Board of Governors Meeting

In-person and Via Teleconference/Webinar

September 18, 2019
9:00 AM – 12:00 PM ET
Welcome and Introductions

Grayson Norquist, MD, MSPH
Chairperson, Board of Governors

Joe Selby, MD, MPH
Executive Director
Agenda

9:00 AM  Call to Order and Welcome
9:00 – 9:10  Consider for Approval: Consent Agenda
9:10 – 10:00  Executive Director’s Report & Q3 Dashboard Review
10:00 – 10:30  Consider for Approval: FY2020 Budget
10:45 – 11:30  Research Portfolio Exploration Series: Focus on Mental Health
11:30 – 12:00  Public Comment
12:00 PM  Wrap up and Adjournment
Consent Agenda

Grayson Norquist, MD, MSPH
Chairperson, Board of Governors
Summary of Nominations

• That the Board approve:
  • 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
  • Appointment 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
Board Vote

Call for a Motion to:

- Approve each of the Motions on the Consent Agenda

Call for the Motion to be Seconded:

- Second the Motion
  - If further discussion, may propose an Amendment to the Motion or an Alternative Motion

Voice Vote:

- Vote to Approve the Final Motion
  - Ask for votes in favor, opposed, and abstentions
Transition of Board Chairperson

Please join me in thanking Grayson Norquist, MD, MSPH, for his service as Board Chairperson. During his tenure, which began in 2013, he modeled leadership in engaging patients and stakeholders, commitment to funding rigorous research and steadfast support of PCORI.

We’re thankful Dr. Norquist will continue to serve as a member of PCORI’s Board of Governors and remain an invaluable contributor towards PCORI’s mission.
New Chairperson and Vice Chairperson of the Board of Governors

Christine Goertz, DC, PhD
Chairperson

Sharon Levine, MD
Vice Chairperson
Hope to see you at our 2019 Annual Meeting

Details

• Immediately following this Board meeting
• September 18-20, 2019
• Washington Marriott Wardman Park in Washington, D.C.

Theme

Spotlighting 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

Sessions

Plenary and breakout sessions will feature such topics as:
• Practical approaches to personalized medicine and putting new evidence into practice
• What we know about engagement and its impact on making research more useful
• How shared decision making can be more effective and routine
• The future of patient-centered research
• Addressing the opioid epidemic through better pain management
• Reducing disparities and improving access and equity
Dashboard Review
Third Quarter of FY-2019

Joe Selby, MD, MPH
Executive Director
Goal 1: Increase Information for Health Decision-Making
Breast MRI Leads to More Biopsies than Mammography for Women with History of Breast Cancer

Summary: There is lack of consensus regarding the use of breast MRI for routine surveillance for second breast cancer events in women with a personal history of breast cancer. In developing screening recommendations, the benefits of early detection must be weighed with the harms associated with biopsies and false positives, which include scarring, pain, infection, and worry.

This observational cohort study compared mammography alone versus breast MRI with or without mammography in detecting new breast cancer events. The research team also compared surveillance performance measures, such as biopsy rates, cancer detection rates, sensitivity, and interval cancer rates.

The study found that **surveillance breast MRI resulted in twofold higher biopsy rates than mammography alone** (odds ratio [OR], 2.2; 95% CI: 1.9, 2.7) and increased cancer detection (OR, 1.7; 95% CI: 1.1, 2.7) but showed no difference in sensitivity or interval cancer rates.

For women at intermediate risk because of personal history of breast cancer, **careful consideration should be given to both the benefits and the risks before integrating MRI into a routine screening paradigm.**

**More testing isn’t always better...**

because of these extra biopsies, breast MRI detected more second cancers, but probably no additional ones that routine annual mammography would not have found... **the extra screening is not necessarily an improvement over what would have been detected in usual care with mammography.**

-Dr. Karen J. Wernli
Principal Investigator

**Quote from:** Kaiser Permanente News Article. *Using breast MRI after cancer may lead to unneeded biopsies.* June 4, 2019.
Summary: Blood thinning medication reduces the formation of blood clots, which can cause strokes. The blood thinner warfarin requires frequent lab tests and a limited diet. Newer direct oral anticoagulants (DOACs), don’t have these limitations, but it is unknown how the two options compare in terms of side effects.

This retrospective cohort study compared warfarin to DOACs (dabigatran, rivaroxaban, or apixaban) after ischemic stroke in patients with atrial fibrillation and focuses on patient-centered outcomes such as time spent at home, days alive and out of the hospital, and major adverse cardiovascular events.

