

# Board of Governors Meeting via Teleconference/Webinar

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March 20, 2018

12:00 - 1:30 pm ET



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

# Welcome and Introductions

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**Kerry Barnett, JD**

Vice Chairperson, Board of Governors

**Joe Selby, MD, MPH**

Executive Director



# Agenda

| Time        | Agenda Item                                                                                                                                                                 |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 12:00       | Call to Order, Roll Call, and Welcome                                                                                                                                       |
| 12:00-12:10 | <b>Consider for Approval: Consent Agenda</b><br>Minutes of the February 27, 2018 Board Meeting and Nominations for the Advisory Panel on Clinical Trials Chair Positions    |
| 12:10–12:40 | Q1 Dashboard Review                                                                                                                                                         |
| 12:40-1:20  | PCORnet Update: <ul style="list-style-type: none"><li>• PCORnet Demographics Query</li><li>• PCORnet Demonstration Study Updates</li><li>• Select PCORnet Queries</li></ul> |
| 1:20        | Wrap up and adjournment                                                                                                                                                     |

# Consent Agenda Items

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**Kerry Barnett, JD**

Vice Chairperson, Board of Governors



# Motion for Consent Agenda Items

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That the Board approve:

- Minutes from February 27, 2018 Board meeting
- Nomination of Chair and Co-Chair for Advisory Panel on Clinical Trials (CTAP)
  - Chair: Kaleab Abebe, MA, PhD, Univ of Pittsburgh School of Medicine
    - Term to end August 2019
    - Representing Researchers
    - Assoc Professor, University of Pittsburgh School of Medicine
    - Founding Director, Center for Clinical Trials and Data Coordination
    - Research focus is design, analysis and coordination of clinical trials
  - Co-Chair: Andrea Troxel, ScD, New York University School of Medicine
    - Term to end August 2020
    - Representing Researchers
    - Professor and Director, New York University School of Medicine
    - Expert in statistical methods for longitudinal and missing data and the design and analysis of randomized clinical trials
    - Collaborative research focus is in oncology and behavioral economics



# Board Vote

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## 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



# Dashboard Review

## First Quarter of FY-2018

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**Joe Selby, MD, MPH**

Executive Director



# PCORI Board of Governors Dashboard

## First Quarter FY-2018 (As of 12/31/2017)

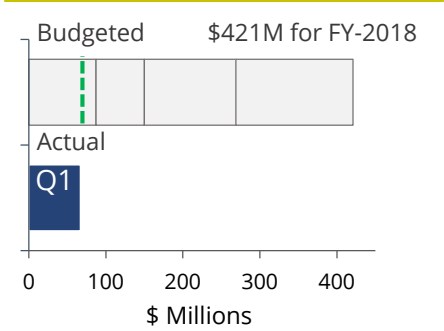
**Dashboard Key**

- Projected
- Q1 Target

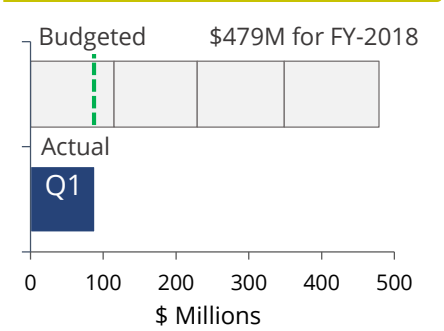
- Meeting Target
- Off Target
- Needs Board Attention
- No Target

