PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI Advisory Panels April 19-20, 2013 Meeting Summary

June 11, 2013

About PCORI

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input to enhance its work.

Our Mission: PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

Our History: PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a non-profit, nongovernmental organization. PCORI's purpose, as defined by the law, is to help patients, clinicians, purchasers, and policy makers make better informed health decisions by "advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions."

The statutory language defining PCORI is broad and authorizes research that will support a strong patient-centered orientation, inform better choices among alternative treatment and prevention strategies, and direct attention to individual and system differences that may influence strategies and outcomes. PCORI was designed to produce knowledge through the analysis and synthesis of existing research and the support of new research.

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I. Overview

PCORI convened the first meeting of four advisory panels April 19–20, 2013, in Alexandria, Virginia, for a two-day training and working session. The four advisory panels were brought together in the program areas of Assessment of Prevention, Diagnosis, and Treatment Options; Improving Healthcare Systems; Addressing Disparities; and Patient Engagement. Each of the advisory panels included 21 members, drawn from a pool of over 1,000 applicants. Patients, caregivers, patient/caregiver advocates, clinicians, researchers, organizational providers, representatives from payers, industry, and purchasers are represented on each of the advisory panels.

During the meeting, three of the advisory panels—the Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Option, the Advisory Panel on Improving Healthcare Systems, and the Advisory Panel on Addressing Disparities—reviewed proposed research topics for PCORI funding, discussed and ranked topics, and reached consensus on a small number of topics to recommend to PCORI's Board of Governors for development into targeted funding announcements. (See below, "Advisory Panel Deliberation Process," for more on the deliberation process followed by these panels.)

A fourth panel, the Advisory Panel on Patient Engagement provided guidance on new PCORI engagement initiatives; input to assure meaningful patient engagement in the research process, including topic generation/prioritization; the review of research proposals; the design and conduct of research; the dissemination and implementation of the research findings; and the evaluation of engagement in research.

This brief summarizes the plenary session and the work of the four advisory panels over the course of the two-day meeting.

Plenary

The plenary began with a welcome and orientation to the mission of PCORI and the charge to the advisory panels by Executive Director Joe V. Selby. Dr. Selby reviewed PCORI's legislative mandate, the key characteristics of research eligible for PCORI funding, and the areas of research that PCORI has committed to so far. Next, Sue Sheridan, Director of Patient Engagement, outlined the roles for patients in the work of PCORI and the myriad forms that patient engagement in outcomes research takes. These include articulating research questions, reviewing research proposals for funding, conducting PCORI-funded research, disseminating findings, and evaluating PCORI's effectiveness in patient engagement and answering questions of importance to patients.

During the second half of the plenary, Rachael Fleurence, Acting Director, PCOR Methods, and Kara Odom Walker, Program Officer led an orientation and training in PCORI's research prioritization criteria and process and the use of Expert Choice© and SurveyGizmo©, two software assessment and ranking tools. Their presentation slides are available on PCORI's website.[1]

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[1] Available at pcori.org/events/advisory-panel-kickoff-training.

Advisory Panel Deliberation Process

In advance of the Kickoff and Training meeting, each of the advisory panels reviewing proposed research topics received "An Orientation to PCORI's Research Prioritization Process," which described the application of five criteria by which individual research topics should be assessed for their suitability and priority for PCORI funding. In addition, advisory panel members received a set of research briefs or topic summaries that described the problem and state of current knowledge for each of the topics the particular panel would be discussing. PCORI commissioned these topic briefs from three clinical research teams: Duke University (Assessment of Options); Johns Hopkins University (Healthcare Systems); and University of North Carolina (Addressing Disparities). The Assessment of Options panel reviewed 20 topics; Healthcare Systems 15; and Addressing Disparities 12.

