

Mark Helfand, MD, MPH
Scientific Resource Center, Oregon EPC
Mail code: BICC
3181 S.W. Sam Jackson Park Road
Portland, Oregon 97239-3098

Re: Comments on draft Engaging Stakeholders To Identify and Prioritize Future Research Needs report

Dear Dr. Helfand:

The Partnership to Improve Patient Care (PIPC) is pleased to have this opportunity to comment on AHRQ's Draft Methods Future Research Needs Report entitled "Engaging Stakeholders To Identify and Prioritize Future Research Needs."¹ PIPC exists to advance proposals for comparative effectiveness research (CER) that are patient-centered by being focused on supporting providers and patients with the information they need. PIPC appreciates the report's effort to determine the extent to which stakeholders are consulted to identify and prioritize future research needs.

PIPC urges AHRQ to recognize patients as stakeholders in their own right in a final report. PIPC urges AHRQ to recognize that patients are different than consumers, and that patient views, experiences and needs are very distinct from a consumer. We are deeply concerned by the draft report's failure to identify patients as a separate stakeholder category, which could reinforce prevailing biases against inclusion of the patient voice in decisions about comparative effectiveness research. Full recognition and inclusion of patients may not always be easy, but it is essential for achieving the goal articulated at the opening of the report on developing high-quality evidence that directly addresses the informational needs of patients, physicians, and other care providers.²

In my October 2010 article in *Health Affairs*, I called for organizing CER "in support of a common bias—in favor of the patient," noting that "too often [patients] have ended up operating at the margins of federal programs."³ Lack of recognition of patients as stakeholders in the draft report appears to underscore this concern.

¹ O'Haire, Cristen, Ph.D.;McPheeters, Melissa, Ph.D., M.P.H., et al. (June 2011) Engaging Stakeholders To Identify and Prioritize Future Research Needs (prepared by the Oregon Evidence-based Practice Center and Vanderbilt Evidence-based Practice Center, under Contract No. 290-2007-10057-1) (Agency for Healthcare Research and Quality, Rockville, MD) AHRQ Publication No. 11-EHC044-EF.

² O'Haire at ES 1

³ Coelho, Tony, (2010). A Patient Advocate's Perspective On Patient-Centered Comparative Effectiveness Research. *Health Affairs*, vol. 29 no. 10, 1885-1890, October, 2010.

While PIPC's comments are focused on the draft report on engaging stakeholders, our concerns are amplified by the issuance of a separate AHRQ draft report on use of modeling and value-of-information analysis for future research prioritization.⁴ This draft report appears to embrace an approach to research prioritization that defines research value based on the cost-containment needs of government agencies. As noted in the report, this approach has been used almost exclusively by the National Institutes for Health and Clinical Excellence in the United Kingdom. We are concerned that the AHRQ draft report advocates a utilitarian model rooted in NICE's use of comparative and cost-effectiveness research to make recommendations about patient access to medical care, and recommends further collaboration between AHRQ and NICE in its conclusion.

Related to this, we note that the citation to patient involvement in the first paragraph of the report on stakeholder engagement references the U.K. NICE process.⁵ PIPC recommends that the report replace this with a citation to a U.S.-based program illustrating how patient engagement can positively impact research and its applicability to the public (e.g., the Institute of Medicine process to develop national priorities for comparative effectiveness research, or the Center for Comparative Effectiveness Research in Cancer Genomics' process).

More generally, PIPC has identified several areas of particular concern and offers suggested changes to address them.

First, AHRQ should address language in the report that appears to diminish the role of patients in favor of payers and policy-makers. PIPC is very concerned that "all EPCs discussed the question of whether and how to engage patients or consumers in the process of identifying research gaps and future research needs."⁶ While this may be an accurate reflection of discussions with AHRQ's research centers, it points to a culture of marginalization that is troubling. We believe the report should include discussion of more extensive steps that EPCs and AHRQ could take to address this by more fully including patients throughout the EPC procedures.

Similarly, we are concerned with language that discounts the role of patients and consumers, while giving deference to payers and policy-makers. In particular, the report states several times that key informants expressed concern with the "time, patience, and attentiveness required" in engaging consumers (and, we presume, patients).⁷ Conversely,

⁴ Myers, Evan, M.D., M.P.H.; Sanders, Gillian D. Ph.D; et al. (June 2011) Evaluating the Potential Use of Modeling and Value-of-Information Analysis for Future Research Prioritization Within the Evidence-based Practice Center Program, (prepared by the Duke Evidence-based Practice Center Durham, NC under Contract No. 290-2007-10066-I) (Agency for Healthcare Research and Quality, Rockville, MD) AHRQ Publication No. 11-EHC030-EF.