The study found that patients who were prescribed DOACs when discharged had relatively better outcomes including more days at home (adjusted difference, 15.6 days [99% CI, 9.0-22.1]) and fewer adverse events (adjusted hazard ratio [aHR], 0.89 [99% CI, 0.83-0.96]) compared with patients prescribed warfarin.

This reinforces findings from prior research on the subject and builds on several previously-published results from the PROSPER study.
The number of publicly-available primary CER results is steadily increasing.

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. This number is steadily increasing.

**Update:** As of 9/10/19, **204 CER studies** have publicly available primary results.

During Q3-19, there were 36 publications from PCORI-funded studies that contained CER Results (both Primary and Secondary CER Results). The Q3 Primary CER Results with high Altmetric scores are highlighted below:

  
  
  
  
- **Chandler MJ, et al.** *Comparative Effectiveness of Behavioral Interventions on Quality of Life for Older Adults With Mild Cognitive Impairment: A Randomized Clinical Trial.* *JAMA Netw Open.* May 2019.
  
  
  
Goal 2: Speed Uptake and Use of Information
We are tracking uptake of results from PCORI-funded studies into UpToDate® point-of-care decision tool

For the 2019 Dashboard, we are now specifically tracking uptake into the UpToDate® point-of-care decision tool. The target is to see increasing uptake of PCORI study results.

**Uptake into UpToDate®**
(Citations of PCORI CER Results on Topic Pages)

![Graph showing citations per quarter]

Cumulative: 32 Citations in UpToDate® Topic Pages

Q3-19 Details: Topic Pages with Citations of PCORI CER Results:

1. Asthma education and self-management, update 4/22/19
2. Subacute and chronic low back pain: Nonpharmacologic and pharmacologic treatment, update 6/9/19
4. Medical care of sexual minority women, update 6/17/19
5. Prescription drug misuse: Epidemiology, prevention, identification, and management, update 6/20/19
6. Outcomes of bariatric surgery, update 6/27/19
Results from a PCORI-funded study of shared decision-making interventions for patients with asthma in the emergency room were cited in the UpToDate® topic page, Asthma education and self-management, updated Apr 22, 2019.

"ESTABLISHING A PARTNERSHIP: The clinician should make efforts to establish open communication and a sense of shared responsibility and decision-making by doing the following at every asthma visit:

- Involve the patient and family in decision making. For school-age children, the partnership also should involve the school
- Encourage the patient and family in their self-management efforts
- Ask openly about patient preferences and goals and incorporate these into treatment when possible
- Enquire about patient and family concerns and fears about chronic illness, medication use, dependency, health beliefs, and cost
- Foster a trusting relationship that allows patients to express the barriers they face that impede successful self-management"

PCORI has also funded an implementation project to promote use and implement findings from the completed PCORI-funded research project.

---

Apter AJ. Asthma education and self-management. In: UpToDate®, Waltham, MA, 2019


Research Study Title: Comparing Traditional and Participatory Dissemination of a Shared Decision Making Intervention

Implementation Project Title: A Shared Decision Making Intervention for Patients with Asthma in the ED

Principal Investigator (both awards): Hazel Tapp, PhD, BSc, Carolinas Medical Center
In addition to focusing on any Dashboard items that are noteworthy, off target, or in need of attention, we provide a consistent in-depth focus in each quarter for items that are top priority.
More than half of our funded research projects are in PCORI Peer Review or have been completed, with their results posted to PCORI.org

Current Status of PCORI-Funded Research Projects
N=627, as of Q3-19

- Awarded; Contract Pending: 11
- Too early for quarterly project evaluation or MOU: 9
- Eligible for quarterly project evaluation: 255
- Undergoing Pre-Review Edits: 3
- In PCORI Peer Review: 52
- Summaries being developed for posting: 23
- Complete; Results posted to PCORI.org: 267
- Terminated: 7

*Includes 50 Pilot Awards and 4 Systematic Reviews
*Does not include Infrastructure or D&I awards
*Does not include studies awarded in Q4-2019

71 Final Research Reports (FRRs) Posted as of Q3
The majority of our funded research projects are on track and the proportion on track has increased over the past year. We continue to monitor all projects.

We are monitoring trends and shifts in project status (most recent 8 quarters shown).

