PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

# Board of Governors Meeting via Teleconference / Webinar

Tuesday, March 16, 2021

**1:00-3:30 pm Eastern**

## MINUTES

**Board Members Present:**
Christine Goertz, DC, PhD, *Chairperson;* Sharon Levine, MD, *Vice Chairperson*; Kara Ayers, PhD; Kate Berry; Tanisha Carino, PhD; Michael Lauer, MD (designee for Francis Collins, MD, PhD); Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Christopher Friese, PhD, RN; Michael Herndon, DO; Russell Howerton, MD; James Huffman; Connie Hwang, MD, MPH; Michelle McMurry-Heath, MD, PhD; Barbara McNeil, MD, PhD; David Meyers, MD; Eboni Price-Haywood, MD, MPH; James Schuster, MD, MBA; Ellen Sigal, PhD; Kathleen Troeger, MPH; Danny van Leeuwen, MPH, RN; Robert Zwolak, MD, PhD

**Board Members Absent:** Janet Woodcock, MD

| Agenda Item | PCORI Speakers |
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| **Welcome and Call to Order**<br><br>**Consider for Approval:**<br>• Minutes of the February 9, 2021 Board Meeting<br><br>*Christine Goertz, DC, PhD, Board Chairperson* | Dr. Goertz chaired and opened the meeting, welcomed all to the March 16, 2021 meeting of the PCORI Board of Governors, and read the Chair Statement on Conflict of Interest. She then reviewed the agenda for the meeting. Goertz noted that the meeting included a very ambitious agenda and stated that presentations have been condensed to allow more time for Board discussion.<br><br>With no additions or corrections to the minutes offered, Goertz then presented the minutes of the February 9, 2021 Board meeting for approval.<br><br>*The following motion was made by Barbara McNeil and seconded by Kara Ayers.*<br><br>**Motion:** Approve minutes from the February 9, 2021 Board of Governors meeting.<br><br>*Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions) Sharon Levine was not present during this vote.* |
| **Consider for Approval: Research and Dissemination & Implementation Award Slates**<br><br>*Nakela L. Cook, MD, MPH, Executive Director; Mike Herndon, DO, Chair, Engagement, Dissemination, and Implementation Committee; Barbara McNeil, MD, PhD, Chair, Selection Committee* | Dr. Cook began the presentation by providing an overview of the five Research and Dissemination & Implementation award slates being presented to the Board for approval with a total funding amount of $48.5M. She indicated that none of the proposed slates of awards exceeds the applicable allocated funding.<br><br>While discussing the two slates relating to targeted PFAs in Cycle 2 2020, Cook noted that PCORI received a robust response to these announcements, highlighting that funding rates for the slates relating to these PFAs were above or at PCORI's historical average. In addition, two |

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| | applications were deferred from the Cycle 1 2020 Broad PFAs due to the COVID-19 pandemic. However, despite the high number of deferrals and the pandemic, Broad PFAs in Cycle 1 2020 performed similarly to historical averages in terms of the number of applications submitted and the overall funding rate.<br><br>Cook addressed the proposed research commitments in the context of the FY2021 Commitment Plan, noting that the FY2021 commitment target for research awards is $290M. With three slates of research awards under consideration today, along with the Cycle 1 2020 Broads that were previously approved by the Board, the cumulative FY2021 funding for research awards is $84M. Thus $206M remains available to fund research awards for FY2021.<br><br>Cook reviewed the status of LOIs, applications, and funding rate relating to the Cycle 2 2020 Limited Competition Dissemination and Implementation PFA and indicated that the FY2021 targeted commitment for D&I awards is $28M. Two slates of Cycle 2 2020 awards are being presented for consideration and the cumulative funding for these slates of D&I awards is $6M. Thus $22M remains available to fund D&I awards for the PFAs in FY2021.<br><br>Dr. McNeil made introductory remarks on behalf of the Selection Committee, noting that the Committee met on February 3, 2021 and recommended three slates of awards for Board approval. She then introduced PCORI staff to present the slates. |
| Slate of Awards from the Cycle 2 2020 Second-line Pharmacological Agents in Type 2 Diabetes PFA<br><br>*Kim Bailey, MS, Interim Associate Director, Clinical Effectiveness and Decision Science (CEDS)* | Ms. Bailey introduced the proposed slate of awards for the Cycle 2 2020 Observational Analyses of Second-Line Pharmacological Agents in Type 2 Diabetes PFA. She provided an overview of the PFA and indicated that the Selection Committee recommended funding a slate of 4 projects for a proposed total commitment of $18.4M. Bailey noted that evidence generated by studies funded through this initiative may help to inform clinical decision-making and the design of future trials. *(See Attachment A for award project titles.)*<br><br>*The following motion was made by Alicia Fernandez and seconded by Robert Zwolak.*<br><br>**Motion**: Approve funding for the recommended slate of awards from the Cycle 2 2020 Observational Analyses of Second-Line Pharmacological Agents in Type 2 Diabetes PFA.<br><br>*The motion was approved by a majority vote of the voting Board members by voice vote: none opposed, none abstained, 2 recused (Christine Goertz, Barbara McNeil). Sharon Levine, who had earlier indicated her intention to recuse herself, was not present during the vote.* |
| Slate of Awards from the Conducting Rare Disease Research Using PCORnet® PFA | Ms. Mohr introduced the proposed slate of awards for the Cycle 2 2020 Conducting Rare Disease Research using PCORnet® PFA. She provided an overview of the PFA and indicated that the Selection Committee recommended funding a slate of 4 projects for a proposed total |