In each of the panels, one, two, or three panel members were assigned primary responsibility for a given topic or two. Panelists presented summaries of the material in the research briefs and described the merits and limits of each proposed topic. After each topic had been presented, panelists engaged in an open conversation about the merits of the research questions. Panelists shared opinions about whether and why certain questions should be prioritized and funded by PCORI. After the topic briefs were presented, panelists had the opportunity to suggest alternative questions for the group's consideration. At the end of the review and discussion of each topic (which took at least all of the first day's session), panel members used the Expert Choice© software to rank the research topics. Much of the second day's panel sessions involved rankings and discussions of relative priority among the proposed research topics.

Each of the advisory panels included discussions of alternative topic formulations at some point, either before or after initially rating the topics using Expert Choice©. After tallying and collating the scoring of research topics using Expert Choice©, panel members reviewed their group's aggregated scoring and rankings of topics and discussed the results. Each panelist had the opportunity to comment on the rankings and which topics he or she considered funding priorities.

Although the specific applications of the ranking software and reformulation of topic descriptions varied from one panel to the next, each panel initially used Expert Choice© and ultimately ordered its small number of high-priority topics using SurveyGizmo©. As PCORI staff generated the ranking results, panelists discussed the direction of future research, including research areas that should be raised during the next panel meeting. Panelists also discussed the ranking tools and panel process, and they recommended modifications for future meetings.

II. Advisory Panel on Assessing Options for Prevention, Diagnosis, and Treatment

Overview

David Hickam, PCORI Program Director, led off with an overview of how the research topics were nominated and winnowed down to the topics referred to the panel for prioritization. PCORI received almost 600 research questions via the web that were related to the assessment of options for prevention, diagnosis, and treatment. From this pool, PCORI staff identified 20 topics that best met criteria for PCORI funding (see below) and commissioned a research brief on each topic to inform the panel's review[2]. The advisory panel presented and discussed each topic and, during the second meeting day, ranked the topics and discussed their relative suitability and priority for PCORI research support.

Assessing Options for Prevention, Diagnosis, and Treatment:
Topics for Research Prioritization

Topic 1: Attention Deficit Hyperactivity Disorder (ADHD)
Topic 2: Bipolar Disorder
Topic 3: Hip Fracture
Topic 4: Carotid Artery Disease
Topic 5: Cerebral Adrenoleukodystrophy (ALD)
Topic 6: Coronary Artery Disease
Topic 7: Ductal Carcinoma
Topic 8: Gestational Diabetes
Topic 9: Eczema
Topic 10: Epilepsy
Topic 11: Generalized Anxiety Disorder (GAD)
Topic 12: Hearing Loss
Topic 13: Chronic Kidney Disease
Topic 14: Treatments for Liver Cancer
Topic 15: Macular Degeneration
Topic 16: Melanoma
Topic 17: Migraine Headache
Topic 18: Multiple Sclerosis
Topic 19: Obstructive Sleep Apnea
Topic 20: Osteoarthritis

The following synopsis is organized by the general themes that emerged over the course of the meeting and concludes with the panel's recommendations for research priorities and next steps in the ongoing work of the panel.

Discussion

Discussions focused on several key themes:

Developing research tools and methods needed for comparative effectiveness research (CER). In narrowing down the topics to those of highest priority for PCORI, panelists realized that the final decisions on funding and study design will need to be made in consultation with the PCORI

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[2] These briefs are available at pcori.org/funding-opportunities/assessment-of-prevention-diagnosis-and-treatment-options-research-topics.

Methodology Committee. For example, some areas of great importance and potentially fruitful CER lack precise and consistently applied diagnostic criteria or measures of response to treatment (e.g., ADHD), which ideally should be developed prior to a full-scale CER study. Depending on how PCORI interpreted its mandate, adjunctive non-CER research might or might not be fundable. One panelist noted that, if the Methodology Committee considers the importance of applications of new methods for certain fields of research, it could lead to new ways of doing science that could influence how studies are conducted and they could prove to be valuable.

Topics related to other panels: healthcare systems, disparities, patient engagement. The panel members recognized that several of the research topics for their consideration also were relevant for the other advisory panels meeting concurrently. Issues of access to care, affordability, and insurance coverage are healthcare system issues; treatment of hearing loss, for example, entails access issues, specifically affordability, of auricular implants and hearing aids. Other topics were related closely to patient adherence, engagement, and effective communication with providers. In its discussions of specific topics, the panel frequently focused on PCORI's role in disseminating information and educating patients because, for patients to be able to make optimal decisions, they need information on the benefits and harms of the available options.