**Project Status by Color Zones**
Q4-17 to Q3-19

- **Green Zone**: On Track
- **Yellow Zone**: 77 71 68 66 67 69 71 74
- **Orange/Red Zone**: Off Track

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Percent of Projects (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4-17</td>
<td>77</td>
</tr>
<tr>
<td>Q1-18</td>
<td>71</td>
</tr>
<tr>
<td>Q2-18</td>
<td>68</td>
</tr>
<tr>
<td>Q3-18</td>
<td>66</td>
</tr>
<tr>
<td>Q4-18</td>
<td>67</td>
</tr>
<tr>
<td>Q1-19</td>
<td>69</td>
</tr>
<tr>
<td>Q2-19</td>
<td>71</td>
</tr>
<tr>
<td>Q3-19</td>
<td>74</td>
</tr>
</tbody>
</table>
Recruitment Status of PCORI Projects as of Q3-19

Prospective studies Involving recruitment

Total Projects: 392

139 Recruitment Ongoing or Not Yet Started
- 42 Yet to Start
  Recruitment milestones available but not yet initiated actual recruitment
- 97 Ongoing
  Recruitment initiated but not finished

253 No Longer Recruiting
- 238 Completed as Planned
  Recruitment initiated and completed; >85% of planned sample size achieved
- 15 Not Completed as Planned
  Study Terminated (7) or awardee suspended recruitment activities before reaching planned sample size (8)

392 Projects: 74% Broad, 11% PCS, 15% Targeted
Results from our early cohorts indicate that PCORI-funded studies are doing better on recruitment than available points of reference.

Through literature searches and working with other funders, we identified points of reference for research projects:

- 55% of studies meet original enrollment target
- 47% of studies meet agreed upon recruitment timeline
- Around 10% of research projects are not successfully completed

To meet desired recruitment levels, average enrollment timelines are 194% of planned duration (nearly double)

Points of Reference:
### Relationship of Recruitment to Original Study Timeline
For projects that have completed recruitment (N=238)

<table>
<thead>
<tr>
<th>Category</th>
<th>Enrollment Start as Projected?</th>
<th>Enrollment Rate as Projected?</th>
<th>Enroll Period As Planned?</th>
<th># of Projects</th>
<th>% of Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>All aspects on schedule</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>67</td>
<td>28%</td>
</tr>
<tr>
<td>Delayed start, but caught up</td>
<td>X</td>
<td>✓</td>
<td>✓</td>
<td>42</td>
<td>18%</td>
</tr>
<tr>
<td>Started early enough to cushion for slow enrollment</td>
<td>✓</td>
<td>X</td>
<td>✓</td>
<td>20</td>
<td>8%</td>
</tr>
<tr>
<td>Delayed start, slow enrollment, but had built-in cushion time</td>
<td>X</td>
<td>X</td>
<td>✓</td>
<td>13</td>
<td>5%</td>
</tr>
<tr>
<td>Delayed start, enrollment rate on track, extension needed</td>
<td>X</td>
<td>✓</td>
<td>X</td>
<td>17</td>
<td>7%</td>
</tr>
<tr>
<td>Started on time, but slow enrollment, extension needed</td>
<td>✓</td>
<td>X</td>
<td>X</td>
<td>49</td>
<td>21%</td>
</tr>
<tr>
<td>Delayed start, slow enrollment, extension needed</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>30</td>
<td>13%</td>
</tr>
</tbody>
</table>

**Completed On Schedule:**
- 60% of studies completed on schedule, many overcoming recruitment challenges

**Required Study Extension:**
- 40% had recruitment challenges that led to extensions
- Average study extension in this group: 7.5 months (median: 6.5)

---

-This slide reflects adherence to original contract milestones
-This does not show extensions unrelated to recruitment
Most PCORI-funded studies started recruitment early or on time, and the majority of those that started late were less than 3 months late to start.

### Timeliness of Recruitment Initiation (N=349)

- **Early**: 17%
- **On Time**: 46%
- **Late**: 37%

62% started on time or early.

Timelines in this slide refer to current contractual milestones, not to originally-intended timelines (explored separately.)
Most PCORI-funded studies complete recruitment early or on time, and the majority of those that completed late were less than 3 months late.

69% Completed on time or early

Timelines in this slide refer to current contractual milestones, not to originally-intended timelines (explored separately).
Some PCORI-funded studies require modest extensions of their recruitment timeline

Definition of Extension/Late: 6+ months

To what extent do studies extend their recruitment timelines to complete recruitment?

80/238 (34%) of studies that have completed recruitment had an extended recruitment time by 6+ months

Among all completed studies, the average time to complete recruitment was 137% of the original planned recruitment timeline (median 110%)

11% (N=26) of completed studies took more than twice as long as originally planned.

PCORI Average: 137% of planned enrollment time, vs. Point of Reference: 194% (Tufts 2013)

PCORI: 11% took more than 2x planned enroll time, vs. Point of Reference: 17% (Tufts 2013)
Almost all PCORI-funded studies achieve at least 90% of their enrollment targets, and the large majority of them meet or exceed the target.