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| *Penny Mohr, MA, Senior Advisor, Emerging Technology and Delivery System Innovation Research Initiatives* | commitment of $19M. Mohr noted that studies on the slate span a variety of rare diseases and conditions, focusing both on pediatric conditions and those affecting adults. *(See Attachment A.)*<br><br>*The following motion was made by Barbara McNeil and seconded by Ellen Sigal.*<br><br>**Motion**: Approve funding for the recommended slate of awards from the Cycle 2 2020 Conducting Rare Disease Research using PCORnet® PFA.<br><br>*The motion was approved by a majority vote of the voting Board members by voice vote: none opposed, none abstained, 5 recused (Kara Ayers, Alicia Fernandez, Christine Goertz, Michael Lauer, and Eboni Price-Haywood). Sharon Levine was not present during the vote.* |
| Slate of Awards Deferred from the Cycle 1 2020 Broad PFAs<br><br>*Steve Clauser, PhD, MPA, Program Director, Healthcare Delivery and Disparities Research (HDDR)* | Dr. Clauser introduced the additional proposed awards to the Cycle 1 2020 Broad slate. In November 2020 and January 2021, the Board approved funding for a slate of eight research projects. Nineteen applications were deferred in Cycle 1 2020, and of these, the Selection Committee in February 2021 recommended two additional projects for Board approval.<br><br>The two additional awards, which have a total of $5.3M requested, come from the Addressing Disparities and Improving Methods for Conducting PCOR priority areas. *(See Attachment A.)*<br><br>With the additional projects, the Cycle 1 2020 Broad PFAs slate now consists of 10 projects and the proposed total award is $45.8M.<br><br>*The following motion was made by Jennifer DeVoe and seconded by Mike Herndon.*<br><br>**Motion**: Approve funding for the addition of the recommended projects to the slate of awards from the Cycle 1 2020 Broad PFAs.<br><br>*The motion was approved by a majority vote of the voting Board members by voice vote: none opposed, none abstained, 3 recused (Christopher Friese, Michael Lauer, David Meyers). Sharon Levine was not present during this vote.* |
| Slates of Awards from Cycle 2 2020 Dissemination and Implementation PFAs:<br>• Limited Competition Dissemination and Implementation PFA<br>• Dissemination and Implementation Shared Decision Making PFA<br><br>*Joanna Siegel, ScD, Program Director, Engagement, Dissemination, and Implementation* | Dr. Herndon made introductory remarks on behalf of the Engagement, Dissemination, and Implementation Committee, noting the committee's discussion and recommendation of the Limited Competition and Shared Decision Making funding slates to the Board for consideration and approval. He then introduced Dr. Siegel to provide details on the two slates.<br><br>Siegel provided a brief overview of the Limited Competition funding announcement which provides awardee teams who have completed a PCORI-funded study the opportunity to take the next steps in promoting uptake of the evidence into practice, in the context of the related body of evidence, laying the groundwork for broader future uptake. The three implementation projects on the slate are proposing to implement findings |

