



Thursday, April 21, 2011

Patient-Centered Outcomes Research Institute
5185 MacArthur Blvd. NW
Suite 632
Washington, DC 20016

Dear Members of the PCORI Board of Governors:

Thank you for your ongoing work to establish the Patient-Centered Outcomes Research Institute (PCORI) and to define its program for patient-centered outcomes research. The Partnership to Improve Patient Care (PIPC) supports PCORI's work to develop a program for patient-centered outcomes research, and we particularly appreciate the recent emphasis placed on inviting public comments, as articulated by PCORI Board members during recent meetings.

PIPC is pleased that PCORI has released four draft definitions of "patient-centered outcomes research" early in the process of their development. The definition of this term is a very important issue for our members, and is foundational to PCORI's work. As you know, this term is central to the provisions in the Patient Protection and Affordable Care Act (PPACA) that created PCORI, but is not well-characterized in existing literature and practice. Thus, PCORI's work to define the term has broad, long-term implications for the field. Therefore, in response to the Board's verbal requests for comments, PIPC would like to take this opportunity to articulate some basic principles that we hope can guide the definition of the term.

The statute itself, while not defining "patient-centered outcomes research," does provide some guidance on how it should be defined. These can be found in several places: first, the definition of comparative clinical effectiveness research that the statute does provide; second, in describing the purpose of the Institute (PCORI) that will carry out this research; and third, in factors that the statute emphasizes in regard to this research. With this in mind, we believe that the definition of "patient-centered outcomes research" should include the following principles:

- **Align with the definition of "comparative clinical effectiveness research."** Any definition of "patient-centered outcomes research" should align with the statute's definition of "comparative clinical effectiveness research." The Institute is mandated to conduct comparative clinical effectiveness research, which involves research that evaluates and compares health outcomes and the clinical effectiveness, risks, and benefits of two or more medical treatments, services, and items. It also includes a broad range of interventions that relate to the delivery of high-quality patient care, including "protocols for treatment, care management, and delivery,

procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.”¹

- **Reflect the purpose and program of the Institute:** The statute’s provisions on research priority-setting and dissemination of results emphasize research results that consider “patient needs, outcomes and preferences,” are relevant to patients and clinicians “in making informed health decisions,” and take into account “potential for differences in the effectiveness of health care treatments, services, and items as used with various subpopulations, such as racial and ethnic minorities, women, age and groups of individuals with different co-morbidities, genetic and molecular subtypes, or quality of life preferences...” The Institute’s definition of patient-centered outcomes research should reinforce these points.
- **Clearly focus on needs of patients, their caregivers and providers:** Patient-centered outcomes research should be relevant to the patient and/or the primary health care decision-maker. To do so, we recommend including the concepts of patient individualization, dignity, relationships, preferences and choice articulated in Dr. Donald Berwick’s definition of patient-centeredness.² PIPC strongly supported the creation of PCORI in large part due to the frustration among patients and providers that many existing CER programs were not designed to answer their questions, and did not include research questions that go beyond benefit and risk to include the full range of outcomes that matter to patients, including quality of life, productivity, and patient reported outcomes. We believe approaching CER with patients, their caregivers and providers in mind would facilitate better health care decisions.
- **Recognize variation in outcomes of medical treatment.** As recognized in the statute itself, patients differ from one another for many reasons. Patient-centered outcomes research must recognize variation in individual patients’ needs, circumstances, preferences, and responses to particular therapies. If appropriately defined and implemented, patient centered outcomes research can enrich our understanding of these variations, rather than ignoring them by focusing on population averages that mean little for any individual patient or subgroup. Acknowledging individual patient variation in the definition will help to ensure that study designs themselves generate data on different patient subgroups, and that dissemination of research outcomes reflects differing patient needs based on genetic, clinical and other factors. Issues of variation are very important to patients but, unless expressly recognized, can be minimized in study designs and dissemination.

¹ PPACA §6301, codified at 42 U.S.C. §1320e.

² <http://content.healthaffairs.org/content/28/4/w555.full>



PIPC appreciates your consideration of these comments. As PCORI moves forward on this and other elements of its work to establish its procedures and programs, it will be important to have mechanisms in place to elicit input from the broader stakeholder community. To that end, when PCORI develops a single draft definition of patient-centered outcomes research, we recommend that you post it on your web site and announce the opportunity for public comment on it, and establish this as a more general, regular policy for obtaining public input on proposed PCORI decisions. Broad stakeholder participation will ultimately allow PCORI to produce outcomes research that is credible and meaningful to patients and that supports clinical decision-making.

We hope that our comments are useful to PCORI as it seeks to define “patient-centered outcomes research” and look forward to future opportunities to comment on the important work you are doing.

Sincerely yours,

A handwritten signature in black ink, consisting of a stylized 'T' and the name 'Coelho' written in cursive script.

Tony Coelho
Chairman
Partnership to Improve Patient Care