Proportion of Enrollment Target Achieved
N=238

- Less than 80%: 2%
- Between 80% - 89%: 4%
- Between 90% - 94%: 7%
- Between 95% - 99%: 11%
- 100% or above: 76%

95% achieved >90% of enrollment target

PCORI: 76% met or exceeded enrollment target, vs. Point of Reference: 52% (Tufts 2013)

PCORI: 64% met or exceeded original enrollment target vs. Point of Reference: 55% (Trials 2013)
Most PCORI-funded studies that have completed enrollment enrolled between 100 and 1000 participants.

- **Median:** 360 participants per study
- **Average:** 745 participants per study
- **18%** Enrolled more than 1000 participants

**Number of Participants Enrolled**

- N=238 Studies
- **PCORI Average:** 745 Enrolled vs. Point of Reference: Average 622 Enrolled (Tufts 2013)
Next quarter, Q4-19, we will provide an in-depth End of Year Summary

The discussion is scheduled for the December 2019 Board Meeting (in-person)
Discussion Questions

• Do our FY-2019 Dashboard and associated background materials cover the topics that are most important for the Board to review?

• Does the in-depth annual focus on the Progress of Our Projects and Recruitment this quarter tell you what you need to know about whether our portfolio is on track to be successfully completed on time?

• What questions do you have for the next Dashboard, the Q4-19 End-of-Year metrics?
Proposed FY2020 PCORI Budget
(October 1, 2019 – September 30, 2020)

Larry Becker
Chair, Finance & Administration Committee

Regina Yan, MA
Chief Operating Officer
Agenda

- **Key Definitions**
- **Funding Commitment Plan**
  - Current Funding Commitment Plan
  - Cumulative Award Commitments vs. Award Payments
- **Revenue and Expenditures**
  - Estimated Revenue and Expenditures
  - Total Revenue vs. Total Expenditures per Year
- **Fund Balances**
  - Projected FY2019 Fund Balance
  - Projected FY2020 Fund Balance
- **FY2020 Budget Overview**
  - Budget Development Process
  - FY2020 Budget: By Major Component
  - FY2020 Budget vs. FY2019 Projection
- **Motion to Approve**
Key Definitions
Commitments and Expenses

COMMITMENTS
• **Award Commitments**: the amount of funding PCORI intends to award or has awarded, mostly in the form of multi-year contracts for Research, Research Infrastructure, Engagement, and Dissemination awards.

EXPENSES
• **Award Payments**: the amount PCORI pays to Research, Research Infrastructure, Engagement, and Dissemination awardees in response to invoices received for costs incurred under awarded contracts. These are direct costs associated with the PCORI’s award commitment plan.
  
  Note: Award commitments occur earlier than award payments. Award payments lag award commitments and the associated payments are spread over multiple years.

• **Program Services**: all program award payments, as well as all other direct operating costs (including personnel associated with the Science, Infrastructure, Engagement, and Dissemination departments, as well as the Methodology Committee).

• **Program Support**: all operating costs, including personnel, associated with the Evaluation & Analysis, Program Support & Information Management, and Communications departments.

• **Administrative Support**: all operating costs associated with general institutional support (such as the Board, General Counsel, administrative staff, rent, IT system infrastructure, human resources, finance, etc.).
Current Funding Commitment Plan
Through FY2021

At the end of FY2020, PCORI plans to have committed approximately $2.713 billion, or 99%, of its total award commitment funds of $2.754 billion, based on revenue projected through Sept 2019.

<table>
<thead>
<tr>
<th>AWARD COMMITMENTS ($ in millions)</th>
<th>Inception to FY2019</th>
<th>FY2020 and Beyond</th>
<th>Total Cumulative Commitments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Commitments</td>
<td>$ 2,541</td>
<td>$ 213</td>
<td>$ 2,754</td>
</tr>
</tbody>
</table>
Cumulative Award Commitments vs. Award Payments

$2.754 billion will be committed by fiscal year 2021 (including Dissemination Awards). Award payments are anticipated to continue through fiscal year 2024 until all research projects are completed.

<table>
<thead>
<tr>
<th>Year</th>
<th>Cumulative Award Commitments</th>
<th>Cumulative Award Payments</th>
<th>Unpaid Obligations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior</td>
<td>2,295</td>
<td>1,260</td>
<td>1,035</td>
</tr>
<tr>
<td>FY2019</td>
<td>2,541</td>
<td>1,565</td>
<td>976</td>
</tr>
<tr>
<td>FY2020</td>
<td>2,713</td>
<td>1,877</td>
<td>836</td>
</tr>
<tr>
<td>FY2021</td>
<td>2,754</td>
<td>2,216</td>
<td>538</td>
</tr>
<tr>
<td>FY2022</td>
<td>2,754</td>
<td>2,500</td>
<td>254</td>
</tr>
<tr>
<td>FY2023</td>
<td>2,754</td>
<td>2,675</td>
<td>80</td>
</tr>
<tr>
<td>FY2024</td>
<td>2,754</td>
<td>2,754</td>
<td>0</td>
</tr>
</tbody>
</table>
## Estimated Revenue and Expenditures