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| | from studies funded through PCORI's Communication and Dissemination Research and Addressing Disparities priority areas. *(See Attachment B.)* The total funds requested for the proposed slate is $3.8M.<br><br>Siegel then provided a brief overview of the Shared Decision Making funding announcement which is designed to promote the uptake of shared decision making in healthcare settings, in line with PCORI's goal of supporting patients in making informed, evidence-based decisions about their care, with their clinicians. The project on the Shared Decision Making funding slate will use a learning collaborative approach to support the uptake of tested conversation aids to support women with early-stage breast cancer make a treatment decision. *(See Attachment B.)* The total funds requested for the proposed slate is $2.1M.<br><br>The two award slates represent a total commitment of $6M out of the $28M budgeted for FY2021. This was the first cycle of proposed funding related to this fiscal year's budget.<br><br>Mr. van Leeuwen noted his support for the slates and commented that attention should be paid toward dissemination and implementation efforts reaching the lives of the general public outside academic and specialty channels. Siegal noted the example that just one of the projects was reaching 16,000 adolescent girls at the time of decision-making, and that this is where PCORI wants to be relevant.<br><br>*The following motion was made by Russell Howerton and seconded by Kathleen Troeger.*<br><br>**Motion:** Approve funding for the recommended award slates:<br>• Cycle 2 2020 Limited Competition Dissemination and Implementation PFA<br>• Cycle 2 2020 Implementation of Effective Shared Decision Making Approaches in Practice Settings PFA<br><br>*The motion was approved by a majority vote of the voting Board members by voice vote (20 approved, 0 opposed, 0 abstained, 2 recused, Jennifer DeVoe and Alicia Fernandez). Sharon Levine was not present during this vote.* |
| **Consider for Approval: Research Topics for Targeted PFAs for Cycle 2 2021 and Set of Topics for Development for Future Cycles**<br><br>*Nakela L. Cook, MD, MPH and Alicia Fernandez, MD, Science Oversight Committee (SOC) Chair* | Dr. Cook provided introductory remarks and reminded the Board of the discussion which took place at the meeting on February 9, 2021 on PCORI's expedited approach to targeted PFA development. While PCORI is utilizing an expedited approach as strategic planning is underway, topic development still includes the core components of literature review, including examination of systematic reviews and clinical practice guidelines, portfolio review, and consultation with stakeholders and other funders. She outlined the anticipated advantages the enhanced approach to targeted PFAs will allow and shared that the enhanced approach will include PFAs with study parameters that are designed to be more open, and targeted PFAs that are open for more than one cycle and could be reissued with additional cycles. Cook indicated that the Board would be |

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| | reviewing for approval the development of and allocated funding for three targeted PFAs relating to the following topics:<br>- Improving Postpartum Outcomes for Populations Experiencing Disparities;<br>- Comparative Effectiveness of Interventions Targeting Mental Health Conditions in Individuals with Intellectual and Developmental Disabilities; and<br>- Nonsurgical Interventions for Women with Urinary Incontinence. |
| Targeted PFA for Cycle 2 2021: Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities<br><br>*Els Houtsmuller, PhD, Associate Director, HDDR* | Dr. Fernandez made opening remarks on behalf of the Science Oversight Committee, which met in February 2021 and recommended that the Board approve the development of the Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities PFA. She then turned to Dr. Houtsmuller to present the Targeted PFA.<br><br>Houtsmuller explained that studies under this PFA would compare the effectiveness of multicomponent interventions to improve early detection of and timely care for risk factors for postpartum complications, and for complications during the first six weeks of postpartum for Black, American Indian/Alaskan Native, and Hispanic women, women who live in rural areas, and women with low socioeconomic status. PCORI expects to fund 4-6 studies with a total amount requested for awards under this PFA of $50M in total costs.<br><br>*The following motion was made by James Huffman and seconded by Christopher Friese:*<br><br>**Motion**: Approve the development of a PFA on "Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities" with funding up to $50M in total costs.<br><br>*The motion was approved by a majority vote of the voting Board members by voice vote. (21 approved, 0 opposed, 0 abstained, 0 recused)*<br>*Sharon Levine was not present during this vote.* |
| Targeted PFA for Cycle 2 2021: Comparative Effectiveness of Interventions Targeting Mental Health Conditions in Individuals with Intellectual and Development Disabilities (IDD)<br><br>*Holly Ramsawh, PhD, Senior Program Officer, CEDS* | Dr. Ramsawh explained that studies under this PFA would compare the effectiveness of evidence-based approaches that address mental health conditions in individuals with intellectual and developmental disabilities. Feedback from various stakeholder groups was leveraged in the identification of this research question for this funding announcement. PCORI expects to fund 10-12 studies under this PFA with a total amount requested of $40M in total costs.<br><br>When questioned whether interventions will consider comparative effectiveness research of health systems relating to evidence-based approaches to addressing mental health conditions, Ramsawh noted that PCORI would allow proposals that address health care systems questions.<br><br>*The following motion was made by Russell Howerton and seconded by Barbara McNeil:* |

