

Comments submitted electronically at <http://pcori.org/provideinput/tier1input.html>

August 31, 2011

Patient-Centered Outcomes Research Institute  
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**RE: Comments on the Initial Topics for PCORI's Tier 1 Pilot Projects**

The National Council for Community Behavioral Healthcare (National Council) welcomes the opportunity to comment on the Initial Topics for PCORI's Tier 1 Pilot Projects. The National Council, a non-profit association representing over 1,900 community-based mental health and addiction providers, is dedicated to fostering clinical and operational innovation and promoting policies that ensure that the more than 8 million low-income children, adults, and families our members serve have access to high quality services. Our community mental health and addiction organizations have more than 40 years of experience and expertise in providing a range of services and recovery supports for millions of individuals with multiple chronic conditions.

*1) Developing, testing, and/or evaluating novel methods and approaches that can inform the process of establishing and updating national priorities for patient centered outcomes research (PCOR)*

Developing an authentic, principled partnership is and should be a parallel goal to conducting the research priorities of PCOR (Gust and Seifer, 2011). Basic to accomplishing this goal are: 1) creating an interim patient advisory committee immediately that will be tasked with developing criteria for and establishing a patient committee to the Board that has the same status as the methodology committee; 2) developing a process for incorporating broadly based, authentic patient input into priorities; 3) developing a process for presenting PCOR and CER to primary consumers – with the skills and strategies needed by and for engaging traditionally excluded groups in mind.

Establishing a shared governance model is essential to putting these recommendations into action and ensuring a transparent and accountable partnership with the primary user community. We suggest that the process of developing, testing, and evaluating these research topics should be self-reflective so that the PCORI can learn from this process.

Gust, S. & Seifer, S. (2011). The Central Role of Governance in Community-Based Participatory Research. Progress in Community Health Partnerships: Research, Education, and Action, Volume 5.2.

2) *Developing, testing, and/or evaluating methods for bringing together patients, caregivers, clinicians and non-traditional partners in all stages of a multi-stakeholder research process, from the generation and prioritization of research questions to the conduct and analysis of a study to dissemination of study results.*

Establishing effective research partnerships that incorporate service interventions and outcomes that are meaningful to patients goes beyond patients' acquiring research skills. Lessons may be learned from methodologies like Community Based Participatory Research to identify successful components of research that involves diverse stakeholders. In order to successfully engage all partners in research, we know that advocates and people with chronic conditions need skills to engage meaningfully in research. We continue to look at established models of patient engagement and recommend PCORI continue to test established and promising models and practices of patient involvement in research.

Guidance for patient involvement in research typically focuses on developing skills for the user community to participate in research. However, researchers and traditional partners (policy makers, funders) need skills in order to engage in a fully participatory relationship with patients in all stages of research. There are virtually no materials or approaches available to guide research and academic communities in the reciprocal skills to understand how to conduct high quality research that incorporates patient values into their processes, including their questions, designs, methods, analyses, interpretation of their data and dissemination of their findings. The promotion of patient centeredness in research must help to bridge empirically driven and value informed perspectives in research, and a focus must be assisting researchers who are involved in more conventional scientific paradigms identify methods and outcomes that are important to patients.

3) *Developing, testing, and/or evaluating novel processes for translating research findings into changes in health care practices*

We urge PCORI to consider the value of including lived experience of patients into the practical application of research findings. Clearly, research is needed that guides health professionals and providers in adopting research findings into practice. It is at least an equal research challenge to understand the notion of 'personal medicine' (Deegan, 2003)

-- why and how patients choose and use innovations so that the full spectrum of their values –rather than their treatment regimens-- remain central in their daily lives. Patients may seek symptom relief, risk reduction, relapse prevention, disability minimization and ease of use in treatments, but these outcomes may be offset by concerns about disfiguring side effects, impaired concentration, lack of control over dosage, integration with ancillary health-restoring practices. Tolerance for treatment processes may be tempered by the severity and duration of illness. Persons may be willing to tolerate more uncomfortable side effects of treatments with a specified duration (e.g. cancer treatment) as contrasted with chronic care regimens. Additional supports may be necessary for persons with longer duration illnesses and/or illnesses that require more complex management.

Further, we urge PCORI to go beyond the care setting in their definition of health care practice to include health and social policies that affect the places where people live, work and play and where their health begins and ends.

Focusing on the meanings that individuals share and on the explanatory models they use to discuss their health problems provides a richer understanding of these individuals and can yield a cultural understanding that is rooted in their real lives rather than in stereotypes. This meaning-centered approach can also help reveal how community conditions are determined by social, economic, and political forces rather than simply by individual choices (Carpenter-Song et al , 2007; Kleinman et al , 2006; Kumagai et al , 2009; Silka et al , 2008)

Carpenter-Song, E.A., Nordquest Schwallie, M., & Longhofer, J. (2007). Cultural competence reexamined: critique and directions for the future. *Psychiatric Services*,58, (10):1362-1365.

Kleinman, A. (1980). *Patients and healers in the context of culture* (vol. 3). Berkeley,CA: University of California.

Kleinman, A.& Benson, P. (2006). Anthropology in the clinic: the problem of cultural competency and how to fix it. *PLoS Medicine*;3(10): e294.

Kumagai, A.K., Lypson, M.L. (2009). Beyond cultural competence: critical consciousness, social justice, and multicultural education. *Academic Medicine*;84(6): 782-787.

Silka, L., Cleghorn, G.D., Grullón M, & Tellez, T. (2008). Creating community-based participatory research in a diverse community: a case study. *Journal of Empirical Research on Human Research Ethics*;3(2):5-16.

