



Patient-Centered Outcomes Research Institute Board of Governors Meeting

Washington Marriott Wardman Park
2660 Woodley Rd NW
Washington, DC 20008

September 18, 2019

Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Christine Goertz, DC, PhD; *Vice Chairperson*; Kara Ayers, PhD; Larry Becker; Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Christopher Friesse, PhD, RN; Trent Haywood, MD, JD (via phone); Michael Herndon, DO; Gail Hunt; Freda Lewis-Hall, MD; Michelle McMurry-Heath, MD, PhD; Barbara McNeil, MD, PhD (via phone); Kathleen Troeger, MPH; Janet Woodcock, MD; Robert Zwolak, MD, PhD

Board Members Absent:

Francis Collins, MD, PhD; Russell Howerton, MD; Gopal Khanna, MBA; Sharon Levine, MD; Ellen Sigal, PhD

Methodology Committee Members Present:

Robin Newhouse, PhD, RN, Chair; Steve Goodman, MD, MHS, PhD, Vice-Chair; Brian Mittman, PhD

Executive Staff Present:

Joe Selby, MD, MPH, *Executive Director*; Mary Hennessey, Esq.; Michele Orza, ScD; Jean Slutsky, PA, MSPH; Regina Yan, MA

AGENDA ITEMS	RELATED MINUTES
Welcome and Call to Order Consider for Approval: Consent Agenda • Minutes of August 20, 2019 Board Meeting • Nominations for Committee Appointments - <i>Grayson Norquist, MD, MSPH, Board Chairperson</i>	Dr. Norquist chaired and opened the meeting, welcomed all to the meeting of the PCORI Board of Governors and read the Chair Statement on Conflict of Interest. Dr. Norquist asked if anyone had any additions or edits to the August 20, 2019 Board of Governors minutes and gave the opportunity to Board members to discuss any of the matters on the Consent Agenda. There were no additions or edits offered and no separate discussion was requested. <i>The following motion was made by Larry Becker and seconded by Robert Zwolak.</i> Motion: Approve each of the motions on the Consent Agenda as reflected below: • Minutes from the August 20, 2019 Board meeting • Appointment of Steven Goodman, MD, MHS, PhD, as Chair and Robin Newhouse, PhD, RN as Vice Chair of the Methodology Committee effective on September 28, 2019 for a two-year term or until their successors are appointed • Nomination of Grayson Norquist, MD, MSPH to serve as a member of the Engagement, Dissemination and Implementation Committee at the conclusion of his term as Board Chairperson <i>Approved by a majority vote of the voting Board members present by a show of hands (no opposed; no abstentions; 1 recusal, Grayson Norquist); Trent Haywood, Michelle McMurry-Heath and Barbara McNeil were not present for the vote.</i>
Executive Director's Report & Q3 Dashboard Review - <i>Joe Selby, MD, MPH, Executive Director</i>	Dr. Selby opened the report by noting that Dr. Norquist's second three-year term as Board Chairperson, a role which he has held since 2013, was coming to a close. Selby acknowledged and thanked Norquist for his unique and valuable contribution to PCORI's continued efforts to support patient-centered research. Board members also expressed their appreciation for Norquist's leadership as Board Chairperson. While Norquist's role as Chairperson has ended, he will remain on the Board through September 2020. Selby also announced that the U.S. Government Accountability Office has appointed Dr. Christine Goertz as the new Board Chairperson and Dr. Sharon Levine as the new Vice Chairperson. Selby then highlighted PCORI's 2019 Annual Meeting that is scheduled to take place on September 18-20, 2019,