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| | ***Motion**: Approve the development of a PFA on "Comparative Effectiveness of Interventions Targeting Mental Health Conditions in Individuals with IDD" with funding up to $40M in total costs.*<br><br>*The motion was approved by a majority vote of the voting Board members by voice vote. (21 approved, 0 opposed, 0 abstained, 0 recused) Sharon Levine was not present during this vote.* |
| Targeted PFA for Cycle 2 2021: Nonsurgical Interventions for Women with Urinary Incontinence Targeted PFA<br><br>*Nora McGhee, PhD, Senior Program Officer, CEDS* | Dr. McGhee explained that studies under this PFA would compare the effectiveness of nonsurgical interventions for non-pregnant women with urinary incontinence (UI). Extensive stakeholder interest and evidence gaps led PCORI to undertake an update of a 2012 AHRQ systematic review on non-surgical treatments for urinary incontinence in women. The update was completed in 2018 and found good evidence for many non-surgical treatments for UI. However, many evidence gaps remain, particularly in regard to the direct comparison of the options. Building on this work, PCORI seeks to fund 5-8 studies under this PFA with a total amount requested of $40M in total costs.<br><br>Board members asked whether nerve stimulators would be considered a surgical or non-surgical intervention. McGhee noted that this is considered a non-surgical intervention, and thus would be allowed to be a studied treatment in this PFA.<br><br>McGhee also noted that the focus of this PFA was on non-surgical treatments to further the work that had already been done in the 2012 AHRQ systematic review, but future PFAs may include surgical treatments. She also noted that this PFA is distinct from the work AHRQ is doing in this topic area but is complimentary.<br><br>*The following motion was made by Michael Herndon and seconded by Barbara McNeil*<br><br>**Motion**: Approve the development of a PFA on "Nonsurgical Interventions for Women with Urinary Incontinence" with funding up to $40M in total costs<br><br>*The motion was approved by a majority vote of the voting Board members by voice vote. (21 approved, 0 opposed, 0 abstained, 0 recused) Sharon Levine was not present during this vote* |
| Targeted PFAs for Cycle 2 2021 and Topics for Development for Future Cycles<br><br>*Nakela L. Cook, MD, MPH* | Dr. Cook indicated that staff will share a set of candidate topics for consideration of approval for future targeted PFA development at the Board meeting on April 13, 2021 that are expected to be implemented through 2022. Topics under consideration for development are at the idea stage, leverage ongoing work, are high burden, of interest to stakeholders, and align with themes emerging in PCORI's strategic planning efforts. Topics in the candidate set are in addition to COVID-19, Maternal Mortality and Morbidity, and Intellectual and/or Developmental Disabilities research priorities. She indicated that approving the set of candidate topics for development will allow for longer-range prospective |

