

September 13, 2012

Joseph Selby, MD, MPH
Executive Director
Patient-Centered Outcomes Research Institute
Public Comments
1701 Pennsylvania Ave, NW Ste. 300
Washington, DC 20006

Re: Draft Methodology Report: *Our Questions, Our Decisions: Standards for Patient-Centered Outcomes Research*

Dear Dr. Selby:

On behalf of the Council of Academic Family Medicine (CAFM), which represents the membership of the Society of Teachers of Family Medicine, the Association of Departments of Family Medicine, the Association of Family Medicine Residency Directors, and the North American Primary Care Research Group, in conjunction with the American Academy of Family Physicians (AAFP), we are writing in response to the Patient-Centered Outcomes Research Institute's (PCORI) Draft Methodology Report, released July 23, 2012. We appreciate the opportunity to provide comments on the draft methodology report.

We applaud the methodology committee for their work in producing these draft standards. The report is comprehensive, outlines actions for PCORI to undertake, and recommends research to be developed. What is most attractive about this report is the emphasis on defining and developing research methods and protocols related to patient-centeredness and patient engagement.

Our organizations point out two areas relating to patient-centeredness that we feel the report should explicitly include. Though the report makes great strides in defining patient-centered outcomes research and patient-engagement, we urge PCORI to include more analytical work, specifically on what patient-centeredness means across the continuum of clinical care delivery. A fundamental question that needs to be answered in primary care is what is the frequency and importance of patient centeredness as a diagnostic and therapeutic approach for problems that patients bring to the health care system? There is a tacit assumption by both patients and physicians that the disease-centered model of health care delivery works most of the time and produces optimal patient centered outcomes. Yet, in primary care, we know that multi-morbidity, terminal conditions, mental health disorders, substance abuse, diffuse unexplained somatic complaints, etc., do not lend themselves to optimal outcomes if a disease centered approach is utilized. The research paradigm should include efforts to test this hypothesis. We see a risk of patient-centered outcomes research being defined by traditional reductionist thinking. To take our multi-morbidity thinking a step further, wouldn't a new paradigm for patient-centered outcomes research necessarily include broader contextual factors that shape health for the patient - families, communities, and the social determinants that shape real patient outcomes in real life?

For example, relevant to patient-centered outcomes research and PCORI's agenda is the recent American Diabetes Association panel recommendation against using A1c<7 as a universal quality measure because tight glycemic control produces widely variable outcomes across populations. The panel highlights the patient-centered outcomes message - to build measures of quality around the specific patient and in context of their income, education, activation, and likelihood of following through on recommended actions.

We believe the report attempts to get at these themes in its descriptions of patient engagement and the development of methods for increased participation of patients in design of studies and research question, but we would like the report to explicitly identify the need for outcomes related to patients' health and function, not disease burden. We hope that PCORI does not continue to define patient-centered outcomes research within the context of disease states as the National Institutes of Health currently does.

The organizations of family medicine are encouraged by the activity and efforts of the methodology committee and PCORI as a whole. We look forward to working with PCORI and the family medicine research community to strengthen our nation's capacity to design and implement vital patient-centered outcomes research and reap the dividends of that research to improve patient care.

Should you have any questions regarding this letter, please feel free to contact Hope R. Wittenberg, CAFM Director of Government Relations, at hwittenberg@stfm.org or 202-986-3309 or Robert Bennett, AAFP Federal Regulatory Manager, at rbennett@aafp.org or 202-232-9033.

Sincerely,



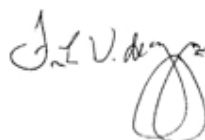
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