



External Meeting Summary

Advisory Panel on Clinical Effectiveness and Decision Science (CEDS) Winter Meeting

December 6th, 2021 (12:15-3pm ET)

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Overview

The Advisory Panel on Clinical Effectiveness and Decision Science (CEDS) Winter 2021 Meeting began with a welcome of the CEDS Advisory Panel members and attendees and an overview of the day's agenda. Before beginning her presentation, Dr. Holly Ramsawh thanked former CEDS Advisory Panel member, Dr. Maureen White, for her service and contributions to PCORI and to the CEDS Advisory Panel. PCORI then provided an overview of the CEDS research program, reviewed updates to the CEDS research portfolio, and shared a sampling of new research awards. Following a brief break, PCORI provided an overview of its strategic plan and proposed research agenda and solicited feedback from the CEDS Advisory Panel members. In the final two presentations, PCORI staff shared updates regarding two special areas of emphasis for which PCORI is interested in funding research. In the first presentation, PCORI discussed the first national priority area, intellectual and developmental disabilities (IDD) and their approach to supporting IDD research, including stakeholder engagement. In the last presentation, PCORI discussed its commitment to maternal morbidity and mortality (MMM) as another national priority area of interest. CEDS Advisory Panel members provided feedback and suggestions following each presentation. The meeting concluded with CEDS Advisory Panel Co-Chair and PCORI staff thanking the CEDS Advisory Panel members for their time and thoughtful feedback and adjourned.

Welcome and Introduction

- Stanley IP, MD, CEDS Interim Program Director
- Kari Gali, DNP, APRN, PNP-BC, Advisory Panel Chair
- Julie Eller, BS, CEDS Advisory Panel Co-Chair

Stanley IP, CEDS Interim Program Director, welcomed the CEDS Advisory Panel members and other attendees to the CEDS Advisory Panel's Winter 2021 Meeting. He then reviewed housekeeping items and noted that due to unforeseen circumstances, Kari Gali could not attend the meeting and that Holly Ramsawh would be moderating the meeting alongside Julie Eller, co-chair of the Advisory Panel. Julie Eller introduced herself, then allowed for CEDS Advisory Panel member introductions. Eller thanked panel members and opened the floor for Holly Ramsawh to begin her presentation.

CEDS Research Area Overview

- Holly Ramsawh, PhD, CEDS Senior Program Officer

Holly Ramsawh, CEDS Senior Program Officer, opened the discussion by giving a formal farewell to panel member Dr. Maureen White. Ramsawh then provided an overview of the CEDS research program and current research portfolio, followed by a sampling of newly awarded research projects. Ramsawh then asked CEDS Advisory Panel members if they had any

questions or comments regarding the CEDS program updates or awards. Below is a summary of the CEDS Advisory Panel members' questions and comments.

Discussion

Generation of Priority Areas for Research

- One CEDS Advisory Panel member asked for clarification about where special areas of interest or priority areas originate and the process by which they are ultimately selected by PCORI. Ramsawh answered that the special areas of interest are cultivated from multiple inputs including public opinion, stakeholder suggestions, and internal discussions.
- Another panel member posed a similar question on the origins of the intellectual and developmental disabilities (IDD) special area of interest broadly, and specifically related to the transitions in care for individuals with IDD. Ramsawh noted that because IDD is a new national research priority, there will be a number of future research opportunities related to IDD. Ramsawh also clarified that the IDD special area of emphasis emerged from feedback in meetings where patients, providers and other stakeholders expressed interest in IDD, particularly around transitions of care.
- Another panel member expanded on Ramsawh's points and added that his organization is interested in IDD care transitions across the life span including geriatric, palliative, and hospice care. This member further noted improving access to care for individuals with IDD does not always mean access to competent care which should also be a priority.

Strategic Planning: National Priorities for Health

- Kim Bailey, MS, CEDS Associate Director

Kim Bailey provided an update on PCORI's strategic planning activities. Bailey first provided the scope of strategic planning activities, starting with the National Priorities for Health, which were recently approved by PCORI's Board of Governors. The priorities were informed by a broad range of stakeholders, including the CEDS Advisory Panel and are designed to be mutually reinforcing to create synergistic opportunities for progress. Bailey then shared PCORI's research agenda which will serve as a framework for achieving progress on the National Priorities for Health. Six statements comprise the proposed research agenda; each was reviewed, and an illustrative example shared to provide further context.

Discussion

Following Bailey's presentation, Eller moderated a discussion centered on the following questions:

1. How might the proposed research agenda meet the needs for PCORI's strategy of funding CER?
2. How could the proposed research support a research portfolio that is inclusive of this panel's topics of interest?
3. Is there an important research area that you would like to see better reflected in the proposed research agenda?
4. What kinds of research portfolios will be important to support the specific statements?