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| | planning for PCORI as well as the investigator and stakeholder communities.<br><br>Members of the Board endorsed the enhanced process and reminded PCORI staff of the urgency of funding research which addresses the COVID-19 pandemic and asked about the scale of PCORI's response and its breadth. Board members stated that it is important to identify how to deploy PCORI's resources, including PCORnet, in a way that is additive, given the level of activity by other agencies. Cook indicated that staff would share an overview of PCORI activities addressing the pandemic with the Board, including ongoing work and opportunities for funding and collaboration with federal agencies. |
| **Consider for Approval:**<br>**PCORI's Principles for the Consideration of the Full Range of Outcomes Data**<br><br>*Nakela L. Cook, MD, MPH; Andrew Hu, MPP, Director, Public Policy and Government Relations and Joanna Siegel, ScD, Program Director, D&I* | Dr. Goertz made introductory remarks and turned it over to Dr. Cook to introduce this topic. Cook briefly provided the Board with an overview of PCORI's Principles for the Consideration of the Full Range of Outcomes Data and the process that has led to this discussion, including the implementation activities around the proposed Principles, the public comment, and prior presentations to the Board. Cook also highlighted that the Principles are meant to serve as a framework and guide as PCORI further develops guidance and methods related to the consideration of the full range of outcomes data. Cook then turned the discussion over to Mr. Hu for the presentation.<br><br>Hu reminded the Board of the plan and the three Pillars of activity to implement PCORI's new mandate to consider the full range of outcomes, as dictated by the reauthorizing law. Hu noted that Pillar One, which included the development of Principles and an initial set of guidance for applicants, is nearing completion as the Principles were considered for approval during this meeting; Pillar Two's activities are ongoing and will be conducted in coordination with the Methodology Committee to develop methods and standards related to the consideration of the full range of outcomes data; and Pillar Three's activities, which will focus on public policy topics, are also underway as PCORI seeks opportunities to engage with patients, caregivers and stakeholders to support discussions related to a patient-centered approach to addressing healthcare value and rising healthcare costs.<br><br>A vast array of input was received during the public comment period and Hu emphasized the implications for PCORI, including input on and revisions to the Principles and additional implementation aims and activities. Based on that input, Hu presented the Principles to the Board:<br><br>**Principle One** focuses on identifying outcomes important to patients and caregivers. Public comments urged that this Principle be central to PCORI research and that engagement with patients and caregivers is critical to ensuring relevant cost burden and economic impact measures are identified. Commenters also noted that these outcomes should be prioritized in research and that PCORI should consider options to monitor the potential unintentional consequences as a result of the use of cost data. Based on the input received, the Principles emphasized the importance of patient-centeredness. Hu clarified the definition of full |

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| | range of outcomes to mean relevant health outcomes, patient reported outcomes, in addition to burden and economic impact outcomes.<br><br>**Principle Two** centers on outcomes important to stakeholders and comments reflected the desire for PCORI to facilitate ongoing engagement and to provide opportunities for them to engage at individual project levels. Based on the input, no changes were made to the Principle but examples of outcomes important to patients, caregivers and stakeholders were identified.<br><br>**Principle Three** focuses on criteria for the collection of data, when appropriate and relevant. Commenters strongly supported PCORI's authority to collect relevant and appropriate burden and economic impact data, but also agreed that it should not be a requirement across all PCORI-funded studies. Commenters also sought input on outcomes PCORI would prioritize in research and noted that PCORI should factor in social risk factors when considering cost and economic impact data. He noted that Principle Three encourages applicants to collect cost burden and economic impact data, but that it will not be required. Hu also highlighted that, as part of Principle Three, social risk factors and social determinants of health are an area of particular interest for PCORI when considering cost and economic impacts.<br><br>**Principle Four** focuses on the conduct of certain economic analysis. Hu noted that commenters requested additional clarity on what types of analyses PCORI will support. Even with broad support for the collection of burden and economic impact data, commenters still noted strong support for the prohibitions from PCORI's authorizing law that prevent PCORI from developing a dollar-per quality adjusted life year threshold measure and maintaining PCORI's policy of not funding cost-effectiveness analysis. He clarified that specific analysis may be permitted during PCORI funded studies, or independently when appropriate, and noted that the limitations included in PCORI's authorizing law apply only to PCORI-funded research.<br><br>In addition to the Principles, Hu provided an update on the additional implementation activities that were identified in the public comments. These include undertaking additional steps to further ensure patient-centeredness across PCORI's work, including looking for opportunities to advance and support discussions related to a patient-centered approach to rising healthcare costs and value; supporting ongoing patient and stakeholder engagement; and the development of additional guidance and methodology standards related to the collection of cost burden and economic impact data.<br><br>Board members noted the potential for further uptake of research as a result of widening the range outcomes that can be collected in PCORI research. Additionally, it was noted that PCORI has resources that support patient and stakeholder engagement in research and sought input on how PCORI can build on those. Hu noted the interest from patients, caregivers and stakeholders in additional support when engaging in research and |