- 4) *Developing, testing, and/or evaluating approaches that could systematically, without bias, identify gaps in evidence that most affect low-income populations; minorities; children; elderly; women; people with disabilities, multiple medical conditions, rare conditions, and other vulnerable populations.*

AHRQ has identified a framework to identify research gaps while compiling a systematic literature review based on the premise that this is an important finding that is difficult to search. Their framework includes (a) insufficient or imprecise information; (b) biased information; (c) inconsistency or unknown consistency, and (d) not the right information.

We suggest that PCORI support the further development of criteria for this framework that highlights the inclusion of patients from communities most affected by health disparities, outcomes that are relevant to these communities, the involvement of these communities in the research process. We suggest that PCORI research announcements include these criteria, and that the inclusion of patients be included in the grant review protocol.

AHRQ. Frameworks for Determining Research Gaps During Systematic Reviews  
Contract No. 290-2007-10061- Prepared by: The Johns Hopkins University Evidence-based Practice Center Baltimore, MD August, 2011-c.

- 5) *Identifying, testing, and evaluating novel predictive outcomes instruments of interest to patients.*

Identifying, testing, and evaluating outcomes of interest to patients cannot be realized without the meaningful involvement and leadership of patients. In this process, patients can help the other members of the team to develop the ability to truly understand what it is *really* like for an individual living with a particular condition. This will take some training and skill development on the part of many patients to identify those important factors in their lives and be able to express them in a way that resonates with the other members of their team. Only then, can real lived experience of the patient be understood and outcomes for an intervention can be identified and measured.

Some data indicate that patients prefer self-rated to staff-rated outcome measures, and would like to see negative as well as positive impacts of treatments and interventions included in research reports (Crawford, et al. 2011). However, we know little about how well any standard outcome measures predict patient health and well-being. In order to move toward this objective, it is essential that patient centered outcomes research include multiple and long term perspectives on health. For patients with multiple persistent conditions, the process of their recoveries may be non linear and therefore poorly

documented. PCORI should solicit mixed-methods research to provide the basis for developing novel predictive outcomes instruments that fill this gap.

The evidence that demonstrates how powerfully social factors determine health suggests that PCORI should encourage the use of research methods that assess the social psychological as well as material processes that underlie the social determinants of health as well as the meanings that individuals share and on the explanatory models they use for their health problems. This meaning centered approach will yield an understanding of individual health that is rooted in people's real lives and is contextualized by culture. Ultimately these models will allow us to go beyond individual choice and develop an empirical base to address the social economic and political forces that affect health

Crawford, M.J., Robotham, D., Thana, L., Patterson, S., Weaver, T., Barber R. , Wykes, T., & Rose, D. (2011).Selecting outcome measures in mental health: the views of service users. *Journal of Mental Health*, 20 (4) 336-346. (doi:10.3109/09638237.2011.577114)

*6) Identifying, testing, and evaluating novel methods for researching behaviors, lifestyles, and choices within patient control that may influence their outcomes.*

It is essential to recognize the role that technologies and supports for individual behavior change can play in facilitating positive health outcomes. However, we urge PCORI **NOT** to lose sight of key bodies of evidence that demonstrate 1) the interactive role of social and individual factors in behavior change, especially the ways that social and cultural factors may limit individual autonomy and choice (Archer, 2003 )

Furthermore, since individuals with multiple chronic conditions are an important focus of health expenditures and disparities, we question how well standard criteria for inclusion in research reflect the actual view of patients themselves. Patient centered research needs to understand patients' multiple identities and their motivations for entering into research partnerships and ultimately into health promoting relationships. We suggest that PCORI or its partner institutions support the development of methods and approaches that allow research to incorporate these complexities into study design and analysis.

*7) Identifying, testing, and evaluating novel methods for studying the patient-clinician interaction in situations where multiple options for prevention, diagnosis or treatment exist.*

Shared decision making is a critical component in a patient centered health system. PCOR should support research that addresses key challenges to broadly based shared health decisions for people with multiple chronic conditions and vulnerable populations. Effective approaches must be developed to teach and support health care providers to

present multiple treatment options – including alternative treatment options – to patients. This complicated issue must address the skills providers may require to navigate power-sharing. One point worth researching is to determine how shared decision making and personal medicine can be more efficient and are not perceived by physicians as another burden on their already onerous work load. *(There are a number of assumptions made here about how physicians “usually” view these issues; these may be points of research interest in order to determine how physicians and patients actually view these issues.)*


PCORI should also solicit research that leverages current technology to survey patients to determine how they actually use health information and whether or not it impacts their healthcare decision making. For instance, on line communities such as Patientslikeme.com tracks a number of health-related factors that would provide an ideal platform for researching self-reported health behaviors. A goal for PCORI might be to move from inventorying and measuring the amount and strength of the evidence to inventorying what actually matters to patients and within the patient-client interaction.

*8) Identifying, testing, and evaluating methods to assess strategies that respect patient autonomy and promote informed decision-making, incorporating the best healthcare knowledge into the application of care.*

We consider this final objective the main aspect of the PCORI mission. The strategies for promoting patient autonomy must be a consideration for all steps of the research process with a special focus on vulnerable populations. Technology will play a crucial role in ensuring that patients are well informed, as well as in dissemination and incorporation of best practices into actual healthcare practice. However, technology will not be the answer for many patients, especially vulnerable populations who do not speak/read English, have multiple conditions, do not have access to technology, have a severe illness, or generally have low health literacy. The engagement of patient caregivers is especially important in this domain, as proxies may assist in clinical decision-making for many.

If you have questions about these comments please contact: Chuck Ingoglia, Vice President, Public Policy at [ChuckI@thenationalcouncil.org](mailto:ChuckI@thenationalcouncil.org) or 202-684-7457 ext 249.

Sincerely,



Linda Rosenberg  
President/CEO