Shared decision making/personalized medicine. Across many topics, panel members noted that research to facilitate shared decision making was a "natural" for PCORI funding. In particular, such research should consider how patient choices and preferences would be reflected in the development of new research questions and hypotheses, for example, by using patient-reported outcomes to identify quality-of-life issues.

Chronic illness management. A recurring theme across many topics was effective management of chronic illness. Panel members viewed many topics, including those they referred to the Board of Governors as of highest priority, as rooted in one or more chronic conditions that require attention over time. Panel members opined that a study in this area will bring value across topics.

Taking the topic "upstream" to a preventive intervention. Another recurring theme in the panel's deliberations was attention to the precursors of the condition or disease presented in the research topic briefs. For example, panelists observed that reducing the prevalence of obesity will have positive repercussions on a variety of problems, including sleep apnea, osteoarthritis, chronic kidney disease, coronary artery disease, and carotid artery disease. PCORI has already released a public funding announcement in obesity research.

Head-to-head trials and appropriate comparators. Panel members addressed important opportunities for PCORI to fund head-to-head trials that other funding agencies and commercial entities were unlikely to support. In particular, post-licensing trials of pharmaceuticals, trials involving devices and surgical procedures and techniques, and medical versus surgical treatment strategies are understudied. The panel also debated the circumstances under which “usual care” was an appropriate comparator.

Clarity and interpretation of PCORI’s criteria for prioritization of research topics. Panel members explicitly addressed PCORI’s five criteria for reviewing topics in their initial presentations and discussion of each one. They discussed whether each criterion should have equal weight, as Expert Choice©, the ranking tool, implicitly assigns. They also considered how the third criterion, “Options for Addressing the Issue,” should be interpreted. The panel agreed on the following definition: “Potential for PCORI study to make a difference, to add to what we already know, and lend itself to CER research.”

Rare diseases. PCORI is committed to include studies of patients with rare conditions, as well as those with more common illnesses. Given the difficulty of considering rare diseases in the same context as highly prevalent conditions, the panel suggested that PCORI find another approach for prioritizing rare diseases. PCORI staff reported that work is underway to tackle this issue.

Action

During the second day of the meeting, after scoring the 20 topics and rank ordering the highest scoring topics, panel members agreed to recommend the top seven topics to the Board of Governors because of the clustering of scores among the fifth through seventh topics. The seven topics selected included:

1. Ductal Carcinoma
2. Osteoarthritis
3. Migraine Headache
4. Bipolar Disorder
5. Chronic Kidney Disease
6. Multiple Sclerosis
7. Coronary Artery Disease

Next Steps

The panel discussed issues that will need to be addressed at future meetings and teleconferences. Panel members suggested that this advisory panel hold a joint meeting with, or consult with, PCORI’s Methodology Committee to better understand the kinds of studies that PCORI is able to fund and the Methodology Committee’s own research agenda. The panel agreed to hold at least one conference call before the next meeting. Finally, Dr. Hickam invited nominations for the advisory panel chair and co-chairperson.[3]

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[3] On March 26, 2013, Alvin Mushlin, MD, ScM, was selected to chair this panel and Margaret Clayton, RN, PhD was selected to co-chair. For more information please see pcori.org/2013/eight-healthcare-community-representatives-named-chairs-co-chairs-of-pcori-advisory-panels.

III. Advisory Panel on Improving Healthcare Systems

Overview

Chad Boult, PCORI Program Director, led off the advisory panel session with an overview of the role of Improving Healthcare Systems among PCORI's national priorities. Dr. Boult noted how "healthcare system" could have different meanings for patients, providers, payers, and decision makers, and he identified broad areas of systems research, including improving support for patient self-management, coordination of care for complex conditions, improving access to services, and comparing alternative strategies for workforce deployment. He provided a brief overview of the prioritization process, an orientation to the research briefs commissioned to inform the panel's review [4], and the software that panel members would use to help rank the group's assigned topics. Panel members introduced themselves by giving their individual perspectives on the healthcare system and on areas they believe require an increased focus on patient-centered outcomes. During the rest of the afternoon and the following day, advisory panel members discussed the research topics (see box below), potential revisions to the topics, and new topics for PCORI's consideration, and they reached consensus on the highest priority topics for consideration by the PCORI Board of Governors.

