension, and heart failure) require rigorous study. Patients with kidney disease face challenges from fragmented care, polypharmacy, and inadequate guidance in navigating the healthcare system and managing their health; and we know very little about the choices they make, what outcomes they care about, and what assistance they require to enhance quality of life. Research in these patients may provide important insights that may prove useful for the care of other complex, chronic disease patient populations.

Moreover, primary care physicians and nephrologists need more evidence to effectively diagnose and treat early stage kidney disease and to help prevent its progression. Physicians must better understand the risk factors, effective preventive strategies, and best treatments for kidney disease. Use of dialysis provider data on quality and clinical outcomes also provides an opportunity to test use of electronic health data to better design clinical trials. Furthermore, the high cost of CKD and need for strong coordination to effectively manage patients makes kidney disease an ideal test of the effectiveness of coordinated care systems for complex patients.

Patients with chronic illnesses such as CKD experience a broad range of outcomes that extend beyond traditional measures of health and impact quality of life, including pain, disability, poor physical function, cognitive dysfunction, and educational challenges. Despite this, little work has been done regarding the best ways to incorporate these measures into clinical studies that can influence decision-making about CKD care.

Patients with kidney failure and their families represent an ideal population to study patient attitudes toward quality and end-of-life decisions, to understand the dynamics by which a debilitating illness affects family structures and economics, and to identify the outcomes most important to patients with serious and complex illnesses. Patients may value research into how to incorporate conservative care and palliative care as an option. *ASN therefore recommends AHRQ determine where affected people find interest and value in research, identify strategies to engage patients and their families as research participants, and focus on closing knowledge gaps that prevent optimal delivery of patient care.*

Again, thank you for the opportunity to provide comments regarding the proposed information collection project on “Use of Deliberative Methods to Enhance Public Engagement in AHRQ’s Effective Healthcare Program and Comparative Effectiveness Research Enterprise.” We appreciate your consideration of these suggestions and welcome the opportunity to discuss them further if it would be helpful. Please contact ASN Manager of Policy and Government Affairs Rachel Shaffer at (202) 640-4659 with any questions.

Sincerely,

A handwritten signature in dark ink, appearing to read "Ronald J. Falk". The signature is fluid and cursive, with the first name "Ronald" and last name "Falk" clearly distinguishable.

Ronald J. Falk, MD, FASN
President