<table>
<thead>
<tr>
<th>Description</th>
<th>$ In Millions</th>
<th>% of Total Expenditures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue (thru September 2019)</td>
<td>$ 3,334</td>
<td></td>
</tr>
<tr>
<td>Program Services (thru FY2024)</td>
<td>2,988</td>
<td>90%</td>
</tr>
<tr>
<td>Award Payments</td>
<td>2,754</td>
<td>83%</td>
</tr>
<tr>
<td>Other Direct Program Costs</td>
<td>234</td>
<td>7%</td>
</tr>
<tr>
<td>Program Support (thru FY2024)</td>
<td>125</td>
<td>4%</td>
</tr>
<tr>
<td>Admin Support (thru FY2024)</td>
<td>221</td>
<td>6%</td>
</tr>
<tr>
<td>Total Expenditures (thru FY2024)</td>
<td>$ 3,334</td>
<td>100%</td>
</tr>
</tbody>
</table>
PCORI has modeled its cash flow to ensure proper management and closing out of research obligations. Based on revenue received via the PCOR Trust Fund through September 2019, operations are expected to occur through fiscal year 2024.
# Projected FY2019 Fund Balance

**PROJECTED FUND BALANCE**

**Accrual Basis**

($ in millions)

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fund Balance at September 30, 2018</td>
<td>$ 1,063</td>
</tr>
<tr>
<td>Revenue (FY2019)</td>
<td>578</td>
</tr>
<tr>
<td>Expenses (FY2019)</td>
<td>(381)</td>
</tr>
<tr>
<td>Fund Balance at September 30, 2019</td>
<td>$ 1,260</td>
</tr>
<tr>
<td>Outstanding Award Obligations - September 30, 2019</td>
<td>$ 976</td>
</tr>
</tbody>
</table>

*Includes PCOR Trust Fund and bank accounts*
Projected FY2020 Fund Balance

The projected FY2020 fund balance assumes no new revenue from the PCOR Trust Fund. Revenue will be updated when re-authorization and new funding level is known.

**PROJECTED FUND BALANCE** *

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fund Balance at September 30, 2019</td>
<td>$1,260</td>
</tr>
<tr>
<td>Revenue (FY2020)</td>
<td>$21</td>
</tr>
<tr>
<td>Expenses (FY2020)</td>
<td>$(396)</td>
</tr>
<tr>
<td>Fund Balance at September 30, 2020</td>
<td>$885</td>
</tr>
<tr>
<td>Outstanding Award Obligations - September 30, 2020</td>
<td>$836</td>
</tr>
</tbody>
</table>

*Includes PCOR Trust Fund and bank accounts*
Annual Budget Development Process

PCORI’s budget is developed through a comprehensive process grounded in its strategic plan:

1. **Board Approved Strategic Plan and Priorities**
   - *(Board Approved 11/2013)*

2. **Board Reviews Strategic Plan and Priorities**
   - *(Annually)*

3. **PCORI Staff Draft and Refine Operating Plans and Budgets based on Priorities**
   - *(Spring/Summer)*

4. **Strategy Committee-Level Review of Key Activities and Proposed Budget**
   - *(Summer)*

5. **Proposed Budget Brought to the Board for Approval**
   - *(September)*
**FY2020 Budget Overview**
**By Major Component**

### Proposed FY2020 Budget

**$396M**

- **79%** Award Payments
- **8%** Other Direct Program Costs
- **4%** Program Support
- **9%** Administrative Support

### 2020 Budget

<table>
<thead>
<tr>
<th>Category</th>
<th>Amount</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue</strong></td>
<td>$20,697,828</td>
<td></td>
</tr>
<tr>
<td><strong>Expenses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Program Services</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Award Payments</td>
<td>312,405,875</td>
<td>79%</td>
</tr>
<tr>
<td>Other Direct Program Costs</td>
<td>31,217,155</td>
<td>8%</td>
</tr>
<tr>
<td><strong>Total Program Services</strong></td>
<td>343,623,030</td>
<td>87%</td>
</tr>
<tr>
<td><strong>Program Support</strong></td>
<td>17,274,140</td>
<td>4%</td>
</tr>
<tr>
<td><strong>Administrative Support</strong></td>
<td>35,430,210</td>
<td>9%</td>
</tr>
<tr>
<td><strong>Total Expenses</strong></td>
<td>$396,327,380</td>
<td>100%</td>
</tr>
</tbody>
</table>
# Proposed FY2020 Budget vs. FY2019 Projection