- Q2 2017
- Q3 2017
- Q4 2017
- Q1 2018

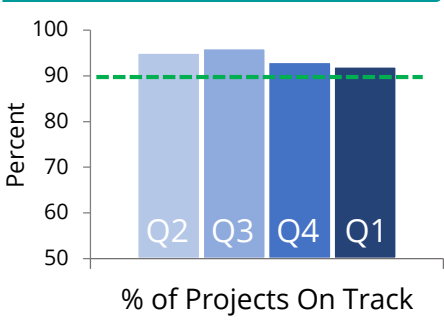
### Funds Committed to Research



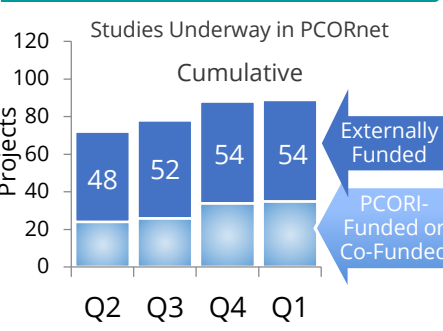
### Expenses



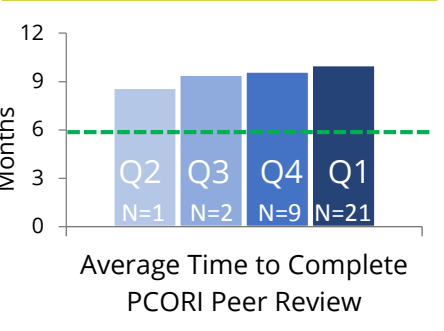
### Project Performance



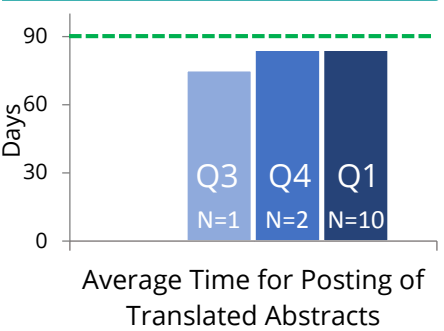
### Research Using PCORnet



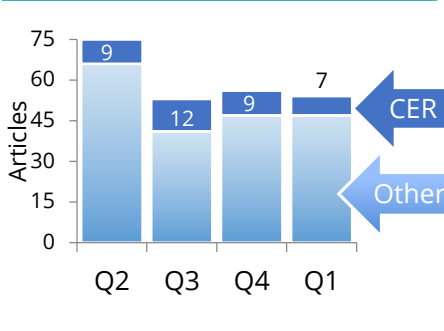
### Speed of PCORI Peer Review



### PCORI Abstracts Posted to Website



### Results Published in Literature



### Altmetric: Attention to PCORI Research



## Featured Results on PCORI's Strategic Goals

### Results on Goal 1

#### Increasing Information

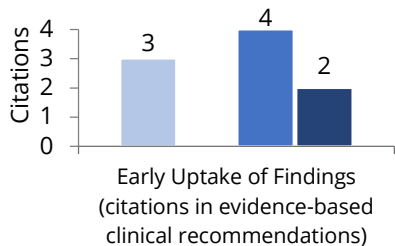
**Results Highlight:** A PCORI-funded study found that for pediatric respiratory infections, narrow-spectrum antibiotics (vs. broad) were associated lower rates of adverse events and higher quality of life for patients.

### Results on Goal 2

#### Speeding Uptake

As of Q1, results from PCORI studies have been cited 10 times in evidence-based clinical recommendations.

**Uptake Highlight:** Results from a PCORI-funded study on self-monitoring of blood glucose were taken up into the ADA's Standards of Medical Care in Diabetes 2018



### Results on Goal 3

#### Influencing Research

A PCORI award that established an engagement program at Southern Illinois Healthcare Foundation (SIHF) is credited with **unanticipated improvements in health outcomes for patients engaged in research**, including mental health stability and overall quality of life.

