

Working Definition of Patient-Centered Outcomes Research

Summary Report on Synthesis of Public Input Received (July 20-September 2, 2011)

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Published by PCORI November 14, 2011

On July 20, 2011, the Patient-Centered Outcomes Research Institute (PCORI) invited public comments on PCORI's [working definition](#) of "patient-centered outcomes research" (PCOR). Over the next 45 days, until September 2, 2011, 119 organizations and 449 individuals responded. PCORI selected, through an open RFP (request for proposals) process, NORC at the University of Chicago, a social science research organization, to review the comments and prepare a report that highlights and discusses the common and noteworthy themes conveyed in the responses, and to summarize the responses given to the [four specific questions](#) that PCORI asked about its working definition. This document provides a summary of the responses received. The following are representative of the range of comments PCORI received for each of the four questions.

Question 1: Does the definition appropriately emphasize and convey the importance of patient-centeredness?

- The term "people" should be replaced by "patients," "patient and their doctors" or "patients and their caregivers," to emphasize the focus on patients. The definition should refer to healthy individuals as well as patients so that it is clear that preventive measures are included.
- The definition should reflect that patients and physicians collaborate in making decisions about care.
- The concerns of family caregivers and the burdens that different treatment choices impose on the family should be mentioned.
- The definition should express a commitment to making access to health care and the benefits of research available to all.
- The definition should acknowledge the individual's responsibility for their own health.

Question 2: Is the definition consistent with the intent of the [statute](#)?

Twice as many organizations agreed as disagreed that the definition of PCOR was consistent with the statute, with roughly the reverse proportion among individual respondents. Comments typically offered suggestions for rewording some or all of the definition. A few suggested that comparative effectiveness research (CER) should be included in the definition of PCOR. A number of commenters challenged the final statement of the definition, that PCOR “Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, resources, and other stakeholder perspectives.” They asserted that this conflicts with the statute because it implies that resources or costs would be taken into account.

Question 3: Is the definition broad enough to include the range of research that PCORI should fund?

Many respondents recommended expanding the range of research topics and methods that should be mentioned in the definition. These suggestions include:

- Specific types of studies or research designs
- Community-based population health interventions; support services; public health and public health systems research; supportive and palliative care; integrative and alternative medicine
- Strategies to improve health literacy and patient-provider communications, with a focus on risk and patient decision-making
- Costs of alternative services, particularly those costs as faced by patients and their families

A few respondents conveyed the belief that the definition of PCOR was too broad, making clinical research implementation unfeasible.

Question 4: Does the definition adequately convey the rationale outlined in PCORI's [rationale document](#)?

Almost three-fourths of respondents said that the definition adequately conveys PCORI's rationale. Comments included suggestions for changing the language and wording of the rationale document, reconciling the inconsistencies of the working definition with the rational document, and explicitly defining research topics and outcome methods.

Other frequently stated comments:

- It would be better to use the term "risks" rather than "harms" so that the uncertainty of outcomes of care is conveyed and people are not unnecessarily alarmed.
- Address health status and health care disparities and focus on how different groups vary in terms of health needs and responses to treatment. This was mentioned for racial and ethnic groups and also for patients with mental and behavioral health issues.
- The terms used in the definition are ambiguous; it is difficult to formulate a single definition that can be understood by non-specialists and also satisfy all stakeholders.
- A large number of respondents, many of whom referred to comments submitted by the Citizens' Council for Health Freedom, expressed the view that PCORI should not exist.

Status Update on the Process to Revise the Working Definition of PCOR

NORC at the University of Chicago will conduct for PCORI a series of focus groups in November and December 2011 with patients and caregivers to make sure the definition resonates with those audiences and reflects their interests. Based on the public input received July 20-September 2, 2011, and feedback received from the focus groups, PCORI will consider revisions to the working PCOR definition at the public Board meeting in January or March 2012.

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