## Revenues

<table>
<thead>
<tr>
<th></th>
<th>2020 Budget</th>
<th>2019 Projection</th>
<th>Variance</th>
<th>$</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>REVENUES</td>
<td>$20,697,828</td>
<td>$578,337,034</td>
<td>$(557,639,206)</td>
<td>(96%)</td>
<td></td>
</tr>
</tbody>
</table>

## Expenses

### Program Services

<table>
<thead>
<tr>
<th>Service</th>
<th>2020</th>
<th>2019</th>
<th>Variance</th>
<th>$</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research</td>
<td>242,220,280</td>
<td>233,152,659</td>
<td>9,067,621</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>Infrastructure (PCORnet)</td>
<td>48,767,530</td>
<td>54,679,590</td>
<td>(5,912,060)</td>
<td>(11%)</td>
<td></td>
</tr>
<tr>
<td>Engagement</td>
<td>30,828,695</td>
<td>33,623,470</td>
<td>(2,794,775)</td>
<td>(8%)</td>
<td></td>
</tr>
<tr>
<td>Dissemination</td>
<td>21,806,525</td>
<td>11,534,986</td>
<td>10,271,539</td>
<td>89%</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL PROGRAM SERVICES</strong></td>
<td>343,623,030</td>
<td>332,990,705</td>
<td>10,632,325</td>
<td>3%</td>
<td></td>
</tr>
</tbody>
</table>

### Program Support

<table>
<thead>
<tr>
<th>Support</th>
<th>2020</th>
<th>2019</th>
<th>Variance</th>
<th>$</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Support and Information Management</td>
<td>7,950,068</td>
<td>7,152,570</td>
<td>797,498</td>
<td>11%</td>
<td></td>
</tr>
<tr>
<td>Communications</td>
<td>6,714,045</td>
<td>7,176,030</td>
<td>(461,985)</td>
<td>(6%)</td>
<td></td>
</tr>
<tr>
<td>Evaluation and Analysis</td>
<td>2,610,028</td>
<td>2,668,905</td>
<td>(58,877)</td>
<td>(2%)</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL PROGRAM SUPPORT</strong></td>
<td>17,274,140</td>
<td>16,997,505</td>
<td>276,635</td>
<td>2%</td>
<td></td>
</tr>
</tbody>
</table>

### Administrative Support

<table>
<thead>
<tr>
<th>Support</th>
<th>2020</th>
<th>2019</th>
<th>Variance</th>
<th>$</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Board of Governors/Governance</td>
<td>784,000</td>
<td>772,715</td>
<td>11,285</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Management and General</td>
<td>34,646,210</td>
<td>30,556,355</td>
<td>4,089,855</td>
<td>13%</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL ADMINISTRATIVE SUPPORT</strong></td>
<td>35,430,210</td>
<td>31,329,070</td>
<td>4,101,140</td>
<td>13%</td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL EXPENSES**

<table>
<thead>
<tr>
<th>Budget</th>
<th>2020</th>
<th>2019</th>
<th>Variance</th>
<th>$</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>$396,327,380</td>
<td>$381,317,280</td>
<td>$15,010,100</td>
<td>4%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Variance:
Board Vote

Call for a Motion to:
- Approve the proposed FY2020 Budget

Call for the Motion to be Seconded:
- Second the Motion
- If further discussion, may propose an Amendment to the Motion or an Alternative Motion

Roll Call Vote:
- Vote to Approve the Final Motion
- Ask for votes in favor, opposed, and abstentions
BREAK

We will return at 10:45 am ET

Join the conversation on Twitter via @PCORI
PCORI’s Portfolio on Mental Health

Els Houtsmuller, PhD
Associate Director, Healthcare Delivery & Disparities Research

Holly Ramsawh, PhD
Program Officer, Clinical Effectiveness & Decision Science
1. Background & Scope of Review
2. Overview of PCORI’s Mental Health Portfolio
3. Notable Study Findings to Date
4. Highlights from Engagement
Background

The high prevalence and heavy burden of mental illness remain a major public health concern.