# Goal 1: Results of PCORI-Funded Research

## Public Availability of Primary CER Results

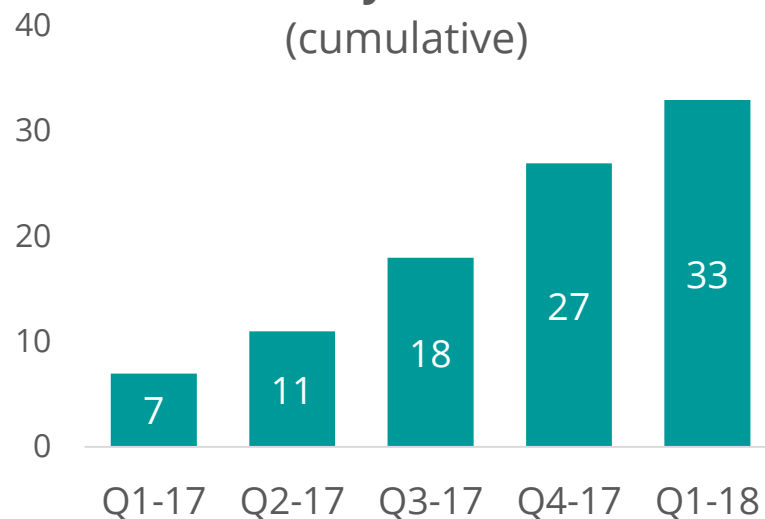
As of Q1-18, **33 CER Projects** have their **primary results peer-reviewed and publicly available**, and this number is steadily increasing

- **Primary results** are results that report on a comparison of clinical approaches using the pre-specified primary outcome(s).
- Primary results can be **made publicly available** by being published in a peer-reviewed journal, and/or by completing the PCORI Peer Review Process and having abstracts posted to PCORI.org

### Of the 33 CER projects with primary results:

- 28 (85%) were first made available via publications
- 5 (15%) were first made available via PCORI.org

**Primary CER Results Publicly Available**  
(cumulative)



#### Update:

As of 3/15/18, **46 CER projects** have publicly available primary results, and at least 3 more results papers in-process

# Goal 1: Results of PCORI-Funded Research

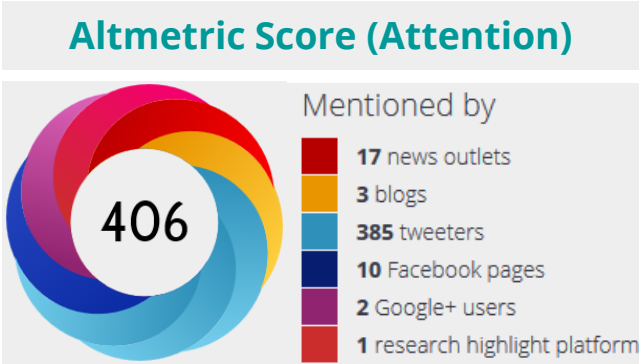
For Pediatric Respiratory Infections, Narrow-Spectrum Antibiotics Associated with Better Outcomes than Broad

|                     |                                                                                                                                                                                                                                              |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PCORI Study         | <b>Study Title:</b> Comparative Effectiveness of Broad- versus Narrow-Spectrum Antibiotics for Acute Respiratory Tract Infections in Children<br><b>Principal Investigator:</b> Jeffrey Gerber, MD, PhD, Children's Hospital of Pennsylvania |
| Results Publication | Gerber JS, Ross RK, Bryan M, et al. Association of Broad- vs Narrow-Spectrum Antibiotics With Treatment Failure, Adverse Events, and Quality of Life in Children With Acute Respiratory Tract Infections. <i>JAMA</i> . Dec 2017.            |

**Summary:** Antibiotics are the most common medicines prescribed to children, the majority resulting from respiratory tract infections. Experts recommend starting treatment with narrow-spectrum antibiotics, but guidance is inconsistent, and comparative data has been lacking.

This large retrospective cohort study compared the effectiveness of broad- vs. narrow-spectrum antibiotic treatment for acute respiratory tract infections in children. Investigators worked with patients' families to identify and gather data on key patient-centered outcomes.

The study found that **narrow-spectrum antibiotics were associated with lower rates of adverse events and higher quality of life** for patients. There were no other differences between clinical or patient-centered outcomes.



