Overview

On July 22, 2015, the PCORI Advisory Panel on Addressing Disparities (AD) held its seventh meeting in Washington, DC. The 14 returning panelists were joined for the first time by seven new members, who replaced outgoing members who had fulfilled their term of service. The 21-member multi-stakeholder panel includes patients, caregivers, clinicians, researchers, providers, payers, and purchasers. The meeting was open to the public via teleconference, and meeting materials were posted to the PCORI website in advance.

PCORI staff provided updates on the AD portfolio and recent programmatic activities, and discussed the panel’s interest in exploring research gaps that exist in the treatment and management of sickle cell disease, a topic brought to PCORI by multiple stakeholders. AD staff also presented on the program’s analysis of projects using community health worker interventions.

After program updates, Debra Kay Moser, an awardee funded through the AD program, discussed her project, a patient-centered, self-care intervention that uses community health workers to reduce disparities among people in Appalachia who are at risk for cardiovascular disease. Lastly, the panel discussed two brief summaries on HIV submitted to the AD program by the CDC. The panel will reconvene again on October 21, via webinar.
Introductions
The Advisory Panel on Addressing Disparities (AD) held its first meeting where program staff and 14 returning members welcomed seven new members:

- Ronald Copeland, MD, FACS
- Sinsi Hernández-Cancio, JD
- Barbara L. Kornblau, JD, OTR
- Kenneth Mayer, MD
- Cheryl Pegus, MD, MPH
- Danielle Pere, MPM
- Elinor R. Schoenfeld, PhD

The now 21-member panel represents a multi-stakeholder group that includes patients, caregivers, clinicians, researchers, providers, payers, and purchasers.

Program Updates
General Updates
Romana Hasnain-Wynia, Director of the Addressing Disparities (AD) program, provided an overview of the current portfolio, recently funded projects, and research topics for future consideration.

- As of April 2015, the AD program has funded 55 comparative effectiveness research (CER) projects for $148 million, which includes 45 projects from the Broad PCORI funding announcement (PFA) for $80 million, eight trials from the Treatment Options for Uncontrolled Asthma in African Americans and Hispanics/Latinos targeted PFA for $23.2 million, and two trials from the Obesity Treatment Options in Primary Care for Underserved Populations targeted PFA for $20 million. Details on these projects are available on the PCORI website.
- While the AD program portfolio includes studies across the six target populations and studies in 31 states, there are certain areas that have received limited funding, such as LGBT populations and rural states such as North and South Dakota. Future efforts will be made to solicit proposals that contribute to these areas.
- The Pragmatic Clinical Studies PFA includes five topics previously prioritized by the panel:
  - Reduction of cardiovascular disease risk in underserved populations,
  - Integration of mental and behavioral health services into primary care,
  - Multicomponent interventions to reduce tobacco use initiation and promote cessation,
  - Interventions for improving perinatal outcomes, and
  - Reducing non-traumatic lower-extremity amputations.
- In December 2014, the AD program, in partnership with the National Institutes of Health (NIH), released a targeted funding announcement on Testing Multi-Level Interventions to Improve Blood Pressure Control in Racial/Ethnic Minority, Low Socioeconomic Status, and/or Rural Populations. This PFA solicited comprehensive CER studies that focus on reducing disparities in hypertension outcomes among underserved populations through multi-level interventions. Up to two trials will be awarded and announced in September 2015.
The AD program has been exploring the possibility of funding a trial comparing subcutaneous versus sublingual immunotherapy for the treatment of allergic asthma to complement and leverage findings from the existing portfolio of targeted asthma projects. This topic, brought to PCORI by stakeholders, was vetted by the AD Advisory Panel in April 2015. Following a multi-stakeholder workgroup held in June 2015, a specific CER question with the most potential for PCORI to have an impact was identified: “What is the comparative effectiveness of inhaled corticosteroids (i.e., guidelines-based care) vs. inhaled corticosteroids + immunotherapy (subcutaneous and sublingual) on the treatment of allergic asthma among children.” A number of challenges (e.g., multi-level allergen use would be off-label, no standardized dose exists for the allergen with the biggest potential impact) will require AD staff to continue to work with colleagues at NIH to determine the right timing for a feasible, high-impact study on immunotherapy. PCORI will revisit this topic for a potential targeted PFA in four to six months.

The panel provided feedback to AD program staff, as well as potential strategies for soliciting research that fills current gaps within the portfolio. Their suggestions to the AD program, PCORI, as well as investigators, included:

- Target the state of Florida, given that the state has a diverse population and currently no projects have been funded by the AD program.
- Encourage states with vast Native American populations to submit proposals to PCORI.
- Convene focus groups to understand how various groups, including individuals with disabilities, racial/ethnic minorities, older adults, individuals with multiple chronic conditions, and individuals who communicate through American Sign Language (ASL), self-identify.
- Promote the use of the “Six Question Sequence,” a questionnaire completed by healthcare providers to collect disability data, and further refine for autistic and elderly populations.

The panel also provided suggestions regarding immunotherapy, which included:

- Encourage more granular data collection for race/ethnicity (e.g., Korean, Puerto Rican) that also allows for aggregation to broader racial/ethnic categories (e.g., Asian, Hispanic/Latino).
- Use technology to disseminate data with the purpose of promoting healthy behaviors (e.g., social good advertising campaigns).