Below, we summarize the Advisory Panel members' comments by theme:

Meeting the needs of PCORI's strategy to fund CER

- Multiple panel members cited obesity as an important area of focus. One member suggested obesity as a topic of special interest for PCORI, noting that it is considered a formal disease by many organizations. She further noted that nutrition and diet should not only be considered in terms of disease prevention but also as a form of treatment, for example, to treat diabetes.
- Another panel member expressed caution when considering obesity as a research priority given its extreme complexity.
- Two CEDS Advisory Panel members identified the third proposed research agenda item titled, "Fund research that builds the evidence base for emerging interventions by leveraging the full range of data resources and partnerships" as the area with the most potential to meet the needs for PCORI's strategy of funding CER. One panel member noted the importance of building an evidence base prior to comparing the effectiveness of different modalities.
- One Advisory Panel member noted data harmonization and coordination of research in certain areas is needed to reduce unnecessary duplication of studies. Further, he suggested designing proposals that explicitly encourage collaboration across specialties and disciplines would be helpful to encourage investigators to work outside their siloed environments. He noted that the future of CER needs to include a broad range of researchers, especially to address big public health challenges. The member suggested this could be done in the program announcement and PCORI could even propose which specialties or disciplines should be included.
- Another CEDS Advisory Panel member echoed this sentiment, noting that including all specialties and/or disciplines involved in the care continuum is ideal. Using blood pressure management as an example, she cited taking an interdisciplinary team approach would be helpful and suggested including pharmacists and community health workers since they play important roles in the management of these patients.

Supporting a research portfolio that is inclusive of CEDS Advisory Panel members' interests

- One CEDS Advisory Panel member noted many people, including researchers, do not understand the difference between health equity and health equality. Given that health equity is included in the list of priorities, he noted it is important for PCORI to clearly define what is meant by health equity.
- One member expressed an interest in CER studies of pharmaceuticals, citing an example of multiple anti-inflammatory drugs used among patients with Multiple Sclerosis, yet there is no evidence comparing the effectiveness of these drugs. The member also noted many of these studies are conducted using small sample sizes and the participants are not representative of the general population and that this is an area where PCORI could make an impact.
- Another CEDS Advisory Panel member noted, similar to some of the suggestions shared earlier, that implementation science and team-based approaches should be prioritized when funding research. The member went on to note that training and collaboration opportunities are needed to encourage people from more diverse backgrounds to participate in PCORI-funded research, either as applicants or as stakeholders.

Additional Important Research Areas for Consideration

- Two CEDS Advisory Panel members noted research around patients at high risk or predisposed to certain diseases are important areas for PCORI to consider. The first panel member highlighted the importance of identifying patients at high risk of developing certain cancers early, given the benefits of early screening and diagnosis. The second member noted much is already known about disparities in maternal mortality and morbidity; Black and Latinx women are disproportionately affected and yet the research shows it is not solely a result of income or education, but there also may be biological contributors. Therefore, the panel member suggested not only exploring disparities in maternal morbidity and mortality, but the drivers of those disparities, which may include biological differences.
- Another CEDS Advisory Panel member cited novel or improved measures that can be used to quantify the cost of illness are greatly needed, noting that the current methods are controversial and often lead to unreliable estimates.

Important research portfolios to support the six research agenda statements

- One panel member identified one topic that could be addressed across the six statements as the ongoing issue of populations demonstrating continuously lower health literacy rates. The panel member identified that each of the six statements has the potential to increase health literacy through the promotion and practice of shared and supported decision-making across populations with varying levels of cognition, including those with IDD.

Update on Intellectual and Developmental Disabilities Priority for Research

- Meghan Warren, PhD, MPH, PT, CEDS Program Officer
- Amanda Barbeau, MPH, Program Associate

Amanda Barbeau introduced herself, welcomed the panel members, and provided a brief overview related to legislative mandate updates PCORI has been conducting around intellectual and developmental disability (IDD). Barbeau discussed the origins of IDD prioritization and reviewed the IDD workgroup and presented PCORI's multi-pronged approach to improving health and quality of life for neurodiverse individuals. Finally, Barbeau walked through the current status of PCORI funding for comparative clinical effectiveness studies and research, and its support for IDD projects. She explained that PCORI's most recent areas of focus include improving care transitions from pediatric and adolescent healthcare to adult healthcare, and a targeted funding announcement to compare interventions targeting mental health in individuals with IDD. Barbeau concluded and turned the presentation over to co-lead, Meghan Warren.

Dr. Meghan Warren gave a more in-depth overview of PCORI's targeted funding announcements. Warren noted that a merit review for the first issuance of the funding announcement will occur December 2021 and PCORI will be making slight revisions to the announcement to clarify PCORI's priorities. Warren also reviewed PCORI's special cycle of building capacity engagement awards for PCORI related to transitions of care, health equity and community-based models, telehealth, caregiver needs, and caregivers support for people with IDD. She noted that PCORI has held two workshops, in September and October, as part of IDD-related stakeholder engagement to elicit feedback on the IDD and mental health topic. Warren referred attendees to PCORI's website to learn more about IDD initiatives.