Top 6%  
(Accounting for Journal and Date of Publication)

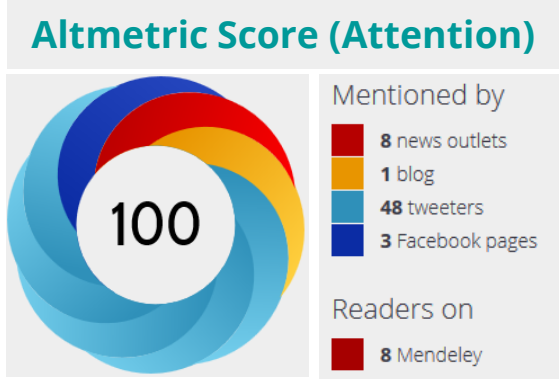
“We want to use antimicrobials to treat diseases in the best way possible without creating collateral damage... We know that **parents and pediatricians want more information to help them balance the risks and benefits** of different antibiotics.”

-Dr. Jeffrey Gerber, Principal Investigator  
[PCORI Research-in-Action Article](#)

# Goal 1: Results of PCORI-Funded Research

For Chronic Pain, Literacy-Adapted CBT and Education Improved Pain and Physical Function

|                     |                                                                                                                                                                                                                                   |
|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PCORI Study         | <p><b>Study Title:</b> Reducing Disparities with Literacy-Adapted Psychosocial Treatments for Chronic Pain: A Comparative Trial</p> <p><b>Principal Investigator:</b> Beverly E. Thorn, PhD, University of Alabama-Tuscaloosa</p> |
| Results Publication | <p>Thorn BE, Eyer JC, Van Dyke BP, et al. Literacy-Adapted Cognitive Behavioral Therapy Versus Education for Chronic Pain at Low-Income Clinics: A Randomized Controlled Trial. <i>Annals Intern Med.</i> Feb 2018.</p>           |



Top 20%  
(Accounting for Journal and Date of Publication)

**Summary:** Chronic pain is common, challenging to treat condition that disproportionately affects low-income populations. Although cognitive behavioral therapy (CBT) is efficacious, its benefit in disadvantaged populations is largely unknown.

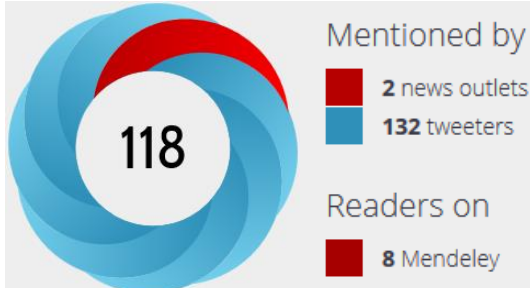
In a low-income clinic setting, this randomized trial compared literacy-adapted and simplified group CBT, group pain education (EDU), and usual care. Outcomes of interest were self-reported postintervention pain intensity, physical function, and depression.

The study found that **CBT and EDU significantly improved pain and physical function compared with usual care.** Observed decreases in depression were not significant.

”  
As our society struggles with health care costs and the opioid crisis, these findings show promise for the safe, effective, and efficient treatment of chronic pain.

# Goal 1: Results of PCORI-Funded Research

## For Crohn's Disease, Anti-TNF Biologics Associated with Lower Mortality than Chronic Steroids

|                     |                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                    |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PCORI Study         | <b>Study Title:</b> Patient Valued Comparative Effectiveness of Corticosteroids versus Anti-TNF Alpha Therapy for Inflammatory Bowel Disease<br><b>Principal Investigator:</b> James Lewis, MD, MS, University of Pennsylvania                     | <b>Altmetric Score (Attention)</b><br> <p>Mentioned by<br/>2 news outlets<br/>132 tweeters</p> <p>Readers on<br/>8 Mendeley</p> |
| Results Publication | Lewis JD, Scott FI, Brensinger CM, et al. Increased Mortality Rates With Prolonged Corticosteroid Therapy When Compared With Antitumor Necrosis Factor-α-Directed Therapy for Inflammatory Bowel Disease. <i>Am J Gastroenterology</i> . Jan 2018. |                                                                                                                                                                                                                    |

**Summary:** Crohn's disease and ulcerative colitis are inflammatory bowel diseases (IBD) that compromise quality of life and may increase mortality.

