PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar

Tuesday, June 18, 2019

12:00 pm - 1:30 pm ET

MINUTES

Board Members Present:
Grayson Norquist, MD, MSPH, *Chairperson;*, Kara Ayers, PhD; Larry Becker; Michael Lauer, MD (designee for Francis S. Collins, MD, PhD); Christopher Friese, PhD, RN; Russell Howerton, MD; Gail Hunt; David Meyers, MD (designee for Gopal Khanna, MBA); Sharon Levine, MD; Michelle McMurry-Heath, MD, PhD; Barbara McNeil, MD, PhD; Ellen Sigal, PhD; Kathleen Troeger, MPH; Janet Woodcock, MD; Robert Zwolak, MD, PhD

Board Members Absent:
Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Christine Goertz, DC, PhD; *Vice Chairperson;* Trent Haywood, MD, JD; Michael Herndon, DO; Freda Lewis-Hall, MD

Agenda Item	**PCORI Speakers**
Call to Order, Roll Call, and Welcome - *Grayson Norquist, MD, MSPH, Chairperson and Joe Selby, MD, MPH, Executive Director*	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. Joe Selby then reviewed the meeting agenda. He noted that the presentation on the Opioids Portfolio is the second in a series of major portfolio reviews.
Consider for Approval: Minutes of the May 13, 2019 Board Meeting - *Grayson Norquist, MD, MSPH*	*The following motion was made by Russell Howerton and seconded by Barbara McNeil.* **Motion:** Approve the Minutes of the May 13, 2019 Board Meeting. *Approved by a majority vote of the Board by voice vote (no opposed, no abstentions).*
FY2019 Mid-Year Financial Review - *Russell Howerton, Vice Chair Finance and Administration Committee and Regina Yan, MA, Chief Operating Officer*	Dr. Howerton, Vice Chair of the Finance and Administration Committee (FAC) and Ms. Regina Yan presented the Mid-Year Financial Review for BOG discussion. The FY2019 Mid-Year Financial review included a review of PCORI's estimated revenues and expenditures, the FY2019 revenue through March 31, 2019, cash balance and outstanding award obligations as of March 31, 2019, and FY2019 budget versus actuals based on the first six months of FY2019 (October 1, 2018 – March 31, 2019). Yan noted the variance between the FY2019 budget and actuals for the period was 0.3%, which is considered a minor variance. There were no additional questions following the presentation.
Research Portfolio Exploration Series: Focus on the Opioids Portfolio - *Layla Lavasani, PhD, MHS, Associate Director, Clinical Effectiveness and Decision Science and Elisabeth Houtsmuller, PhD,*	Dr. Selby introduced Dr. Lavasani and Dr. Houtsmuller, the PCORI staff overseeing PCORI's Opioid Portfolio. Houtsmuller began with a brief overview of the ongoing opioid epidemic in the United States. She stated that almost every county in the United States has been impacted by the opioid epidemic over the past 16+ years. She then went on to further

Associate Director, Healthcare Delivery and Disparities Research	explain PCORI's approach to addressing the opioid crisis through a stakeholder-driven process for Comparative Effectiveness Research (CER). She indicated that the Board first proposed opioids as a topic for research by naming chronic pain and the opioid crisis as a priority area. An iterative process, PCORI started by holding stakeholder interviews and workshops as well as conducting background research and literature reviews. The resulting product led to CER focuses in two key areas: treatment of pain and treatment of opioid use disorders. The PCORI opioid portfolio includes a patient-centered multipronged approach to addressing the opioid epidemic, spanning the care continuum. Lavasani discussed the topic focuses within these two key areas of research: prevention of unsafe prescribing; non-opioid treatment options for pain; management of long-term prescription opioid use; office-based opioid treatment; and vulnerable populations, including pregnant women. PCORI responded rapidly to the opioid crisis, first in 2015 and most recently in 2018, by issuing targeted PFAs addressing opioid misuse. Four targeted PFAs have been issued with 3 reissuances of specific PFAs. As of June 2019, $128 million has been put towards supporting 26 CER studies on opioid use. The greatest percentage of the portfolio looks at the treatment of pain with 10 studies dedicated to the chronic use of opioids for pain and a further 11 studies examining nonpharmacologic options for pain. Lavasani described the Pain Management focus of the opioid portfolio in greater detail. The portfolio looks to address two key evidence gaps: insufficient evidence on interventions to improve safe prescribing, and the lack of long-term effectiveness data for treatment options. Lavasani expressed that opioid prescribing per person is still 3 times higher than it was in 1999 and further work must be done in the way of seeking consensus across the country for a proper prescribing policy and appropriate use. The opioid treatment for pain portfolio highlights includes strong head-to-head comparisons; examining pain, function, and quality of life as measurements for patient-centered outcomes; large sample sizes; and a diverse patient population. Five studies have focused on prevention of unsafe prescribing, totaling $19 million. Studies include provider-focused and look at both provider and patient-facing interventions. Ten studies, totaling $65 million, focus on the management of long-term opioids; 4 of these are pragmatic studies and PCORI staff has sought to harmonize study features across the targeted studies. Lavasani concluded her presentation by highlighting a study that examines pain-cognitive behavioral therapy and chronic pain self-management within the context of opioid reduction. Results are expected to be available in 2024.

	Houtsmuller detailed the second key area of the opioid portfolio: treatment for opioid use disorder. She stated that approximately 2.1 million people are living with an opioid use disorder in the United States today; over 130 people per day die of an opioid overdose. The portfolio looks to address the evidence gap left by insufficient evidence on the effectiveness of psychosocial interventions and which populations are best served by it. This uncertainty serves as a barrier to physicians providing office-based opioid treatment (OBOT). Additionally, there is little to no evidence for treating opioid use disorders (OUD) in vulnerable populations, including pregnant women, and strategies for people with OUD re-entering society. Houtsmuller highlighted the use of psychosocial interventions in the OBOT branch of the portfolio, totaling 3 studies at $15 million. Each study compares the usual care intervention (medical management) with a psychosocial intervention to determine which method works for which populations. Outcomes include buprenorphine adherence and opioid abstinence, and features of the three studies have been harmonized across the portfolio. The second identified evidence gap is the treatment of vulnerable populations. This portion of the portfolio totals 3 studies at $16 million. The population is majority low-income patients and racial/ethnic subgroups, with studies looking at the delivery of OBOT, including organizing care for pregnant women and their infants. Houtsmuller specifically highlighted an observational study with 2,000 patients, results of which are pending. In 2019, 6 of the 26 studies are expected to be completed. By 2021, more than half of these studies are targeted to be complete, with the rest expected to be completed in 2024. The presenters also discussed additional opioid-related activities ongoing at PCORI, including a study utilizing PCORnet, as well as 4 engagement awards totaling almost $1 million. Board members presented questions included how to best enable PCORI's collaboration with NIH to provide complementary research portfolios, as well as potentially examining other substance abuse disorders in the future. Board members expressed support for PCORI's examination of diverse populations, including those who rely on opioids for the management of chronic pain. A discussion ensued regarding changing prescribing practices across the United States and what it could mean for different populations.
Wrap up and Adjournment - *Grayson Norquist, MD, MSPH*	Meeting ended at 1:03 pm.

Minutes were approved by the PCORI Board of Governors 07-23-2019