



Advisory Panel on Addressing Disparities Meeting Summary

March 2015

Overview

On January 13, 2015, the PCORI Advisory Panel on Addressing Disparities (AD) held its sixth meeting in the Washington, DC area.

The 20-member panel includes patients, caregivers, clinicians, researchers, providers, payers, and purchasers. The panel was joined by AD program staff. The meeting was open to the public via teleconference, and slides and meeting materials were posted to the PCORI website in advance.

PCORI staff provided updates on the Obesity Treatment Options Funding Announcement, a new targeted hypertension funding announcement, general programmatic activities, and priority topics identified by the panel at a prior meeting. After presentations on PCORI's evaluation framework and the Asthma Evidence to Action Network (E2AN), Dr. Stephen Teach, an awardee funded through the AD funding announcement on uncontrolled asthma in African Americans and Hispanics/Latinos shared the goals of his project and the influence of patient engagement on the design of his study. During the final session, staff spoke about PCORI's ongoing efforts to enhance the integration of science and engagement in research. This was followed by breakout discussions centered on a draft document describing possible strategies for engaging patients and stakeholders throughout the entire conduct of a study. Representatives of the breakout groups then summarized their group's suggestions for the entire panel.

Related Information

- [About this Advisory Panel](#)
- [Meeting Details and Materials](#)
- [Advisory Panel on Addressing Disparities September 2014 Meeting](#)
- [PCORI Addressing Disparities Program](#)

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help people make informed healthcare decisions.

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Program Updates

Obesity Treatment Options Funding Announcement

Cathy Gurgol, Program Officer on the AD team, provided an update on the PCORI funding announcement (PFA), [Obesity Options Set in Primary Care for Underserved Populations: Pragmatic Clinical Trials from a Real-World Perspective](#), released in February 2014. This PFA called for studies on ways to reduce disparities in obesity outcomes in underserved populations by comparing evidence-based, comprehensive lifestyle interventions set in primary care practices.

PCORI has awarded two \$10 million, five-year contracts under this PFA: the [Louisiana Trial to Reduce Obesity in Primary Care](#) and the [Midwestern Collaborative for Treating Obesity in Rural Primary Care](#). The research teams will collaborate with one another throughout the course of their projects, where appropriate. In addition to continuing to monitor the progress of these teams, PCORI hopes to implement an Obesity Evidence to Action Network.

General Updates

Dr. Romana Hasnain-Wynia, Program Director for the AD program, gave an overview of the recent projects funded by the program, as well as areas for potential future funding announcements. The AD program funded four projects totaling \$7.4 million in September 2014 under its broad PFA. Details on these projects are available on the [PCORI website](#).

PCORI has issued a [targeted hypertension funding announcement](#) in partnership with the National Heart, Lung, and Blood Institute (NHLBI) and National Institute of Neurological Disorders and Stroke (NINDS) at the National Institutes of Health (NIH). Applications were due February 13, 2015, and total funding will be \$25 million for up to two multilevel, multicomponent comparative effectiveness trials to assess strategies for improving blood pressure control among high-risk patients. PCORI will fund these trials, and NHLBI and NINDS will be responsible for the application review process and monitoring study conduct.

The AD program staff is working with the PCORI Board of Governors to determine whether funding announcements will be developed around perinatal outcomes. AD program staff are also reviewing the literature to confirm and identify potential research gaps in topics that the AD Advisory Panel prioritized at previous meetings: lower-extremity amputations, autism spectrum disorders, osteoarthritis, and dementia. The recent [pragmatic clinical studies PFA](#) includes three topics prioritized by the AD Advisory Panel: reduction of cardiovascular disease risk, integration of mental and behavioral health services in primary care, and multicomponent interventions to reduce tobacco use initiation and promote cessation.

PCORI's Evaluation Framework

Dr. Michele Orza, Senior Advisor to the Executive Director, described PCORI's [evaluation framework](#) and efforts to fine-tune the draft usefulness criteria used to assess PCORI's effectiveness in substantially



increasing the quantity, quality, and timeliness of useful, trustworthy information to support health decisions.