This retrospective cohort study compared the mortality risk of two treatment strategies commonly used in IBD: prolonged corticosteroid therapy, versus chronic immunosuppression with antitumor necrosis factor-α (anti-TNF) drugs. Investigators surveyed 812 patients to better understand patient preferences and factors associated with quality of life.

The study found that **anti-TNF drug use was associated with reduced mortality in patients with Crohn's disease** (OR 0.78, 95% CI 0.65-0.93) which may be explained by lower rates of major adverse cardiovascular events and hip fracture.

Top 3%  
(Accounting for Journal and Date of Publication)

“[Reduced mortality] was largely limited to **patients with multiple or serious comorbid conditions**. This population, which is rarely included in clinical trials and for whom some physicians may be reluctant to treat with chronic immunosuppression, may be particularly good candidates for anti-TNF agents as corticosteroid-sparing therapy.

# Goal 1: Results of PCORI-Funded Research

## For Crohn's Disease, Anti-TNF Biologics Associated with Lower Mortality than Chronic Steroids

**PCORI Study**

**Study Title:** Patient Valued Comparative Effectiveness of Corticosteroids versus Anti-TNF Alpha Therapy for Inflammatory Bowel Disease  
**Principal Investigator:** James Lewis, MD, MS, University of Pennsylvania

**Results Publication**

Lewis JD, Scott FI, Brensinger CM, et al. Increased Mortality Rates With Prolonged Corticosteroid Therapy When Compared With Antitumor Necrosis Factor-α-Directed Therapy for Inflammatory Bowel Disease. *Am J Gastroenterology*. Jan 2018.

**Altmetric Score (Attention)**

118

Mentioned by

- 2 news outlets
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Readers on

- 8 Mendeley

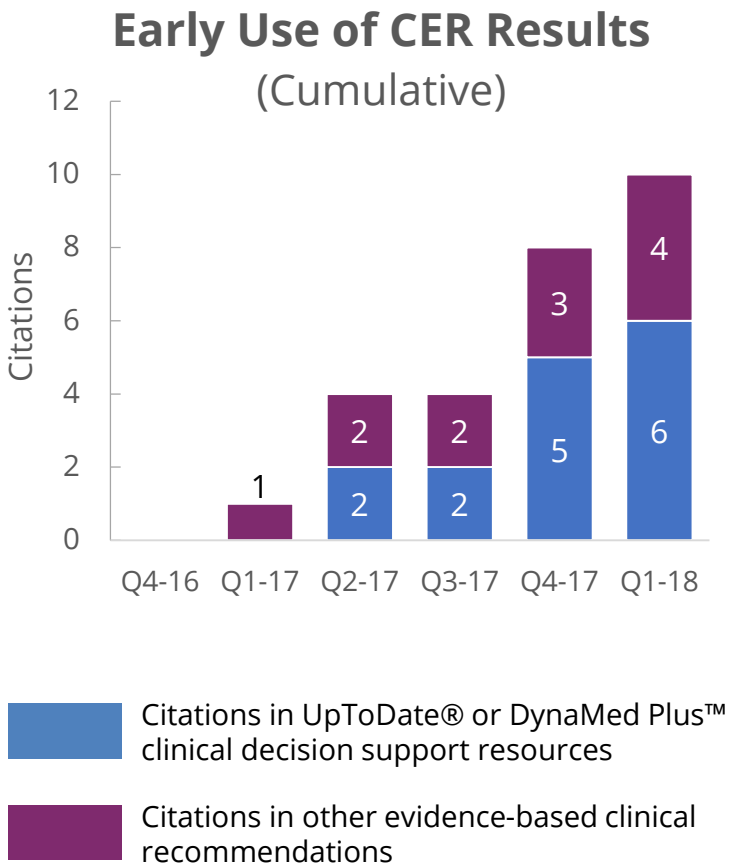
### What are patients and physicians saying about this finding?