- Affects 1 in 5 children and adults
  - Higher rates among LGBTQ community, individuals experiencing homelessness, youth involved in juvenile justice system, other
- A leading cause of disability
- Estimated cost >$467 billion/year (NIMH, 2012)
- Despite evidence-based treatments for many conditions and populations, less than 50% of patients receive treatment due to barriers to care
Scope of Review

• **Inclusion criteria:**
  • Studies that address mental health condition(s) or symptom(s) as *primary focus*
  • Broadly inclusive (tobacco dependence, insomnia)

• **Exclusion criteria:**
  • Studies that address mental health conditions or symptoms as *secondary focus*
  • Neurological diseases (e.g., Dementia, Alzheimer’s, Epilepsy)

• **Classification of Serious Mental Illness (SMI):**
  • Includes schizophrenia and related disorders, bipolar disorder; condition severity associated with significant functional impairment
PCORI’s Investment in Mental Health Research

PCORI HAS AWARDED

$383 MILLION TO FUND 96 CER studies

on mental health, representing \( \frac{1}{5} \) of PCORI’s research portfolio

As of August 2019
PCORI’s Investment in Mental Health Research by Award Type

PCORI’s Mental Health Portfolio by Award Type (Total Investment = $383M)

- **Broad Awards**: 44%, $167.4M
- **Pragmatic Clinical Studies**: 33%, $128.1M
- **Targeted Awards**: 19%, $73.1M
- **PCORnet Research Awards**: 4%, $14.5M

As of August 2019
<table>
<thead>
<tr>
<th>Topic</th>
<th>Number of Studies</th>
<th>Total Awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management Strategies for Treatment-Resistant Depression</td>
<td>3</td>
<td>$40M</td>
</tr>
<tr>
<td>Medication-Assisted Treatment Delivery for Pregnant Women with</td>
<td>3</td>
<td>$15.7M</td>
</tr>
<tr>
<td>Substance Use Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychosocial Interventions with Office-Based Opioid Treatment for</td>
<td>3</td>
<td>$14.8M</td>
</tr>
<tr>
<td>Opioid Use Disorder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment for Anxiety Disorders in Children, Adolescents, and/or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Young Adults</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment of Post-traumatic Stress Disorder in Adults</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Awards will be announced Nov 2019
The Mental Health Portfolio Includes a Range of Conditions

Number of Studies by Mental Health Condition (N=96, categories are mutually exclusive)

- Depression: 23
- Substance Use Disorders: 17
- Serious Mental Illness: 16
- Depression + Anxiety: 8
- Post-Traumatic Stress Disorder: 6
- Anxiety: 5
- Attention-Deficit/Hyperactivity Disorder: 4
- Other: 17
The Mental Health Portfolio Includes a Range of Interventions

**Therapeutic Interventions**
- Behavioral & Psychological
- Pharmacologic
- Device-mediated
- Complementary & Alternative Medicine

**Care Delivery Strategies**
- Telehealth
- Peer-Based Interventions
- Community Health Workers
- Care Management
- Care Integration Models

**Health Education, Decision Support**
Key Portfolio Strengths

• 81% of studies include **understudied and/or vulnerable populations** (i.e., racial and ethnic minorities, low income, low health literacy, rural, LGBTQ, children, and older adults)

• 72% are **Randomized Controlled Trials**

• 74% have **multiple sites**

• 60% have sample sizes >**250 participants**
PCORI’s Mental Health Portfolio

Study Findings To Date
40 studies have undergone peer review by PCORI and/or a scientific journal through August 2019. Notable results show:

- Value of **observational studies** to assess treatment policies and suggest hypotheses to be examined in definitive clinical trials
- Value of **peer-based interventions** in mental health treatment
- Promising opportunities to address unique challenges in managing **serious mental illness**
Many individuals diagnosed with schizophrenia have an inadequate response to a single antipsychotic medication.

What are the **comparative benefits and risks** of different add-on medications for **patients with schizophrenia** who do not respond to a single antipsychotic?

Observational design using claims data; N=81,291

Relative to addition of a second antipsychotic drug, observational data found:

- Antidepressants were associated with lowered risk of psychiatric hospitalization, emergency department visits, and onset of diabetes
- Benzodiazepines were associated with elevated risk of psychiatric hospitalization and emergency department visits
- Mood stabilizers were associated with a higher risk of death from any cause
Spotlight: State Psychotropic Oversight Systems for Youth in Foster Care
Stephen Crystal, PhD, MS  Rutgers, The State University of New Jersey, New Brunswick