⁵ O'Haire at ES 8

⁶ O'Haire at 25

⁷ O'Haire at 18

regarding policy-makers, key informants noted “that it is important to understand the pressing time demands that these policymakers encounter on a daily basis.”⁸

Again, this may be an accurate reflection of the key informants’ views, but appears to reflect a mindset or programmatic goal that is more payer-centered than patient-centered. This likely is due in part to the fact that many of the key informants came from payer organizations in the U.S. and Europe. If this is the case, then achieving research that is indeed responsive to the real-world needs of patients and physicians, rather than giving them a back seat to payers and policy-makers, will require a substantial shift in culture and goals that should be more thoroughly discussed in the report.

Second, PIPC strongly believes the report should be revised to identify patients as separate stakeholders throughout the report. Currently, the report uses the term patient in some places, consumer in others, and patient/consumer in others. PIPC recommends that the report make consistent use of the terms patient and consumer throughout the report. The following specific revisions would provide more appropriate and consistent use of these terms:

- On Page ES-4, the report uses the term patient/consumer. This should be revised to say patients and consumers
- Table 1 definitions of stakeholder groups should be revised. We are concerned that this table defines patients as a subset of “consumer” stakeholders. Patients and caregivers (whose needs and perspectives are closely aligned with those of the patients they care for) should be included as a separate stakeholder category.
- The discussion of the IOM process of engaging stakeholders on page 12 should be revised to identify the extent to which patient groups participated in this process, rather than including patients as a subset of the consumer stakeholder group. Similarly, we are concerned that Table 5 does not include patients (or caregivers) as a separate stakeholder category. This may require the survey of key informants to be re-conducted, or at a minimum to revise the description of the category to state “consumers and patients.”
- The discussion of “specific considerations for stakeholder engagement” should include a separate discussion of patients, not just consumers.

Third, the draft report’s discussion of prioritization criteria should reference the criteria established in the Patient Protection and Affordable Care Act, which will guide the priority-setting of the Patient-Centered Outcomes Research Institute (PCORI). The report included a lengthy discussion about “Criteria Used to Prioritize Research” which included “funding availability, current resources available, the burden of disease, community resonance, policy ‘shelf life,’ and in the case of systematic reviews, having adequate primary research

⁸ O’Haire at 19

to conduct a systematic review.” Notably absent from the discussion was any reference to the research criteria identified by PPACA for PCORI in Section 6301, and particularly “patient needs, outcomes and preferences.”⁹ In the struggle to identify priorities that are “useful to the policymaker” as one key informant was quoted in the report, there seems to be little concern with identifying the questions that patients themselves want to be answered.

In addition, PIPC is concerned that the methods described for identifying stakeholders likely biased the outreach to individuals or organizations that already agreed with EPC’s procedures and decisions. The report notes that “EPCs did not select stakeholders at random, but based selections primarily on availability and convenience, knowledge, and personal contacts.”¹⁰ As noted in the report, a process in which researchers reach out to stakeholders via referrals and personal contacts is likely to identify those who are in closest agreement with the researchers.¹¹ PIPC would welcome a discussion in the report about alternative approaches to identify a broader range of stakeholders and engage them through open, transparent processes. For example, patients and other stakeholders should be included in larger discussion groups led by the EPC to facilitate discussion and further the depth of understanding among researchers about the views expressed.

PIPC sponsored a White Paper in March 2011 that reviewed key elements of priority-setting for comparative effectiveness research. The final report should include the additional procedural elements identified in this White Paper, which included steps to ensure transparency and openness, broad stakeholder participation, a range of input opportunities, the need for clinical guidance and input, and transparency regarding the procedures used to consider and respond to stakeholder input. A copy of this publication is available on the PIPC website¹² and is included as an attachment to these comments.

In conclusion, PIPC appreciates the opportunity to comment, and we look forward to our concerns and recommendations being incorporated where possible into the final report. We believe that, with these changes, the final report will encourage stakeholder input that is open, transparent, and more fully recognizes the value of patients.

Sincerely yours,

Tony Coelho
Chairman
Partnership to Improve Patient Care

⁹ Social Security Act §1181(d)(1)(A)

¹⁰ O’Haire at 26

¹¹ O’Haire at ES 2

¹² http://www.improvepatientcare.org/sites/default/files/CER_Procedure-PIPC_Whitepaper.pdf