- This message needs to be repeated again and again until everyone understands it #IBD <https://t.co/GJo3KUGVPF>
- Steroids can literally & absolutely rescue #patients in the short-term when flaring, but as this study shows, it is NOT a long-term solution, & can truly do more harm than good. An exit strategy w a safe, steroid-sparing drug is 🗝️. #IBD #biologics
- This is so important. Steroids (again and again and again) shown to increase bad outcomes including mortality in #IBD. Here, anti-TNF therapy was assoc with REDUCED mortality. <https://t.co/vmCyO2SZYY>
- Another big reason to always have an exit strategy when steroids are involved. Really important data here. #IBD <https://t.co/uxTCqv9IO>

### Who is Tweeting about it?

| Type                                                    | Count | As % |
|---------------------------------------------------------|-------|------|
| Members of the public                                   | 88    | 66%  |
| Practitioners (doctors, other healthcare professionals) | 23    | 17%  |
| Scientists                                              | 18    | 13%  |
| Science communicators (journalists, bloggers, editors)  | 5     | 4%   |

# Goal 2: Speed Uptake and Use of Information Inclusion in Evidence-Based Clinical Recommendations



## Inclusion in Evidence-Based Clinical Recommendations



**Glycemic Targets: Standards of Medical Care in Diabetes- 2018**  
American Diabetes Association  
*Diabetes Care*, Jan 2018. 41; S55-S64.



**Bone and Joint Infection Guidelines**  
The European Society for Paediatric Infectious Diseases (ESPID)  
*The Pediatric Infectious Disease Journal*; Aug 2017. 36(8); 788-799.



**Pain Management and the Opioid Epidemic Consensus Study Report**  
*The National Academies Press*; Jul 2017.



**Effectively Communicating with Patients about Opioid Therapy**  
CDC Guideline for Prescribing Opioids for Chronic Pain  
Clinician Outreach and Communication Activity (COCA), Dec 2016.



**Citations of PCORI-Results in UpToDate®**  
Topics include post-discharge treatment of osteomyelitis in children, treatment of localized prostate cancer, and treatment of non-insulin dependent type 2 diabetes



**Citations of PCORI-Results in DynaMed Plus™**  
Citations are on the topic of treatment of localized prostate cancer

# Goal 3: Influence Research

## Examples Now Available on PCORI.org

We have created a page on the PCORI website to share our examples of influence:



Patient-Centered Outcomes Research Institute

[Home](#) [ABOUT US](#) [RESEARCH & RESULTS](#) [ENGAGEMENT](#) [FUNDING OPPORTUNITIES](#) [MEETINGS & EVENTS](#)

### Influencing the Culture of Research

PCORI's approach to [comparative clinical effectiveness research](#) (CER) considers patients' and other healthcare stakeholders' needs and preferences, focusing on outcomes most important to them. This patient-centered, stakeholder-driven [approach](#) not only shapes the [research](#) that PCORI funds, but also influences changes in the culture of healthcare research more broadly. Here are some specific examples.

#### FDA Models Advisory Committee after PCORI Panel

PCORI is credited as part of the inspiration for a Patient Engagement Advisory Committee at the **Food and Drug Administration (FDA) Center for Devices and Radiological Health**. The creation of this FDA committee was informed by PCORI's Patient Engagement Advisory Panel and the PCORI Engagement Rubric, which serves as a framework for stakeholder input on PCORI decision making.



# Goal 3: Influence Research

## Increasing Patient-Centeredness Beyond a PCORI-Funded Project

A PCORI Pipeline to Proposal award (project titled “[Behavior Health Research Capacity Development](#)”) is credited with **leading to outcomes beyond the funded project**

Southern Illinois Healthcare Foundation (SIHF), a patient-centered community health center, and Touchette Regional Hospital, a safety net hospital, led ***Together We Can Make It***, a multi-stakeholder research group aimed to facilitate behavioral health research relevant to patients and clinicians. The project successfully:

- ✓ Built SIHF's research capacity and infrastructure
- ✓ Nurtured authentic bi-directional academic partnerships
- ✓ Collaboratively developed patient-centered CER questions for research proposals
- ✓ Established a space for early career researchers to practice community-based participatory research

**Beyond the original aims of the project**, the research group observed that the **engaged patients with mental health conditions demonstrated unanticipated:**

- |                                                                                  |                                                                       |
|----------------------------------------------------------------------------------|-----------------------------------------------------------------------|
| ✓ Levels of confidence, empowerment, and commitment to patient-centered research | ✓ Improvements to mental health stability and overall quality of life |
|----------------------------------------------------------------------------------|-----------------------------------------------------------------------|

“

**The patients now have a sense of community, purpose, intimacy, and their overall health has generally improved...**100% of the patients that I've referred to the PCORI program have improved. They have a vehicle for more meaning, community connection, intimacy.