Discussion

Below, the panel members' comments are summarized by theme:

Importance of early diagnosis of IDD

- One panel member felt that the research was well-documented and emphasized the importance of early diagnosis for conditions like autism and dyslexia. Panelists identified barriers to early diagnosis including lack of regular primary care visits and long wait times for scheduling appointments with specialists. They also suggested teachers could play a major role in public surveillance of autism or dyslexia among students.
- A couple of panel members provided first-hand accounts of their experiences being parents of children with IDD. They noted challenges such as inability to differentiate between normal and abnormal behaviors and lack of access to suitable doctors.

Systematic prioritization and improvements for IDD treatment and clinical research

- Multiple panel members noted clinician reluctance to care for IDD patients because they perceive them to be more time intensive. They also described how clinicians who lack sufficient training avoid interacting with direct support professionals. They added that while early diagnosis and screening are important, education systems are needed to better equip clinicians to care for people with IDD.
- One panel member noted that including the IDD population in research is a double-edged sword due to past abuses, such as those described in the Nuremberg Trials, and subsequent protective policies (i.e., Helsinki Declaration, Belmont Report, etc.) that have set a precedent for who should and should not be involved in clinical trials.
- One panel member inquired about the clinical trials that have been conducted looking at system level interventions. He suggested continued prioritization of funding for large-scale trials that compare system level interventions.
- One family caregiver/panel member encouraged the identification of people with mild symptoms of IDD, as they are often overlooked by the school system and struggle with transitioning into the work force. She also suggested conducting a study on the effectiveness of family therapy to promote a more close-knit community that can support patients with IDD.

Update on Maternal Mortality and Morbidity Priority for Research

- Hillary Bracken, PhD, MHS, HDDS Program Officer

Hillary Bracken introduced herself and reviewed the focus of the PCORI's interdepartmental work to fulfill reauthorization amendments related to research in maternal morbidity and mortality. Dr. Bracken also discussed the short and long-term strategies and investments to address the priority area consisting of evidence products, board-approved targeted funding announcement on postpartum outcomes, and activities related to stakeholder engagement. Bracken also provided a brief history of PCORI awards towards maternal health.

Bracken presented PCORI's framework for improving maternal health, inclusive of preconception, pregnancy, delivery, and postpartum periods. Bracken also noted that PCORI has two systematic reviews co-funded by AHRQ related to postpartum care and hypertensive disorders and a rapid review on telehealth and maternal health. Bracken provided an in-depth overview of funding announcements from PCORI related to maternal mortality. Finally, Bracken directed attendees to a link to view PCORI's annual meeting that included a candid conversation about the barriers stakeholders face in addressing maternal morbidity and how PCORI and others could meaningfully support research on improved maternal outcomes.

Discussion

Below, we summarize the panel members comments by theme:

Addressing biological risk factors and social determinants of health

- Multiple panel members called for more research on biological and genetic risk factors in Black, Latinx, and Native American Indian populations who are at an increased risk of maternal mortality.
- One panel member remarked on the insufficient engagement of disadvantaged minority populations in clinical trials and called for more research to understand reasons for low engagement.
- One panel member noted that women with IDD and those living in low income, rural areas are also considered high-risk groups and should be given priority.
- Bracken responded that there are barriers related to engaging patients in the design and implementation of the research itself, including social determinants such as free time, transportation, or access to technology (when working remotely).
- One panel member expressed concern regarding the transition from pediatric care to adulthood and then to family planning, and how that impacts maternal mortality and morbidity.

Using evidence-based research to improve maternal health outcomes

- One panel member emphasized the importance of getting evidence and evidence-based guidelines into practice in a timely fashion, such as getting practitioners to adhere to evidence-based guidelines related to the COVID vaccine. Another panel member expressed their anticipation for the results of *The Path to Optimal Black Maternal Heart Health: Comparing Two CVD Risk Reduction Interventions* study mentioned in Bracken's presentation.

Considering state health policies

- One panel member noted that evidence-based research has revealed that state-based Medicaid policies have a significant impact. She suggested that Medicaid health policies can contribute to improved maternal mortality and morbidity outcomes.
- Another panel member agreed that location and health policy can impact research and that it's important for PCORI's research agenda to be resilient to policy changes as well as enable data collection that is relevant to the policy conversation.

Closing Remarks/Adjourn

- Julie Eller, BS
- Holly Ramsawh, PhD

Eller encouraged the panel members to contact PCORI staff with any additional feedback or thoughts and thanked the presenters. Ramsawh thanked all attendees for participating in the discussion and provided a summary of feedback shared by the CEDS Advisory Panel members

throughout the meeting. Ramsawh then shared a list of resources where attendees can find more information about the topics discussed during the meeting.