

National Pharmaceutical Council's Prepared Commentary Before the Patient-Centered Outcomes Research Institute
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Thank you for the opportunity to comment. I have enjoyed the opportunity to witness first-hand the progress, careful thought and deliberation, and open dialogue that is ongoing within the Board. My name is [Jennifer Graff and I am a Research Director](http://www.npcnow.org/Public/About_Us/Staff/staff_Bios/NPC_Research_Director_Methods_Evidence_and_Coverage_Jen_Graff.aspx) (http://www.npcnow.org/Public/About_Us/Staff/staff_Bios/NPC_Research_Director_Methods_Evidence_and_Coverage_Jen_Graff.aspx) at the National Pharmaceutical Council (NPC). The National Pharmaceutical Council is a policy research organization dedicated to the advancement of good evidence and science, and to fostering an environment in the United States that supports medical innovation.

Recognizing the importance of identifying the national priorities and the research agenda, my colleague, NPC Chief Science Officer Dr. Bobby Dubois, and I undertook a review of how nine organizations such as the Institute of Medicine Committee on Comparative Effectiveness Research Prioritization, the United Kingdom's National Institute for Health and Clinical Excellence, and the Blue Cross Blue Shield Association Technology Evaluation Center prioritized their research. Based upon this review, we published an article in the [December 2011 issue of Health Affairs](http://www.npcnow.org/Public/Research_Publications/Publications/pub_cer/prioritization_paper_ha.aspx) (http://www.npcnow.org/Public/Research_Publications/Publications/pub_cer/prioritization_paper_ha.aspx) identifying eight key learnings associated with an optimal process for prioritizing research. I'd like to compliment you on your work thus far as the processes outlined to date incorporates many of the "optimal processes" utilized by other organizations.

We recognize the tensions and the spotlight that the board is under to both "get it right" and to initiate the prioritization process. We also can appreciate the tradeoffs between a research agenda that encourages broad, open solicitations of fresh ideas and a research agenda that is more focused on specific clinical questions. In light of these challenges, we offer five areas for your consideration today, and for prioritization in future years:

- 1. Rank order and weight priorities to identify what has greater or lesser importance.**

We recommend not only listing priorities, but also defining the financial allocations among them, much like the National Institutes of Health does with its priorities. For example, PCORI might expend 40% of its efforts on funding comparative clinical effectiveness questions, followed by 20% of its efforts on funding projects to improve health care systems and communication and dissemination, and perhaps another 20% on the acceleration of patient-centered outcomes research. If PCORI's goal is to create a self-sustaining environment where CER will flourish, then it might want to spend a higher percentage of its efforts in that area. Knowing how PCORI's priorities are weighted will provide an important point of reference for the public. By so, doing PCORI would not only identify areas of focus, but would provide clarity regarding the relative importance of each priority.

Without ranking its priorities, PCORI may run the risk of including all areas and prioritizing nothing. We also recognize the upcoming public comment period offers a unique opportunity to seek public input on which priorities are of greater and lesser importance.

2. **Be specific.**

To enhance the likelihood that the most critical questions are undertaken and to ensure an adequate portfolio of projects, we suggest being specific in the research questions that will be funded. Similar to the IOM 100 CER priorities, the research questions would include the clinical question, the outcomes of interest, interventions, and settings.

Despite the influx of funding, not all research questions will be answered. Additionally, it is unlikely that a single research study will answer all of the research questions that decision-makers will have or be sufficiently striking on its own to change practice. This creates the need for a thoughtful and well-orchestrated portfolio of projects for specific clinical questions and an acceptance that not all questions can be answered with current funds.

3. **Ensure that all stakeholders are engaged in all aspects of the prioritization process, including identifying topics and prioritizing among them.**

Without specificity, it will be up to the funding and research review committees to determine the research priorities, losing the important opportunity to seek a broad and representative feedback from stakeholders. PCORI should consider having stakeholders participate not only in the research agenda topic identification (which would currently be sought through open requests for information and topic submissions) but also in the prioritization of the research topics. Without any specified clinical questions (eg, management options for low back pain), it will be unlikely that an alternative research agenda would fund a sufficient number of related projects to create an evidence base to support routine clinical practice demands.

To account for this, we suggest utilizing a series of ad hoc panels to evaluate various research topics on the merits of the topic itself. It will important to reach out beyond the 21 PCORI Board members and seek additional engagement throughout the entire research continuum.

4. **Maintain an open and transparent consensus process to handle inevitable disagreement.**

How feedback from these suggested ad hoc panels will be used will serve as an important guide post for how public feedback is considered. We are encouraged by the discussion from the Board to include quantitative consensus methods and suggest that sharing these results transparently will help the public understand how inevitable disagreements were handled.

5. **Plan for a learning culture within PCORI and evaluate the results of the process.**

The Board and all stakeholders will learn through this prioritization process what steps should be altered in the future. We encourage you to seek not only internal feedback, but also feedback from the general public. Stakeholders who will be commenting in the upcoming weeks on the national priorities may be an optimal source to consider including in this evaluation process.

In this environment, any prioritization process selected will be under scrutiny. We offer these suggestions as a way to enhance the process so that it can withstand inevitable criticism. In particular, signaling PCORI's rank order prioritization, balancing the portfolio with both a broad

call for research ideas as well as specific clinical questions to be addressed, and engaging stakeholders in the actual prioritization in a transparent manner will be beneficial to both the board and the public. We look forward to the transparent dialogue that will begin in the following weeks and wish you much success. Thank you.

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