Improving Healthcare Systems:
Topics for Research Prioritization

Topic 1: Accountable Care Organizations And PCOs
Topic 2: Effects Of Models for Chronic Disease Management
Topic 3: COPD Management
Topic 4: Cancer Management
Topic 5: Palliative Care Management
Topic 6: Pregnancy Management
Topic 7: Care Management of Multiple Chronic Conditions
Topic 8: Medical Homes
Topic 9: Non-Physician Medical Homes
Topic 10: Mental Health and Primary Care Co-Location
Topic 11: Rural Trauma
Topic 12: Health IT and Treatment Guidelines
Topic 13: Quality Improvement Strategies
Topic 14: Effect of Insurance Features
Topic 15: Transitions in Care and Patient Safety

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[4] These briefs are available at pcori.org/funding-opportunities/improving-healthcare-systems-list-of-topics.

Discussion

Discussions focused on several key themes:

Cultural change within the healthcare system. Panel members emphasized the importance of studying interventions that change the culture of the healthcare system, the need for a “culture shift” and “changing the way we think.” Panelists identified several characteristics of a patient-centered healthcare system, including:

- Empowering patients to make choices using transparent information
- Providing individualized care based on unique patient needs, preferences, and risks

They gave examples of healthcare organizations that have focused on creating a patient-centered environment, such as the Cleveland Clinic. Some panel members suggested that research efforts should consider why some providers and institutions have adopted patient-centered models of care while others have not. Because providers who are interested in care management are likely to be focused on patient-centered outcomes, studies that focus on care management models might not impact those parts of the healthcare system that need improvement. It was also suggested that healthcare systems and hospital administrators be part of the deliberation in the future.

“Usual care” and appropriate comparators. Many of the research topics under consideration compared an intervention with “usual care.” Panelists questioned whether “usual care” should be the basis of comparison and instead proposed funding comparisons of different models of care, as “usual care” often represents the least effective practices. Thus, PCORI should compare models that already have an evidence base. These models are already proven to be more effective than “usual care.” Other panel members suggested that because “usual care” exists in the healthcare system, it can be a useful comparator.

Defining models for comparison. Panel members raised several key issues with regard to identifying models of care to be studied, highlighting the need for commonly defined concepts and recognizing the variation within any model of care, such as care management. Other members questioned whether PCORI’s funding announcements should define the characteristics of a given model or allow researchers the flexibility to define concepts. Some panel members expressed particular concern about funding research that targets new models of care (e.g., ACOs) that have not been developed fully. Another concern regarding studies of specific models of care was the issue of replicability. Models of care may work well in specific settings, but they may not be generalizable to different environments and health markets.

Patient-Centeredness. Panel members shared important insights regarding patient empowerment and patient-centered outcomes research. Several panelists commented that the research questions seemed “provider-focused” and not “patient-centered.” Some panel members noted that quality improvement efforts are not necessarily patient-centered and are more often provider- and system-centered. Many of the research topics under consideration addressed some form of care management. Panelists questioned the assumption that care management and care coordination are patient-centered. For example, one panel member noted that the concept of care management assumes that patients cannot manage their own care; a care manager can often be an additional burden for the patient.

Action

On the first day of the meeting, panel members conducted an initial ranking exercise to prioritize the 15 research topics (see box below). Based on this preliminary ranking, the panel decided to focus its discussion on the seven highest scoring topics, with topics 1, 11, and 13 being removed from consideration. Through further deliberation, the group agreed to propose a broad research topic addressing care management strategies by merging topics 2, 3, 4, 5, and 7. Panelists also agreed to reword topic 6 to focus on perinatal care rather than pregnancy alone. After reviewing the results for the seven most highly ranked research topics, the panel deliberated as to which of the research topics should be recommended to the PCORI Board of Governors as funding priorities.