*-Dr. Christopher Loynd, Psychiatrist  
Southern Illinois Healthcare Foundation (SIHF)*

# Discussion Questions

- Do our FY-2018 Dashboard and associated background materials cover the topics that are most important for the Board to review?
- Do you agree with the targets we have proposed?
- Do you have concerns about our progress or performance on any of our Dashboard indicators?
- What questions do you have for our Q2-18 in-depth focus on PCORnet?

# PCORI Board of Governors Dashboard

## First Quarter FY-2018 (As of 12/31/2017)

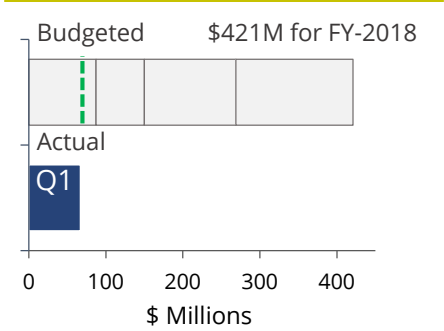
**Dashboard Key**

- Projected
- Q1 Target

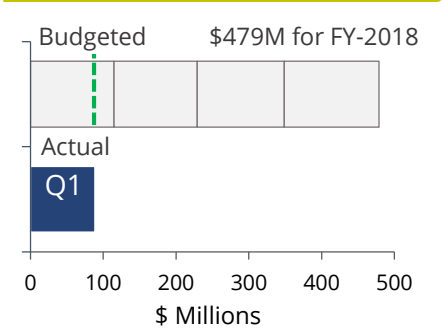
- Meeting Target
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- Needs Board Attention
- No Target

