Dashboard Review
Third Quarter of FY-2016

Joe Selby, MD, MPH
Executive Director
Results of Engagement in Research
Co-authors from 7 PCORI-funded studies focused on Kidney Disease shared 3 early examples where engagement improved their research:
1) Stakeholders paved the way for a study implementation, 2) A patient advisory panel ensured appropriateness of a decision aid in development, and 3) Tribal community engagement helped identify barriers to study implementation.

Highlight: Health Affairs Special Issue
Health Affairs Special Issue on Patients’ and Consumers’ Use of Evidence featured 6 articles written by PCORI awardees or PCORI staff.
Results of PCORI Research: Network Metaanalysis of Treatments for Lupus Nephritis


- Awarded 2013, Assessment of Prevention, Diagnosis, and Treatment Options project
- Principal Investigator: Jasvinder Singh, MBBS, MPH- University of Alabama at Birmingham

This systematic review and Bayesian network metaanalyses assessed the comparative effectiveness of immunosuppressive drugs and corticosteroids for the treatment of Lupus Nephritis. 65 RCTs were included in the analysis.

For renal outcomes, **immunosuppressive drugs were better than corticosteroids, both clinically and statistically**. There were differences in side effects including herpes zoster, alopecia, gastrointestinal tolerability, etc.

This study provides data on relative and absolute differences of treatment options, which will help with patient-physician discussions around medication use. This data is being incorporated into a patient-decision aid that is being tested in a PCORI-funded RCT in patients with Lupus Nephritis.
Results of Engagement in Research: PCORI Studies of Patients with Kidney Diseases


Co-authored by researchers, patients, and stakeholders from 7 PCORI-funded studies focused on Kidney Disease, including a Patient-Powered Research Network focused on nephrotic syndrome, the article identified 3 early examples where engagement made a difference in the study:

1. Stakeholder advocacy motivated a major dialysis provider organization to find creative solutions to accommodate novel treatment delivery options in order to participate in the study (PI: Mehrotra)

2. Patient advisory panel feedback on the development of a decision aide helped ensure it was appropriate for the target audience of predialysis CKD patients and their caregivers (PI: Tentori)

3. Community engagement with the Zuni people helped identify psychologic and structural barriers that could be a challenge in a population with the highest prevalence of dialysis-requiring kidney diseases (PI: Shah)

“...The nephrology research community could serve as a model for implementing the ideals of community-based participatory research and patient-centered methodologies.

PCORI Projects with contributing authors:
- PI: Lewis Cohen
- PI: Elizabeth Cope
- PI: Nashrollah Ghahramani
- PI: Denise Hynes
- PI: Rajnish Mehrotra
- PI: Vallabh Shah
- PI: Francesca Tentori
Health Affairs Theme Issue
Patients’ and Consumers’ Use of Evidence

Six articles in the April 2016 Special Issue of Health Affairs: Patients’ and Consumers’ Use of Evidence, were authored by PCORI awardees or PCORI staff:


Altmetric Scores > 20 are typically in the “Top 5%” of Research Scored
We actively monitor our projects, support them to be successful, and classify their progress as shown below.

| GREEN | Project is meeting >85% of milestones on time  
|       | -AND-  
|       | Recruitment occurring on schedule, at expected rate  
|       | -AND-  
|       | PO judges that the project has a high probability of meeting its objectives as planned. PO judgment is based on close review of study progress, including recruitment status. |

| YELLOW | Project does not meet all criteria for “Green”  
|        | -AND-  
|        | Project is meeting >65% of milestones on time.  
|        | -OR-  
|        | Recruitment is ≤75% and >50% of target accrual  
|        | -OR-  
|        | PO has concerns that without remediation efforts the project will not be able to meet objectives within project period. |

| ORANGE | Project does not meet all criteria for “Yellow”  
|        | -AND-  
|        | Project is meeting >50% of milestones on time.  
|        | -OR-  
|        | Recruitment is ≤50% of target accrual  
|        | -OR-  
|        | PO has concerns that the project will not meet objectives within the approved project period. Modifications to the Milestone Schedule and/or project plan are likely required. |

| RED | Project does not meet all criteria for “Red”  
|     | -AND-  
|     | Project is meeting ≤50% of milestones on time.  
|     | -OR-  
|     | Recruitment is persistently and significantly ≤50% of target  
|     | -OR-  
|     | PO has significant concerns that the project cannot meet its original objectives. Major modifications to Milestone Schedule are required for the project to be completed. |