The panelists shared different views on the number of topics that should be prioritized. There was concern that if those seven may not be able to be funded and viewed as high priority, the Board of Governors may end up selecting a lower priority topic to include in a funding announcement. Several panelists expressed interest in advancing all but the two lowest scoring topics, as those topics seemed to garner significantly less interest than the other five. After deciding to recommend the five highest scoring topics, the group took a hand vote to gauge consensus on the three mid-range scoring topics.

The final prioritization results included:

Top two:

- **Models of patient-empowering care management**: What are the comparative effects of care management models (designed to optimize care coordination and continuity) on patient-centered outcomes (PCOs) among patients with chronic or progressive conditions, disability, cancer, or other potentially life-changing illnesses?
- **Models of transitional care**: What are the comparative effects of models of transitional care on patient safety and other PCOs?

Next three (in order of priority; * indicates topics that received an equal number of votes):

- **Different features of health insurance coverage:** What are the comparative effects of different insurance features (e.g., benefit designs, utilization management, cost sharing) on chronically ill patients' access to care, quality of care, and PCOs?

- **Models of integration of mental health care and primary care*:** Compared to primary care alone, what is the effect of primary care co-located with mental health services on mental health symptoms, medication use, and other PCOs?
- **Models of perinatal care*:** What are the comparative effects of care management (designed to optimize care coordination and continuity) on PCOs among pregnant and post-partum women?

Next Steps

The panel discussed the potential topics for future research, including research areas that should be raised during the next advisory panel meeting, such as healthcare financing, whole-system redesign efforts, alternative providers and sites for healthcare delivery, and patient-centered outcomes measure development. Panel members also shared their perspectives on the panel process and recommended modifications for future meetings. Panel members want to learn more about the proposed research topics in advance of their prioritization discussions and ranking. Some panelists suggested helping PCORI with landscape reviews of the various research topics.

Following the meeting, PCORI will provide a list of contact information for panel members to stay in touch outside of meetings. Panelists were also asked to submit nominations for a chair and co-chair of the panel for final approval by the Board of Governors.[5] Moving forward, the IHS team will provide ongoing communication about the program's PCORI-funded projects and other key events to keep the panel members informed.

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[5] On May 21, 2013, Trent Haywood, MD, JD, and Doris Lotz, MD, MPH were selected as Chair and Co-Chair of the Advisory Panel on Improving Healthcare Systems. For more information, see pcori.org/2013/eight-healthcare-community-representatives-named-chairs-co-chairs-of-pcori-advisory-panels.

IV. Advisory Panel on Addressing Disparities

The Advisory Panel on Addressing Disparities was opened by PCORI Program Director Romana Hasnain-Wynia and Senior Program Officer Adaeze Akamigbo with a discussion about the role of addressing disparities within PCORI's national priorities. Dr. Akamigbo provided an overview of the goals for the meeting, as well as an orientation to the research briefs commissioned to inform the panel's review [6], PCORI criteria for prioritizing research topics, and the software to help rank the topics. Panel members embarked on discussions of each of the 12 topics that were provided to the panel members for their consideration. The topics are shown in the box below.

Over the course of the two-day meeting, advisory panel members discussed the research topics presented in the briefs, with respect to the PCORI topic criteria. Members also considered potential revisions to the topics and brought forward new topics for PCORI's consideration. By the end of the meeting, the panel reached consensus on the highest priority topics for consideration by PCORI's Board of Governors. Panel members also shared their perspectives on the panel process and recommended modifications for future meetings.

The following synopsis of the panel's deliberations is organized by the general themes that emerged over the course of the meeting and concludes with the panel's recommendations for research priorities.