	immediately following the Board Meeting. The Annual Meeting will spotlight results from dozens of PCORI-funded studies that speak to PCORI's progress in funding research to determine which care approaches work best, for whom, and under what circumstances, with a focus on outcomes important to patients. Selby noted there were a record number of registrants expected to attend this year's Annual Meeting. Q3 Dashboard Review Dr. Selby presented the Q3-2019 Dashboard for the Board's review. The Dashboard demonstrated 7 green-flagged metrics (those that are on track), and 2 yellow-flagged metrics (those that are off target by more than 10%-15%, depending on the metric). There were no red-flagged items (items that are off-target and in need of attention or action by the Board). Selby presented examples of results on PCORI's goals: to increase information, to speed uptake, and to influence research. He shared two publications with CER results from PCORI-funded studies, one on the use of breast MRI for routine surveillance for breast cancer survivors published in <i>Radiology</i> and one on the PROSPER study focused on patient-centered outcomes for stroke patients prescribed warfarin vs direct oral anticoagulants (DOACs) published in <i>JAMA Neurology</i>. He showed as of Q3-19, 187 CER Studies have their primary results peer-reviewed and publicly available, either via publication or PCORI Peer Review and posting to PCORI.org. He then shared an example of results from a PCORI-funded study being taken up into the UpToDate® topic page for asthma education and self-management. For the Q3 Dashboard feature, Selby provided a focused view on progress of projects and recruitment. As of Q3, 93% of projects are on track. This percentage has been steadily increasing over the past year. He shared results from PCORI's first cohorts of studies that have completed recruitment, which indicate that PCORI-funded studies are doing better on recruitment than available points of reference. He also shared data on recruitment start, completion, extensions, enrollment targets, and total participant enrollment numbers. Board Members expressed interest in learning more about studies that were successful with recruitment, studies in the topic pipeline for targeted research, and on the question of whether to maintain PCORnet-related metrics on the Dashboard.
Consider for Approval: FY 2020 Budget	Larry Becker and Regina Yan presented the Proposed FY2020 Budget of \$396 million, as recommended by the FAC, for

