

March 15, 2012

Joseph V. Selby, MD, MPH
Patient-Centered Outcomes Research Institute
Public Comments
1701 Pennsylvania Avenue, NW
Suite 300
Washington, DC 20006

Re: Patient-Centered Outcomes Research Institute Draft National Priorities and Research Agenda

Dear Dr. Selby:

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 Patient-Centered Outcomes Research Institute's "Draft National Priorities and Research Agenda." ASN, which leads the fight against kidney disease through education, advocacy, and research, believes chronic kidney disease (CKD) provides an excellent model for PCORI in the realm of chronic disease research. This disease affects individuals throughout the human lifespan as well as racial and ethnic minority populations, and could serve as a model for patient-provider partnerships in therapeutic decision-making, patient empowerment through education, and information technology platforms that facilitate these partnerships through patient-specific messaging. ASN submits the following comments to PCORI 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 healthcare systems 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 PCORI 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 patient care delivery.*

ASN also recommends PCORI focus on the use of healthcare systems, and engagement of both healthcare and non-healthcare professionals, to improve patient care. How research findings become more widely used in practice (especially among populations with more limited access) is not discussed in PCORI's research priorities and agenda. ASN recognizes the value and importance of patient-centered research, but without an effective plan for dissemination, research dollars are wasted.

Moreover, ASN recommends PCORI make disparities in the development and progression of chronic illnesses, including CKD, a core research priority. Unfortunately, there is little rigorous evidence, either nationally or locally, that current efforts to eliminate ethnic and racial disparities in kidney disease incidence, care, and outcomes are successful.

Education about disparities and clinical care improvement with diverse patients enhances all of medicine and human health. Researchers estimate that racial health disparities cost the US \$229 billion between 2003 and 2006.ⁱ For instance, racial and ethnic minority populations in the US are up to four times more likely than non-minorities to progress to ESRD.

Disparities extend beyond disease incidence to vital treatments. Upon developing ESRD, African Americans and Hispanics are substantially less likely to receive a kidney transplant than their Caucasian counterparts. As such, patients with kidney disease represent an ideal population in which to study the contribution of biological and social determinants of treatment selection as well as differences in disease prevalence and outcomes between the majority and minority populations. In diabetic kidney disease, large disparities appear to be explained by measured social and biological risk factors, and strategies for effective treatment delivery need to be tested. In addition to traditional risk factors in non-diabetic kidney disease, a single genetic susceptibility locus discovered in 2008 (APOL1) may explain much of the increased risk in African-Americans, and strategies to tailor treatment to this high-risk population need to be tested.

Finally, physicians and other providers still poorly reflect the racial and ethnic diversity of the US population. Patients with kidney disease provide an opportunity for healthcare providers to learn how they are perceived by minority patients and to understand how these perceptions affect health outcomes and patient preferences.

Again, thank you for the opportunity to provide comments regarding the PCORI "Draft National Priorities and Research Agenda." 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 black ink, appearing to read "Ronald J. Falk". The signature is fluid and cursive, with a large initial "R" and "F".

Ronald J. Falk, MD, FASN
President

ⁱ Thomas A. LaVeist, Ph.D., Darrell J. Gaskin, Ph.D., Patrick Richard, Ph.D., "The Economic Burden of Health Inequalities in the United States." Joint Center for Political and Economic Studies, September 2009.