**Next Steps**

| GREEN | Continue monitoring project through active portfolio management and per SOPs. |
| YELLOW | Increased communication with the PI to monitor and assist with getting the project back on track |
| ORANGE | Placed Under Review at PCORI to determine if it is able to meet its original project plan.  
|         | Pursue modifications to project plan or milestone schedule as appropriate. |
| RED | Project Remediation Plan (PRP) memo sent to PI with a 30-day completion date deadline.  
|      | Inform Leadership of Status |
The majority of our projects are on track and we are giving additional attention to those that are not.
Of the 29 Unique Projects in Q4-15 or Q1-16 that were Red/Orange:

- 2/3 are now Green or Yellow in Q3-16
- 1/3 are still behind or were terminated
52% of Projects Started Recruitment Early or On Time

For all projects that have or should have initiated recruitment (N=211)

Timeliness of Recruitment Initiation

- Late - Pending Initiation: 5%
- Late: 43%
- Early: 24%
- On Time: 28%

Most Common Reasons for Delayed Initiation

- Subcontract negotiation
- IRB Approval
- Staff turnover
Most Projects Initiated Recruitment within a Few Months of Planned Start Date

For all projects that have initiated recruitment (N=201)

Timeliness of Recruitment Initiation

- Most Projects Initiated Recruitment within a Few Months of Planned Start Date
- 6 months early
- 10 months early
- 35 months early
- 59 projects on time
- 49 months late
- 24 months late
- 12 months late
- 2 months late
- 2 months late
- 1 month late
- 1 month late
62 Projects Have Completed Recruitment

- **Recruitment Initiation**
  - Early: 28% (30%) late: 44%

- **Recruitment Completion**
  - Early or On Time: 24 (37%)
  - Late: 11 (18%)
  - Early: 12 (19%)
  - Late: 15 (26%)

- 63% Stay in same timeliness category
- Of those that started late, 44% ended on time
- Of those that started early, 31% ended late
After one year, Baylor College of Medicine provided an Educational Outcomes Report for the PCORI Methodology Standards CME/CE Activity (with 136 Survey Respondents)

“Substantial knowledge and confidence gains are being achieved in line with, if not exceeding, the gains typically observed for Baylor’s educational initiatives. These strong results suggest that [participants] are anticipating improvements in conducting patient-centered research studies and are seeking to implement the Methodology Standards as applicable.”

Examples:

<table>
<thead>
<tr>
<th>Do you intend to implement the following practice changes?</th>
<th>Yes</th>
<th>No</th>
<th>Already Implementing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engage patients throughout the research process in at least one study in which you are involved</td>
<td>93%</td>
<td>3%</td>
<td>4%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Knowledge of how comparative effectiveness research can contribute to advances in patient care</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Knowledge</td>
</tr>
<tr>
<td>Before program:</td>
</tr>
<tr>
<td>After program:</td>
</tr>
<tr>
<td>Mean</td>
</tr>
</tbody>
</table>
Data Mart Totals:
10 as of 6/30 (Q3)
49 as of 9/30 (Q4)

More than Half of DataMarts Are Now Approved for Research

- Approved for Research
- Data Characterization Review
- Prep-to-Research Ready Phase
- Data Characterization Phase
- Diagnostic Query Phase

Data Characterization Progress

Number of DataMarts

Time (6 month period)
21% of Recent LOIs Proposed Collaboration with PCORnet

Cycle 3 2016

Of the 414 LOIs received for Cycle 3 2016, **21% had a portion of their study proposal that included collaborations with existing PCORnet entities** (including CDRNs, PPRNs, or Collaborative Research Groups).

**Broad (21%)**
- 11% of AD proposals
- 22% of APDTO proposals
- 46% of Methods proposals
- 13% of IHS proposals
- 0% of CDR proposals

**Targeted, PCS, and D&I (22%)**
- 58% of Sickle Cell proposals
- 27% of Palliative Care proposals
- 17% of Opioids proposals
- 16% of PCS proposals
- 7% of D&I proposals
Results of Engagement in Research

Co-authors from 7 PCORI-funded studies focused on Kidney Disease shared 3 early examples where engagement improved their research:

1) Stakeholders paved the way for a study implementation, 2) A patient advisory panel ensured appropriateness of a decision aid in development, and 3) Tribal community engagement helped identify barriers to study implementation.

Results: Increasing Information

A network metaanalysis of treatments for Lupus Nephritis provides data on efficacy and harms of treatments. The analysis demonstrated that for renal outcomes, immunosuppressive drugs were better than corticosteroids.

Highlight: Health Affairs Special Issue

Health Affairs Special Issue on Patients’ and Consumers’ Use of Evidence featured 6 articles written by PCORI awardees or PCORI staff.