Addressing Disparities:
Topics for Research Prioritization

Topic 1: Communicating risks for minorities or low health literacy patients
Topic 2: Care coordination for special needs patients
Topic 3: Care coordination in primary care
Topic 4: Interventions for improving birth outcomes
Topic 5: Heart attacks among racial and ethnic minorities
Topic 6: Telemedicine for rural cardiovascular care
Topic 7: Telemedicine for rural mental health care
Topic 8: Reduce foot amputations in minorities
Topic 9: Breast cancer screening for high-risk women
Topic 10: Rural trauma care
Topic 11: Hypertension in minorities
Topic 12: Complementary medicine for juvenile cancer patients

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[6] The briefs are available at pcori.org/addressing-disparities-research-topics.

Discussion

Discussions focused on several key themes:

Breadth of populations and issues to be considered under health disparities. Panel members discussed the broad range of issues and populations encompassed by PCORI's mandate to address disparities in health care and outcomes. Although disparities are most often thought of in terms of race and ethnicity, systematic health disparities and differences in access to care exist by gender, socioeconomic status, disability status, and geography. The panel endorsed the expansive understanding of the types of disparities—and research—that PCORI should address. At the same time, panelists noted that strategies envisioned in one context, such as telemedicine for rural, underserved communities, may likewise be applicable in urban underserved settings. Similarly, when looking at communication strategies to engage patients in one cultural context who experience disparate health outcomes (e.g., African-American women with breast cancer), PCORI should be mindful of the similar deficits—and possibly different strategies for addressing those deficits—in other subpopulations (e.g., Asian-American women).

Focusing research on broader topics versus specific issues. Panel members agreed that some of the topics were similar enough to be combined, as the underlying research questions addressed were the same. For example, topic 6, telemedicine and cardiovascular care, and topic 7, telemedicine for rural mental health care, are two applications of the same technology and were considered together as a research topic on telemedicine. In addition, panelists suggested that topic 5, heart attacks among racial and ethnic minorities, and topic 11, hypertension in minorities, could be combined and considered as one topic around cardiovascular disease.

In a similar vein, panelists were attracted to broad strategies, such as addressing health literacy and communications strategies with populations at risk of disparate care and outcomes, as these approaches could then be applied across a spectrum of clinical issues.

Redefining the research topics to address prevention and early interventions rather than the downstream consequences of disease. In discussing the topics, panel members considered opportunities for focusing research on the more upstream conditions and services that could precede stark disparities in outcomes from advanced chronic disease. For example, when panelists reviewed topic 8, reducing foot amputations in minorities, they proposed that the research question be recast to include interventions that prevent or treat the underlying disease (diabetes) instead of poor outcomes from the disease. Given that there are many complications of diabetes (e.g., eye disease, cardiovascular disease, lower extremity amputations, and high hospitalization rates), panel members stated that the topic should be broadened to address disparities around diabetes rather than focus on the outcome of foot amputation. At the same time, the panelists acknowledged the persistence of disparities in disease treatments and outcomes, which will not be affected by prevention research for a long time.

Opportunities to link PCORI work to existing studies. In reviewing research topics, panel members considered where there might be opportunities to link PCORI funding for disparities research to ongoing or planned studies funded by other organizations. Potential opportunities for collaboration include federally funded projects (e.g., studies conducted by the National Heart, Lung, and Blood Institute [NHLBI], the Center for Medicare & Medicaid Innovation [CMS Innovation Center], the Centers for Disease Control and Prevention [CDC], the Million Hearts Initiative [prevention of cardiovascular disease conducted by the Department of Health and Human Services]), and projects funded by national and regional foundations, as well as disease-specific philanthropic organizations.

Action

The panel ranked the five highest priority topics in the following order. These topics will be presented to PCORI's Board of Governors.

1. Compare the effectiveness of clinician/patient health communication models on improving outcomes in minority populations, patients with low literacy and numeracy, people with limited English proficiency, underserved populations, and people with disabilities.
2. Compare the effectiveness of health interventions (including place-based interventions in community health centers) to enhance the Million Hearts program and reduce major vascular events among the economically disadvantaged, including racial and ethnic minorities and rural populations.
3. Compare the effectiveness of different delivery models (e.g., home blood pressure monitors, utilization of pharmacists or other allied health providers) for controlling hypertension in racial minorities.
4. Compare the effectiveness of multilevel interventions (e.g., community-based, health education, usual care) on reducing disparities in perinatal outcomes.
5. Compare the effectiveness of interventions on reducing disparities in lower extremity amputations in racial and ethnic minorities.