- <i>Larry Becker, Chair, Finance and Administration Committee (FAC) and Regina Yan, MA, Chief Operating Officer</i>	Board approval. Yan explained key terms relating to the budget, including the difference between award commitments and award payments, and noted that only award payments are expenses and included in the budget. She summarized PCORI's current and cumulative funding commitment plan of \$2,754 million through FY2020 and beyond, noting that it is based on PCORI's available funding from the PCOR Trust Fund through September 30, 2019. Yan also reviewed PCORI's estimated revenue through FY2019 and estimated expenditures through FY2024, totaling \$3,334 million. She reviewed the actual and projected revenue versus expenditures from PCORI's inception through FY2024 and highlighted the projected FY2019 and FY2020 fund balances. She outlined the annual budget development process, which ties to the Board approved strategic plan, and includes review and input from staff and Board-related strategy committees. Yan presented the major components that make up the FY2020 budget of \$396 million and summarized the FY2020 budget vs. the FY2019 projection. Board members were invited to ask questions and discuss the proposed FY2020 budget. Members of the Board raised questions related to the planned FY2020 expenditures associated with PCORnet. Board members were advised that \$40 million of the budgeted \$48 million dollars for PCORnet are for award payments associated with commitments made in previous years. <i>The following motion was made by Larry Becker and seconded by Freda Lewis-Hall:</i> Motion: Approve the proposed FY2020 Budget <i>Approved by majority vote of the voting Board members present by a show of hands (14 in favor; no opposed; no recused, no abstentions). Trent Haywood and Barbara McNeil were not present for the vote.</i>
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Research Portfolio Exploration Series: Focus on Mental Health - <i>Elisabeth Houtsmuller, PhD, Associate Director, HDDR and Holly Ramsawh, PhD, Program Officer, CEDS</i>	Dr. Selby introduced Drs. Houtsmuller and Ramsawh, who presented on PCORI's Mental Health Portfolio. Their presentation began with an overview of the high prevalence and burden of mental health conditions for children and adults across the United States. The presenters explained that, despite the existence of evidence-based treatments for many conditions and populations, less than 50% of patients receive treatment due to barriers to care. The presenters then described the scope of PCORI's mental health portfolio, noting that studies were included in the portfolio only if they address a mental health condition or symptom as a primary focus. Ramsawh went on to provide an overview of PCORI's mental health portfolio. She explained how \$383 million has been invested by PCORI to fund 96 CER studies on mental health, representing one-fifth of PCORI's entire research portfolio. While 44% of the portfolio is comprised of Broad (investigator-initiated) awards, PCORI has also made significant investments in Pragmatic Clinical Studies and Targeted awards on mental health topics. In addition, the mental health portfolio includes a diverse range of conditions and interventions. Depression represents the most-studied condition within the portfolio, followed by substance use disorders and serious mental illness. The portfolio also includes a large range of therapeutic interventions (e.g., behavioral & psychological, pharmacologic) and care delivery strategies (e.g., telehealth, peer-based interventions, care integration models). Ramsawh then highlighted some of the portfolio's key strengths, namely that the majority of studies are randomized controlled trials (RCTs), have multiple sites and large sample sizes, and include understudied and/or vulnerable populations. Ramsawh and Houtsmuller then described notable findings from the portfolio to-date, particularly within three areas: 1) the value of observational methods to assess treatment policies and suggest hypotheses to be examined in definitive clinical trials, 2) the value of peer-based interventions in mental health care, and 3) promising opportunities to address unique challenges in managing serious mental illness. The presenters then provided an overview of key findings from two studies in the portfolio that used observational designs. The first study assessed the comparative benefits and risks of different add-on medications for patients with schizophrenia who do not respond to a single antipsychotic. The study found that, relative to the addition of a second antipsychotic drug, addition of antidepressants was
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	associated with lowered risk of psychiatric hospitalization and emergency department visits, while addition of benzodiazepines was associated with elevated risk of psychiatric hospitalization and emergency department visits, and addition of mood stabilizers was associated with a higher risk of death from any cause. The second observational study compared the effectiveness of different state prescription oversight programs on reducing inappropriate prescribing of antipsychotics and improving metabolic monitoring for youth in foster care. The study found that implementation of a specialized managed care model was associated with a significant reduction in inappropriate antipsychotic prescribing, and implementation of metabolic monitoring guidelines was associated with increased metabolic monitoring rates for youth in foster care. Houtsmuller and Ramsawh then discussed evidence gaps related to the use of peer-based interventions across different populations and settings. They described key findings from three RCTs that evaluated peer-based interventions. The first study found that peer-led group CBT was as effective as clinician-led group CBT in reducing hoarding symptoms and improving daily functioning among adults with hoarding disorder. The other two studies found that adding peer navigators to usual mental health care increased appropriate health service use (i.e. attending scheduled doctor visits), quality of life, and other health-related indices among Hispanic patients with serious mental illness. Houtsmuller underscored the contribution of these studies to the evidence base supporting the role of peer-based interventions within mental health care. Lastly, Houtsmuller highlighted the findings from a large RCT that compared the effectiveness of two interventions within behavioral health homes (nurse-supported vs. self-directed care) for Medicaid-enrolled adults with serious mental illness. The study found that both interventions improved patient engagement in health care, self-reported mental health, quality of life, and patient satisfaction with care. Houtsmuller explained how this study was enhanced by strong engagement with stakeholders, including patients, payers, and policymakers, and that the PI has received a Dissemination & Implementation award to disseminate the study findings and implement the interventions in two additional behavioral health settings. To inform future directions, Board members suggested that PCORI staff should analyze evidence gaps within the mental health field to help identify gaps in PCORI's portfolio and assess the broader funding landscape to help determine how PCORI can best complement other funding efforts. In addition, Board members emphasized the importance of using findings from observational studies to inform
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	subsequent RCTs, as well as the importance of disseminating research findings to end-users. Board members expressed an interest in receiving more in-depth presentations on PCORI's mental health portfolio in the future and exploring specific topics for potential future funding.
Public Comment – <i>Kristin Carman, MA, PhD, Director, Public and Patient Engagement</i>	No members of the public requested the opportunity to make a public comment. Thus, there were no public comments presented during this time.
Wrap-up and Adjourn Meeting of the Board – <i>Grayson Norquist, MD, MSPH</i>	Dr. Norquist noted that this was his last meeting to serve as Chairperson of the Board as his tenure in this position ends on September 22, 2019. On September 23, 2019, Dr. Christine Goertz will assume the position of Board Chairperson and Dr. Sharon Levine will become the new Board Vice Chairperson. Norquist expressed his gratitude at being given this opportunity and honor and looks forward to continuing working with the Board until September 2020 when his Board appointment concludes. Meeting ended at 12:00 pm

Minutes were approved by the PCORI Board of Governors 11-19-2019