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| | highlighted the possibility to build upon the Research Fundamentals toolkit to better support engagement in research. Board members sought clarity on the language of Principle Three, specifically noting that the term "treatment options" should be changed to "intervention options" in order to be more inclusion. The Board agreed to an amendment to change the language of Principle Three from "treatment options" to "intervention options".<br><br>The Board expressed interest in frequent updates to the Board as PCORI moves forward with implementation, including updates on guidance development and updates to the methodology standards.<br><br>When asked whether the implementation strategy includes stakeholder engagement at the Methodology Committee level and whether expert researchers will get involved, Hu noted that PCORI will establish a Resource Center to support PCORI activities, including Methodology Committee activities, and that any updates to the Methodology Standards must be open and transparent and include a public comment period.<br><br>And, when asked about ways the Principles will be operationalized, Hu noted the Principles are meant to serve as a framework and guide as PCORI further develops guidance and methods related to the consideration of the full range of outcomes data.<br><br>*The following motion was made by Russell Howerton and seconded by Mike Herndon:*<br><br>**Motion**: Approve PCORI's "Principles for the Consideration of the Full Range of Outcomes Data in PCORI-Funded Research", subject to replacing the term "treatment options" with "intervention options" in Principle 3<br><br>*The motion was approved by a majority vote of the voting Board members by voice vote. (21 approved, 0 opposed, 0 abstained, 0 recused) Michelle McMurry-Heath was not present during this vote.* |
| **Wrap-up**<br><br>*Christine Goertz, DC, PhD* | Dr. Cook reviewed the Board meeting highlights. Dr. Goertz congratulated all the applicants who were awarded funding and thanked all that joined the call. The Board meeting ended at 2:58 pm Eastern. |

***Attachment A:***
***Research Award Slates***

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| ***Cycle 2 2020 Observational Analyses of Second-Line Pharmacological Agents in Type 2 Diabetes PFA*** | Second-line Therapies for Patients with Type 2 Diabetes (T2D) and Moderate Cardiovascular Disease Risk |
| | Comparison of Type 2 Diabetes Pharmacotherapy Regimens Using Targeted Learning |
| | BESTMED: oBservational Evaluation of Second line Therapy Medications in Diabetes |
| | The Comparative Effectiveness and Safety of Four Second-Line Pharmacological Strategies in Type 2 Diabetes Study (The CER-4-T2D study) |

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| ***Cycle 2 2020 Conducting Rare Disease Research Using PCORnet®*** | Preserving Kidney Function in Children with Chronic Kidney Disease (PRESERVE) |
| | Comparative Effectiveness Research for Neuroendocrine Tumors (CER-NET) |
| | Comparative effectiveness of palliative surgery, versus additional anti-seizure medications for Lennox-Gastaut Syndrome |
| | Utilizing PCORnet to support transition from pediatric to adult centered care and reduce gaps in recommended care in patients with congenital heart disease |

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| ***Additions to Cycle 1 2020 Broad Funding Slate*** | |
| ***Addressing Disparities*** | Advancing Perinatal Mental Health and Wellbeing: The DC Mother-Infant Behavioral Wellness Program |
| ***Improving Methods for Conducting PCOR*** | Development of Methods to Improve Identification of Patients with Rare or Complex Diseases |

***Attachment B:***
***Dissemination and Implementation Award Slates***

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| ***Cycle 2 2020 Limited Competition Dissemination and Implementation PFA*** | Implementation of Health-E You/Salud iTu to Promote Adolescent-Centered Contraceptive Care |
| | Implementation of a Self-Care Plan for Patients with Acute Heart Failure Discharged from the ED |
| | Implementing Advance Care Planning for Dialysis Patients |

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| ***Cycle 2 2020 Implementation of Effective Shared Decision Making Approaches in Practice Settings PFA*** | Taking 'What Matters Most' to Scale by Implementing a Breast Cancer Coproduction Learning Collaborative |