

March 14, 2012

Joe V. Selby, M.D., M.P.H
Executive Director
Patient-Centered Outcomes Research Institute
1701 Pennsylvania Ave. NW, Suite 300
Washington, DC 20006

Re: Public Comment on PCORI National Priorities for Research and Research Agenda

Dear Dr. Selby:

On behalf of the American Academy of Family Physicians (AAFP) and in conjunction with 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, we are writing in response to the Patient-Centered Outcomes Research Institute's (PCORI) [National Priorities and Research Agenda](#) published on January 23, 2012.

We strongly value PCORI's mission, which is to support research providing patients and physicians with information to make informed healthcare decisions. Knowledge derived from PCORI's research, along with the continuity relationship between patients and their personal physicians will be fundamental to improving our nation's health outcomes. We recommend that PCORI initially focus its research on conditions that family physicians encounter every day in their practices in hopes of finding solid clinical evidence to assist the shared decision making process between patients and physicians. All too often, patients and clinicians sit down to make shared decisions, and find that clinical effectiveness information is inadequate.

The following are our direct responses to the specific [questions](#) PCORI asks about the draft National Priorities for Research:

1. How well do the draft priorities cover the comparative effectiveness research that the PCORI should do?

- a. Assessment of prevention, diagnosis, and treatment options: The categories outlined by PCORI are an excellent starting point for research of importance to both patients and clinicians. PCORI research should initially focus on conditions seen every day in our primary care practices -- in hopes that the evidence will provide practitioners with solid treatment options. As such, we must move immediately to secure "quick wins," and disseminate PCORI-funded results as soon as possible. When comparing one treatment with another, we also need to understand what would happen with *no* treatment or intervention. (i.e., is there harm caused by the treatment itself?)
- b. Improving healthcare systems: We support further examination of healthcare delivery systems. We have long-supported the patient-centered medical home (PCMH) model and believe it provides access to quality, affordable care for all patients. We support PCORI's emphasis on care coordination for complex conditions as we frequently see patients with multiple co-morbidities. For example, family physicians must have the best evidence on how to treat a diabetic patient with depression and hypertension.

- c. Communication and dissemination: Patients should receive easy-to-understand information about treatment choices that have similar results, including the choice of *no* treatment. Research should study the effectiveness of these interventions on patient satisfaction. Our organizations have long-supported the use of electronic health systems to share effective results for patients and providers. Our members are eager to receive evidence-based treatment information and clinical decision support.

- d. Addressing disparities: We support PCORI's emphasis on researching health disparities. Family physicians support this research because of our wide variety of patients. While this type of research may be more difficult, it is vital to offering health information that is relevant to patients and their physicians. We also believe that research on disparities should address practice in rural, urban and suburban areas that have differing levels of resources.

- e. Accelerating patient-centered and methodological research: Our organizations urge PCORI to examine *existing*, effective practice-based research networks. The AAFP has played a leading role in a public/private consortium of institutions, called the DartNet Institute. This research collaborative involves thousands of family physicians and other primary care physicians, multiple medical schools, and our organizations. These clinicians collect and share clinical data to improve the quality and safety of medical care, along with best practices. This program uses practice-based research networks, electronic health records, and practical clinical trials. It also looks at how electronic data from a patient's medical home can help us understand effective and safe medical care.

This priority recognizes another key area in need of development. Departments of Family Medicine are uniquely poised to help PCORI develop a rigorous research portfolio dealing with the above priorities because their clinical enterprises and their research interests provide a nexus bridging their diverse patient populations and common problems in primary care. Ninety-one percent of the academic Departments of Family Medicine responded in a recent survey that they would participate in large clinical trials to compare effectiveness of interventions using their clinical enterprises if funding to support this work were available. The development of career physician-researchers in family medicine would support our nation's ability to address the key PCORI priorities.

2. Do you have any concerns about the priorities or the agenda?

We do not have any concerns about the priorities or the agenda. However, we emphasize our strong commitment to issues of the greatest importance to the public's health, and, as such, would suggest the addition of two priority areas: mental health and substance abuse (including prescription drug abuse such as opioids), to PCORI's research agenda. Family physicians regularly manage these issues and refer to subspecialists when appropriate. We realize that there is insufficient evidence to inform physicians of the most effective pathways towards effective long-term treatment of these chronic and often recurring conditions. The long-term health impact on those affected by mental health and substance abuse problems, and their families, is significant. Our patients would benefit from better research and recommendations in these areas.

3. What percentage of PCORI's research budget should be dedicated to each proposed priority area?

We recommend the following order:

- a. Assessment of prevention, diagnosis and treatment;
- b. Communication and assessment;
- c. Addressing disparities;
- d. Accelerating patient-centered and methodological research.

We believe that "Improving Healthcare Systems" could be a lower priority as that is the purpose of the new Innovation Center at CMS. The Innovation Center is looking at various delivery systems, including the patient-centered medical home.

4. If future versions of PCORI's research agenda focus on specific conditions and diseases, how should PCORI choose which ones to target?

We would suggest prioritization based on three axes, weighing each of the following dimensions of a condition or disease:

- a. Its burden on the population;
- b. The overall economic burden that the condition places on the health care system and;
- c. The current level of existing evidence that helps a provider answer the questions required to conduct effective care.

If each aforementioned dimension considered were then assigned a score, based on a scale reasonable to PCORI or its expert advisors, a prioritization index could be created of the sum or product of the dimensions' scores. If one area was to be found of greater significance to PCORI, then that axis easily could be weighted - but we currently believe each axis should have equal weight.

5. How should PCORI address rare or understudied conditions?

Our organizations believe that research on uncommon or rare diseases is best done through large national registries, over a long period of time. This way, physicians can watch for the emergence of best practices or optimal results.

6. Are there any important research topics that are missing from PCORI's research agenda?

At this time, we do not see anything missing from PCORI's broad agenda. Nevertheless, it will take time to understand the projects and results that are funded through the review process. If these reviews lead to projects that are similar to the majority of NIH clinical trials, or other projects, then we may need to reexamine the current draft research agenda.

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

Sincerely,



Glen Stream, MD, MBI
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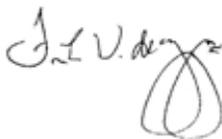
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