Next Steps

The five highest priority research topics will be presented to PCORI's Board of Governors. Panelists were invited to submit nominations for Advisory Panel Chair and Co-Chair to be considered by staff and the PCORI Board of Governors[7]. PCORI staff will consider holding a conference call with the panel prior to its next meeting to provide instructions for preparing for the next meeting.

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[7] On May 21, 2013, Dorian C. Miller, MD, and Grant Jones were selected as Chair and Co-Chair of the Advisory Panel on Addressing Disparities. For more information, see pcori.org/2013/eight-healthcare-community-representatives-named-chairs-co-chairs-of-pcori-advisory-panels.

V. Advisory Panel on Patient Engagement

Overview

Sue Sheridan, PCORI Director of Patient Engagement, began the Patient Engagement Advisory Panel with an introduction to PCORI's legislative mandate and a review of the panel's charge, developed during an October 2012 Workshop:

- Advise on processes to identify research topics and priorities that are important to patients
- Advise on all aspects of stakeholder review of applications for PCORI funding
- Provide general recommendations to PCORI and externally on the conduct of patient-centered research
- Advise on methods to evaluate the impact of patient engagement in research
- Assist and advise PCORI on communications, outreach, and dissemination of research findings
- Provide advice on other questions and areas of interest that may arise that are relevant to PCORI's mission and work.

In providing feedback on the charge, panel members emphasized the need to identify where the panel can have the greatest impact. Panelists suggested a focus on the design and conduct of patient-centered research, highlighting an opportunity to define methods and transform the research process to make it patient-centered.

Over the course of the meeting, the panel discussed the charge to the Advisory Panel on Patient Engagement; the roles of patients in research; the definition of meaningful patient engagement in research; best practices in matching patients and researchers; evaluation of patient engagement efforts; the research prioritization and selection process; patient involvement in PCORI review of research proposals and criteria for evaluating proposals' engagement efforts; best practices in disseminating health information to the community; and the PCORI Engagement Awards and Ambassadors Program.

Discussion

Discussions focused on several key themes:

Need to communicate to the patient/caregiver community the reason why patient engagement in research is important. Panelists encouraged PCORI to recognize that many individuals may not readily grasp the personal and practical significance of patient engagement in research. In order to effectively engage patients and the general public in research, panelists felt PCORI must first clearly articulate the problem and solution in a way that is salient. Panelists agreed that PCORI should clearly state the "why" for engaging patients in PCORI's work and move the current thinking from a “partnership in care” to a “partnership in research.” It was stated that PCORI needs to help the patient/caregiver community understand the opportunity to be transformative in improving patient outcomes by becoming engaged in research. As a result, PCORI may need to rethink how to approach the patient community. This includes being clear on the “ask” of patients and of others engaged through various PCORI initiatives and programs.

Panelists also suggested a **need to reframe the invitation to patients**: “When you invite people to share what they think about, what matters to them, and what they think should be done—people come.” The panel also discussed a need to recognize the differences between the individual patient perspective and an advocacy organization perspective in thinking about the broader societal interests. Panelists suggested that the mechanisms built for engaging patients recognize that the majority of patients are not hyper-engaged. PCORI staff agrees with this point and explained that PCORI is looking at multi-modal capacity-building training for bringing the individual patient to the next level of engagement. Similarly, panelists encouraged PCORI to be clear in the organizational capacities of the Ambassadors Program. They cautioned that without a clear and specific “ask,” groups may try to create their own governance structures instead of building around the core capacities.

Need to overcome barriers to patient-researcher partnerships. Panelists discussed barriers to patient-researcher partnerships, including an imbalance of power; time sensitivity for publishing research findings; a lack of incentives for patients and consumers; an unclear definition of what effective patient engagement entails; and a lack of real-life examples of how engagement can be done well. They also noted patient distrust of the true intentions for research and researcher concerns about competence when involving laypersons in the research process as barriers to partnership.