<table>
<thead>
<tr>
<th>Background/Significance</th>
<th>Youth in foster care are prescribed antipsychotics at high and likely inappropriate rates and without metabolic monitoring. Federally mandated oversight systems vary across states.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Question/Design</td>
<td>What is the comparative effectiveness of different state prescription oversight programs (Texas, Wisconsin, Washington, Ohio) to reduce <strong>inappropriate prescribing of antipsychotics</strong> and improve <strong>metabolic monitoring</strong> for youth in foster care?</td>
</tr>
<tr>
<td></td>
<td>Observational mixed methods pre-post design, using administrative (claims) data; N=15,283</td>
</tr>
<tr>
<td>Key Findings</td>
<td>• A specialized managed care model (TX) was associated with a significant reduction in inappropriate antipsychotic prescribing among youth in foster care.</td>
</tr>
<tr>
<td></td>
<td>• Implementation of metabolic monitoring guidelines associated with increased metabolic monitoring rates for youth in foster care (pre-post TX vs OH).</td>
</tr>
<tr>
<td></td>
<td>• Foster care medical home for metabolic monitoring (WI) and peer-review prior authorization (WA)</td>
</tr>
</tbody>
</table>
Efforts to strengthen the evidence of peer-based interventions require a research agenda that focuses on establishing the efficacy and effectiveness of these interventions across different populations and settings.

### Background/Significance

Hoarding disorder (HD) affects daily functioning and safety of individuals, families, and communities. Cognitive behavioral therapy is effective but hard to access due to limited numbers of practitioners. More accessible forms of treatment are needed.

### Research Question/Design

Is peer-led group cognitive behavioral therapy (CBT) for HD as effective as group CBT led by a trained mental health professional?

RCT; N=323

### Key Findings

Peer-led group CBT was as effective as clinician-led group CBT in:

- Reducing hoarding symptoms
- Improving daily functioning (e.g. food preparation) by reducing clutter
**Spotlight: Peer Navigators for Serious Mental Illness (SMI)**

<table>
<thead>
<tr>
<th><strong>Peer Health Navigation: Reducing Disparities in Health Outcomes for the Seriously Mentally Ill</strong></th>
<th><strong>Integrated Care and Patient Navigators for Latinos with Serious Mental Illness</strong></th>
</tr>
</thead>
</table>
| John Sinclair Brekke, PhD, MS  
University of Southern California | Patrick Corrigan, PsyD  
Illinois Institute of Technology |

**Background/Significance**

Hispanic patients with SMI are at risk for disparities. The effectiveness of peer navigators for this population is unknown.

**Research Question/Design**

Compared to **usual mental health care**, do **peer navigators** improve outcomes for Hispanic patients with serious mental illness?  
RCT; N=151; N=110

**Key Findings**

- Peer navigation increased
  - Appropriate health service use
  - Quality of life
  - Other health-related indices
### Background/Significance
Adults with serious mental illness (SMI) experience a combination of high medical need and difficulty in accessing quality medical care. Behavioral health homes provide support through different methods, but it is not known which method works best.

### Research Question/Design
What is the comparative effectiveness of nurse-supported vs. self-directed care interventions on patient engagement in health care, health status, and quality of life among Medicaid-enrolled adults with SMI who have or are at risk for chronic medical conditions?

RCT; N=1,229

### Key Findings
Both the nurse-supported and self-directed care interventions were associated with increased:
- Patient involvement in health care
- Self-reported mental health
- Quality of life
- Satisfaction with care
“I gave input on the day to day realities of individuals with mental health disorders. I think I brought the "real world" perspective to the project.”

–Patient/Consumer

“I helped design the wellness nurse role for our agency. It allowed us to cater the interventions to our agency/program.”

–Representative of a community-based organization

“[I] helped identify meaningful measures to capture outcomes and helped to focus on outcomes of meaning to patients and practitioners.”

–Payer

“We shared with interested community members, stakeholders and professionals to talk about the important findings and to discuss next steps in our system, building on the strengths of the training and research to improve the system going forward. This was more than just research!”

–Policy Maker
Objectives Engagement Awards:

- To disseminate PCORI-funded CER evidence to stakeholders - patients, clinicians, lay intervention providers, administrators

Activities:

- Develop materials using formats that are accessible to end-users, including patients, caretakers, peer supporters
- Disseminate findings through trained end-user presenters, using various media (websites, webinars, conferences) and promotion through stakeholder channels
- Evaluate dissemination efforts
Summary: Promising Methods and Interventions

• Role for observational methods to analyze public health policy interventions and guide selection of comparators in RCTs

• Merits of peer-based interventions to ensure access, continuity and adherence in mental health care

• Promising approaches to addressing challenges associated with managing serious mental illness
Acknowledgments

• Rebecca Chanis
• Steve Clauser
• Candace Hall
• David Hickam
• Emily Lazowick
• Tshema Nash
• Anne Trontell
• PCORI’s Data Warehouse Team
PCORI’s Mental Health Portfolio: Next Steps

• Questions?

• Discussion: Possible mental health topics for future exploration
Public Comment Period

Kristin Carman, PhD, MA
Director, Public and Patient Engagement
Wrap Up and Adjournment

202.827.7700
info@pcori.org
www.pcori.org

@pcori
/PCORInstitute
PCORI
/pcori