PCORI's Evaluation Framework seeks to address three broad questions:

1. Are we doing what we said we would be doing?
2. Are we reaching our goals?
3. Are we having an impact?

These questions are answered by looking at various processes across PCORI (e.g., the topic selection and research prioritization process utilized by our Advisory Panels). The goal is to measure what impact we are having, or will have, on health decisions, health care, and health outcomes.

In order to further evaluate whether PCORI is indeed building a strong portfolio of useful studies, a set of draft usefulness criteria have been developed. These criteria are meant to capture potential usefulness, as well as the actual usefulness of study findings. A crosswalk of these criteria with other PCORI criteria indicated that these usefulness criteria are already captured partly or wholly in our other criteria (i.e., Topic Selection Criteria, Merit Review Criteria, and Methodology Standards).

Two concepts were not well captured in the draft usefulness criteria:

- whether the demand for the information is coming from end-users and the degree to which they have committed to using it when it becomes available ("user-driven"), and
- whether the study is focused on end-users' needs when some of the primary end-users of the information are not patients ("user-centered").

The criteria were revised to include these missing pieces.

Moving forward, PCORI is exploring ways to emphasize to applicants that their applications should be both user-driven and user-centered.

Asthma Evidence to Action Network (E2AN)

Network Update

Dr. Lisa LeRoy, Principal Associate at Abt Associates, reported on her team's efforts to support the [Asthma Evidence to Action Network](#) (E2AN). The Asthma E2AN comprises 13 PCORI awardees representing eight projects funded by AD, one project funded by the Improving Healthcare Systems program, one project funded by the Accelerating Patient-Centered Outcomes Research and Methodological Research program, one project funded by the Communications and Dissemination Research program, and two projects funded by the Pipeline to Proposal awards. The eight AD studies are evaluating multicomponent approaches to improve health outcomes among African Americans and Hispanics/Latinos with asthma and improve patients' and providers' adherence to treatment guidelines. One of Abt's first tasks was to survey each of the 13 research teams to assess their needs. This assessment showed that their challenges include engaging stakeholders, maintaining engagement, and



reducing staff turnover. Abt will be tailoring the Asthma E2AN to help address these challenges. Abt is also tasked with working with the members of this network to: establish a shared vision, build and strengthen collaboration among awardees, facilitate dissemination, and evaluate the network.

Advisory Panel members provided these recommendations:

- encourage all Asthma E2AN teams, not just those within the AD portfolio, to address issues related to disparities in asthma care
- assess project teams' activities and encourage them to share best practices

Asthma Awardee: Parent-Centered Innovations to Improve Outcomes in at-Risk African-American Youth with Asthma

Dr. Stephen Teach of Children's Research Institute described his project, [Parent-Centered Innovations to Improve Adherence in At-Risk Youth with Asthma](#), funded through the targeted Asthma PFA. This study will develop and test a culturally appropriate program to reduce stress among parents of at-risk urban African-American youth with severe asthma. The goal is to thereby reduce parental stress and reduce asthma exacerbations in children. This randomized controlled trial of up to two 200 dyads will compare usual care plus parental stress management (one-on-one stress-management sessions and peer-support groups) to usual care only.

Advisory Panel members emphasized the need to ensure that the trial results can be implemented in practice.

Intersection of Science and Engagement

Dr. Romana Hasnain-Wynia discussed the intersection of science and engagement at PCORI and the importance of operationalizing the integration of science and engagement. Sue Sheridan, Director of Patient Engagement at PCORI, described the strategies PCORI uses to facilitate the engagement of patients and other stakeholders in research. Kimberley Bailey, PCORI's first [Engagement Officer](#), described the [engagement rubric](#), which provides guidance to applicants, merit reviewers, awardees, and engagement/program officers on engaging various stakeholders. Bailey is responsible for operationalizing the rubric and helping PCORI Engagement and Science programs ensure meaningful engagement of patients and other stakeholders in each research project.