Need to train research community and patients. Panel members identified a need to prepare the environment for meaningful patient engagement by first preparing the research community (e.g., preparing researchers to speak using plain language and discuss their research in an outcomes-oriented way [cures and treatments], and prepping communities with language and tips on how to communicate scientifically). The group suggested PCORI break into the research silo by first conducting outreach to research leadership (PIs and deans) as partners. Panelists also emphasized the importance of making a consistent training structure available to organizations, even those without PCORI funding, who want to involve patients and families in their research. Participants felt that consistent messaging better enables such organizations to apply for the next round of PCORI funding.

Opportunities to learn from existing models of community and patient engagement. Panelists suggested that existing models of community engagement could and should serve as models for PCORI. These include CDC principles of community engagement; hospital advisory councils; community-based participatory research (CBPR); and the Congressionally Directed Medical Research Program (CDMRP). However, there was also recognition of the limited examples of best practices in patient engagement specifically related to research, which highlighted the need to provide examples of what patient engagement looks like for researchers/applicants and reviewers.

Need to define indicators and metrics of "success" in patient engagement. Several panel members called attention to the importance of defining indicators and measures of success for patient engagement. PCORI staff expressed an interest in evaluating the impact of an engaged research model, including the PCORI Engagement Awards, to better identify research and support best practices. Panelists and PCORI staff agreed that PCORI will be better able to evaluate successes if the expectations around actions for what engagement is and thresholds for how engagement is measured are set and shared.

Dissemination activities occur at multiple levels and entail different strategies for different audiences. Anne Beal, PCORI Deputy Executive Director and Chief Officer for Engagement, introduced a discussion on dissemination and communication and described PCORI's three-pronged approach to dissemination:

- Require researchers to develop dissemination plan
- Fund research in the Communications and Dissemination Program
- Develop PCORI dissemination plan and infrastructure in collaboration with AHRQ

Dr. Beal also explained that PCORI is developing a blueprint for dissemination and implementation to guide the organization in disseminating the research findings of funded research conducted in the national program areas; enhance implementation by actively facilitating how PCORI's research findings can be used by healthcare decision makers; and to evaluate how the effect of the dissemination of such findings reduces practice variation and disparities in health care.

In discussing mechanisms for disseminating and implementing research, panel members underscored the importance of involving communities at the outset of the research agenda. They suggested this involvement helps to put the research into action more quickly because the relationships are already established and the priorities are understood. PCORI staff agreed, and explained that it is the intent of PCORI research—through the use of different research designs and methodologies, registries, and a willingness to generate pragmatic research questions upfront based on patient/advocate input—to decrease the bench-to-practice gap for implementing evidence-based practices. Panel members noted this early involvement also helps to mobilize communities in driving the work and allows for measurement of the generalizability of the results. Panelists emphasized the importance of disseminating to individuals, patients/advocates, and communities in parallel time to researchers and recommended PCORI encourage researchers to bring patients/advocates they have partnered with to present their findings at research meetings.

Action and Next Steps

The panel discussed issues that remain to be addressed at future meetings and teleconferences, including collecting and sharing models of engagement, distributing materials and tool kits to use in communities, and determining the best mechanism for continued communication between panel members. Panelists were also invited to submit nominations for a chair and co-chair to be considered by staff and the PCORI Board of Governors[8]. The PCORI Board of Governors approved the final selection.

For the next meeting, panelists suggested more integration of the pre-work materials into the discussions and additional resources for preparation (e.g., a list of suggested resources related to best practices in engagement research for review prior to the meeting). Panel members also recommended more detailed agendas and greater use of the small group breakout sessions.

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[8] On March 26, 2013, Charlotte W. Collins, JD and Darius Tandon, PhD were selected to chair and co-chair this panel. For more information please see pcori.org/2013/eight-healthcare-community-representatives-named-chairs-co-chairs-of-pcori-advisory-panels.