Obesity

Cathy Gurgol, Program Officer on the AD team, provided an update on the PCORI targeted PFA, Obesity Options Set in Primary Care for Underserved Populations. 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.

In September 2014, two $10 million, five-year contracts were awarded 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 have already begun to collaborate with one another in various ways.
including aligning outcome measures and inclusion/exclusion criteria. In addition to continuing to monitor the progress of these teams, AD program staff plan to implement an Obesity Evidence to Action Network (E2AN), similar to the Asthma E2AN.

**Topics in the Pipeline**

Hasnain-Wynia introduced the topic of sickle cell disease, which was brought to PCORI by several stakeholders. The panel was asked to provide AD staff with key points and gaps that should be addressed in the topic brief being developed. The following suggestions were provided:

- Leverage international studies where the information learned can be applied to the US healthcare system.
- Differentiate between sickle cell disease and sickle cell trait, as there are variations in how different traits affect the individual and the treatment received.
- Address access issues that drive patients with hematologists to still seek emergency room (ER) care at the time of a pain crisis.
- Explore factors that cause providers to assume patients are abusing pain medications (e.g., the lack of medical homes, which may promote “ER hopping”).
- Integrate clinical psychologists into SCD treatment to alleviate the behavioral barriers in both the patient and the provider and encourage interventions to focus on mental health (MH) issues in patients with SCD.
- Create an algorithm within electronic medical records (EMRs) to help assess patients’ tolerance to opioids to alleviate provider stigma.
- Incorporate the role of pharmacists in study designs, as they are one of the main points of contact when delivering medication.

**Community Health Workers in the Addressing Disparities Portfolio**

Gurgol presented a preliminary analysis of projects funded in the AD program using community health worker (CHW) interventions. The AD program has invested $2.2 million for 22 projects that use CHW interventions and want a better understanding of the role that CHWs play in addressing health disparities. Projects incorporating CHWs into their intervention were analyzed on a variety of domains, including educational requirements, training, and the intensity of CHW interactions with participants. Panel members were asked to provide feedback on next steps for analysis.

The panel provided the following input on the topic of community health workers:

- Develop criteria to assess patient/family response in working with CHW and CHW self-efficacy in relation to patient health outcomes.
- Support a PCORI-wide effort to compare the role of CHWs to other personnel (e.g., nurses or patient navigators).
- Mobilize efforts to enhance the role of CHWs by empowering them to focus on delivering the intervention versus burdening them with tremendous paper work.
• Compare the various strategies used to match community health workers with patients, such as by race/ethnicity, age, and community factors.
• Consider methods to standardize training of CHWs, as the variability in training modules poses as an obstacle in performing powered data analyses of these types of interventions.

Awardee Presentation: Reducing Health Disparities in People in Appalachia with Multiple Cardiovascular Risk Factors

Debra Moser of the University of Kentucky described her project, Reducing Health Disparities in Appalachians with Multiple Cardiovascular Risk Factors, funded through the Addressing Disparities broad PFA. This study will develop and test a culturally appropriate program to reduce cardiovascular disease among high-risk adults in Appalachian Kentucky. This randomized controlled trial of up to 350 adults will compare HeartHealth, a patient-centered, self-care intervention to usual care only. CHWs are utilized in this intervention to provide interactive modules that teach participants ways to prevent and treat cardiovascular disease in a group setting.

Discussion of CDC HIV Summaries

Hasnain-Wynia led a discussion on two summaries submitted to PCORI from one of their stakeholders, the Centers for Disease Control (CDC): “Early HIV Treatment to Optimize Patient Health and HIV Prevention: A Comparative Effectiveness Study of Immediate Antiretroviral Therapy for Persons with Acute or Early HIV Infection” and “Comparative Effectiveness Trial of Innovative Models of Delivery of HIV Prevention and Care Services for People Living with HIV (PLWH).” The panel was asked to consider the applicability of these summaries to the PCORI criteria, refine the questions posed by the CDC, and consider other specific CER questions that fit and align with the goals and mission of PCORI.

Input from the panel included the following:

• HIV is an area in need of more funding given that suboptimal care is being provided and there is evidence of health disparities. The panel supported the development of a topic brief that has potential to lead to a targeted announcement and proposals in this area; however, the members suggested a fairly targeted announcement with the goal of testing different approaches to optimizing the treatment of patients with HIV to include sub-questions that address early HIV treatment.
• A focused topic brief in this area should address the continuum of care to allow for innovation and treatment of HIV, which is now considered a chronic condition (e.g., models of early detection, identification and retention; early linkage and engagement; early treatment initiation).

Next Steps

The panel requested additional information on PCORI-wide projects targeting individuals with disabilities as well as older adults. AD staff will continue to explore the literature as it relates to SCD and HIV and, after approval from the Science Oversight Committee, will present the panel with topic briefs.
for prioritization at the next in-person meeting. AD staff will also continue to analyze projects that have CHW interventions, not only within the AD program, but PCORI-wide, to understand the data that exists, what gaps remain, and where PCORI can make a contribution to the field.

The next meeting will take place via webinar on October 21, 2015.