PCORI also encourages engagement through the [Pipeline to Proposal Awards](#), which aims to create partnerships among patients, stakeholders, and researchers that lead to high-quality research proposals. In addition, the [Eugene Washington PCORI Engagement Awards](#) encourage active integration of patients, caregivers, clinicians, and other healthcare stakeholders as integral members of the research process. Bailey added that patient and stakeholder engagement in all research starts during the planning phase of each study and continues through all subsequent phases.

Ayodola Anise, Program Officer on the AD team, shared the challenges that awardees face regarding engagement of patients and other stakeholders throughout the conduct of a study. Anise reported that PCORI staff have worked to identify best, promising, and new practices for addressing engagement



challenges. These practices were organized into four broad categories: study design and protocol development, recruitment and retention, data collection and analysis, and DSMBs and other monitoring committees.

Strategies for Engaging Patients and Other Stakeholders in the Conduct of a Study

Advisory Panel members divided into four breakout groups to discuss PCORI's draft strategies for engaging patients and other stakeholders throughout the conduct of a study. Each group discussed one of the four areas and summarized its feedback for the panel. Their suggestions for PCORI, as well as investigators, are summarized below.

Study Design and Protocol Development

For PCORI:

- synthesize available data and recommendations on engaging specific stakeholder groups to help research teams target their engagement approaches to these stakeholders
- provide broad guidance to stakeholders on their roles in PCORI research projects
- define "meaningful stakeholder engagement"
- establish formal mechanisms to encourage meaningful stakeholder engagement throughout all stages of research, from design through dissemination
- determine how to allocate ownership of study data and credit
- educate institutional review boards about PCORI's stakeholder-engagement process

Recruitment and Retention

For PCORI:

- develop general guidance on when and how to recruit and engage patients and stakeholders, specifically for projects funded in the AD program

For Investigators:

- take time to develop relationships with official and unofficial community leaders
- understand how each community uses technology
- identify the best ways to describe the planned research to each stakeholder community and use community ambassadors to explain studies
- provide privacy training to all study personnel who collect data
- plan stakeholder engagement, including timelines for sharing updates, in advance
- teach community partners basic data analysis concepts using lay terms

Data Collection and Analysis

For Investigators:

- identify the contexts in which certain technologies can and cannot be used
- engage community members to contextualize concepts for their peers
- address ethnographic validity
- ensure that the data collected are relevant to the stakeholder community



- work with community members to place study results into the relevant context
- work with Community-Campus Partnerships for Health, the NIH Clinical and Translational Science Award program, and other groups with expertise in stakeholder engagement in research

Data and Safety Monitoring Boards (DSMBs) and Other Monitoring Committees

For Investigators:

- provide ongoing training on the meaning of data and safety monitoring and the scope of work of the DSMB, including how to present controversial ideas
- create a culture that invites stakeholder participation
- include stakeholder reports as standing agenda items for research team meetings
- compensate community stakeholders for their time
- ensure that stakeholders regard the research question as important and are willing to represent their community on the research team
- ensure that stakeholders participate fully in all aspects of the research and that their role is not more limited than that of other team members

Departing Advisory Panel Members

Dr. Hasnain-Wynia thanked the departing AD Advisory Panel members for all of their contributions to the PCORI AD Program: Dr. Tammy Burns, Monique Carter, Dr. Alyna Chien, Dr. Jacqueline Grant, Dr. Kevin Fiscella, and Venus Ginés.

Next Steps

Panelists will send any additional feedback to Bailey and Anise regarding promising practices for engagement. PCORI will revise its strategies for engaging patients and other stakeholders throughout the conduct of a study based on the panel's feedback. The information in the document will be provided to the asthma awardees and other program and engagement officers at PCORI who will share these strategies with other awardees. Applications are currently being reviewed for new AD Advisory Panel members, and the Board of Governors will approve the final slate in late April. The next in-person meeting will take place on July 22, 2015, where we will be joined by six new members.