ACP
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Patient Centered Outcomes Research Institute
1701 Pennsylvania Avenue, NW, Suite 300
Washington, DC 20006

This letter reflects comments by the American College of Physicians (ACP) in response to the request for comment on the Patient-Centered Outcomes Research Institute's (PCORI) first draft "National Priorities for Research and Research Agenda" as required by the enabling provisions under the Affordable Care Act of 2010. These comments were developed with the assistance of an ACP Expert Advisory Work Group including the following: Mark Eckman, MD, FACP; Eric Larson, MD, MACP; Cynthia Mulrow, MD, MACP; Stephen Pauker, MD, MACP; and Hal Sox, MD, MACP.

The ACP represents 132,000 internal medicine physicians and students. Internists specialize in primary and comprehensive care of adolescents and adults. The College has consistently supported the establishment of an adequately funded, trusted national entity such as PCORI to prioritize, sponsor/ produce and effectively disseminate comparative effectiveness information.

The draft document consists of a set of the following broadly-defined national research priority areas that PCORI indicates are based upon the statutory requirements, PCORI's working definition of "patient-centered outcome research", and a review of nine previous national efforts on comparative effectiveness prioritization:

- Assessment of Prevention, Diagnosis, and Treatment Options.
- Improving Healthcare Systems.
- Communication and Dissemination.
- Addressing Disparities.
- Accelerating Patient-Centered and Methodological Research.

Based upon the foundation of these broadly defined priority categories, the document further outlines under each of these categories a set of broad questions and topics that cross a wide range of conditions, interventions and populations to serve as the basis for the first PCORI call for proposals currently scheduled for May of this year,

The College, while endorsing the importance of each of the five proposed priority areas, offers the following comments on this first draft of the "National Priorities for Research and Research Agenda":

Broad Conceptual Concerns

- **Both the defined prioritized areas and the resulting research agenda lack adequate specificity**--PCORI established a set of five general priority categories, which inform a research agenda consisting of a set of broad questions and topics that cross a wide range of conditions and interventions. The specific projects selected for funding, and the specific diseases, conditions, interventions and populations addressed, will be based on these broad questions and topics, and the compelling nature and quality of the research applications received. It appears that the underlying philosophy of this approach is that the best knowledge base for research ideas are collaborations of patients, clinicians and researchers that respond to the broadly based request for proposals. This approach is in contrast to the PCORI Governing Board setting specific research priorities, as informed by the criteria established under the statute, previous public and private efforts at comparative effectiveness prioritization and multi-stakeholder feedback. While this broad-spectrum approach may be effective, it provides reason for concern:
    - This approach places significant responsibility for priority setting and initial research funding by PCORI into the hands of the research community (and their stakeholder collaborators). Thus, the actual prioritization will depend largely on the quality and compelling nature of the grant applications received. The College questions whether this approach is the best means of ensuring an initial portfolio of patient-centered outcome research projects that will be effective and have an impact.
    - The lack of specificity in the defined priority areas and research agenda does not provide stakeholders, during this public comment period, with enough information to make informed decisions about the appropriateness of the set of projects that will be given high priority by PCORI and ultimately funded. This problem is further magnified by the current review process providing no opportunity for stakeholder comment on the finalized initial research agenda and related public research requests.
    - The lack of specificity means that responders to the upcoming funding announcements will be poorly informed about the criteria that PCORI will use to evaluate the importance of their applications.

  As a result of these concerns, the College recommends the following:

    - **PCORI, in its finalized statement of "National Priorities for Research and Research Agenda" should be more specific about the research questions that it considers to have the highest priority and should describe its research agenda with greater specificity. In developing its priorities, it should use prioritization language included in the enabling statute, as well as making greater use of the research**

recommendations provided by the nine previous national efforts towards comparative effectiveness research prioritization --- particularly the work of the Institute of Medicine's "Initial National Priorities for Comparative Effectiveness Research" completed in 2009. This increased specificity will help guide applicants for PCORI funding to propose projects that address consensually agreed upon national priorities and ultimately produce an effective portfolio of initially-funded patient-centered outcome projects that the nation feels will have the greatest impact.

- **PCORI should provide an additional opportunity for public comment, even if it is a brief time period (e.g., 30 days), on the finalized initial draft set of priorities and research agenda, and proposed initial set of PCORI requests for research proposals. The specific selection criteria and decision processes to be used to select the initial portfolio of funded process should also be available for review at this time. This will help ensure increased consensus and support of the initial funding announcements offered and projects ultimately selected.**

- **PCORI should make substantial use of multi-stakeholder advisory committees to assist in the actual selection of initial projects to be funded following receipt of proposals based upon this finalized research agenda. These committees should be guided by a set of priority criteria more specific than those included under the original draft national priorities and consistent with the prioritization language included in the statute and the recommendations of the previous national efforts toward prioritization.**

- **The proposed priorities and research agenda places inadequate emphasis on the need for PCORI to prove its value to society in a timely manner** ---PCORI was approved by Congress within a highly polarized political climate. Many influential constituents were opposed to its creation. These constituents view the efforts of PCORI as a means for an outside entity to inappropriately come between the physician and their patient, and as the first step down the road towards rationing care. While the College does not agree with this view, some people do. Furthermore, the current legislation requires reauthorization of PCORI by 2019. PCORI's case for reauthorization will be strengthened by evidence that the research it sponsors can improve patient care and outcomes that are important to patients. **Given these observations, it is extremely important that a number of the initial PCORI-funded projects focus on high priority research questions that can be answered relatively expeditiously with strong evidenced-based support so that the results can be incorporated into practice in time to measure their effects on the nation's health. This is important for stakeholders to accept and trust PCORI. Currently, the proposed national priorities and research agenda document does not address this intent.**

- **The College recommends that PCORI judge a proposed project in part by its potential to expeditiously provide evidence-based results that will have a significant impact on the nation's healthcare. This criterion should be used to assess the topic of the proposed project and the "track-record" of the applicant in completing projects on schedule. PCORI should inform applicants of this criterion.**

Specific Areas that PCORI Should Prioritize and Address

The College recommends the following specific areas that should be addressed (prioritized) within the research agenda. While some of these are already addressed in the broadly defined questions and topics used to define the proposed research agenda, the College believes that these have not been given appropriate emphasis.

- **Prevention, diagnosis and treatment of chronic illness.**
- **Prevention, diagnosis and treatment of complex, medical co-morbid conditions.**
- **Prevention, diagnosis and treatment of pain.**
- **Methods to provide physicians and patients with information both on the "quality of life" and the cost expected from various interventions.**
- **Interventions that reduce the wasteful, and at times harmful, use of unnecessary and inappropriate diagnostic approaches.**
- **Interventions to facilitate the coordination of primary and specialty care to improve patient outcomes.**
- **Interventions to effectively integrate mental health within healthcare delivery.**
- **Interventions that address improved adherence to treatment.**
- **Interventions to improve the quality of end-of-life and palliative care.**
- **Interventions to reduce disparities in the treatments available to different socioeconomic and racial/ethnic populations.**
- **Methods to improve the ability of physicians to effectively incorporate the results of patient-centered outcome research within their practices in a timely manner.**

The College appreciates this opportunity to comment on this "National Priorities for Research and Research Agenda" document. It also appreciates PCORI's strong commitment towards processes that promote transparency and multi-stakeholder engagement---these are important elements to facilitate PCORI becoming a trusted entity. Please address any questions regarding these comments to Neil Kirschner on our staff at 202-261-4535 or nkirschner@acponline.org.

Respectfully,

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President