- Q2 2017
- Q3 2017
- Q4 2017
- Q1 2018

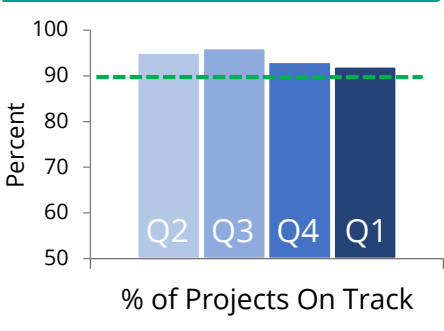
### Funds Committed to Research



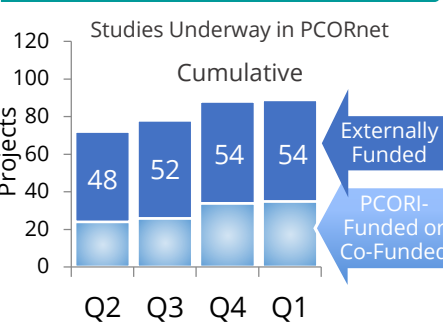
### Expenses



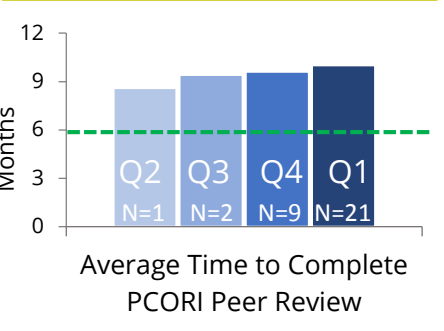
### Project Performance



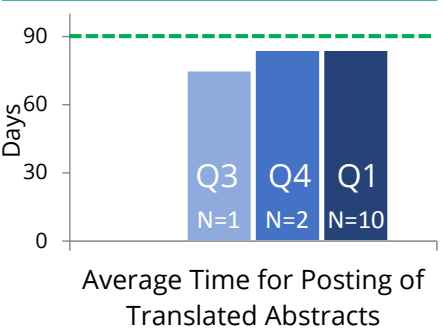
### Research Using PCORnet



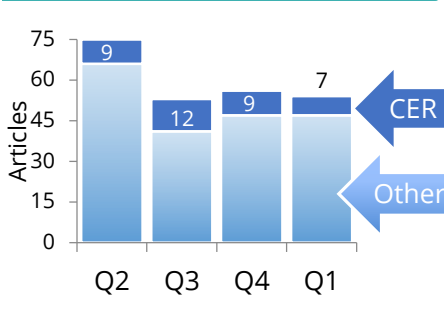
### Speed of PCORI Peer Review



### PCORI Abstracts Posted to Website



### Results Published in Literature



### Altmetric: Attention to PCORI Research



## Featured Results on PCORI's Strategic Goals

### Results on Goal 1

#### Increasing Information

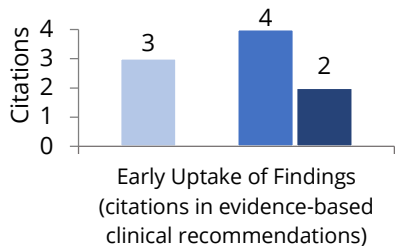
**Results Highlight:** A PCORI-funded study found that for pediatric respiratory infections, narrow-spectrum antibiotics (vs. broad) were associated lower rates of adverse events and higher quality of life for patients.

### Results on Goal 2

#### Speeding Uptake

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**Uptake Highlight:** Results from a PCORI-funded study on self-monitoring of blood glucose were taken up into the ADA's Standards of Medical Care in Diabetes 2018



### Results on Goal 3

#### Influencing Research

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# PCORnet Update

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**Joe Selby, MD, MPH**

Executive Director



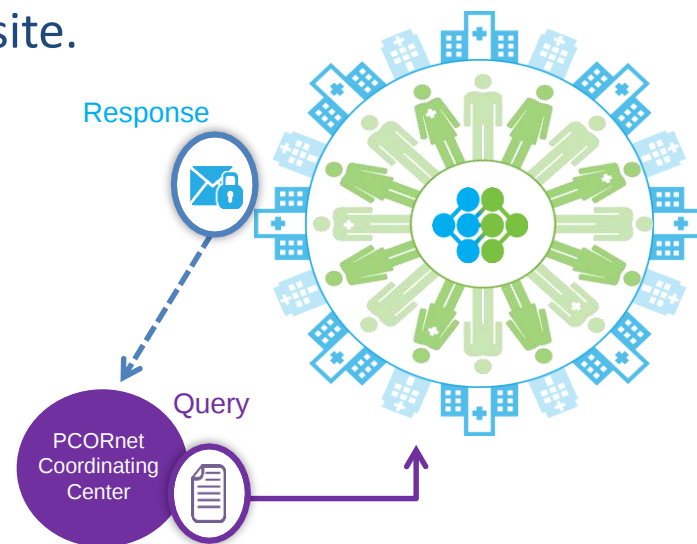
# PCORnet Demographics Query

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# Who is PCORnet? The PCORnet Demographics Query

- PCORnet queries are programmed centrally and securely distributed to Network partners for execution at the partner site. Results are then sent securely back.
  - PCORnet demographics query was distributed in 2016, 2017, and most recently March, 2018
- March 2018 Demographics Query
  - Leveraged the reusable SAS® tool PCORnet Modular Program 2 (PMP2)
  - 11 business days to complete request
    - Requested by PCORI on February 23<sup>rd</sup>. Programmed and distributed to Network on March 1<sup>st</sup>. Responses received back March 9<sup>th</sup>. Report prepared March 9<sup>th</sup>.
- Response received from 75 Clinical Data Research Networks (CDRNs) DataMarts and 2 Health Plan Research Networks (HPRNs) DataMarts



# PCORnet CDRN Demographics (March 2018)

|                                           | Patients with at least one diagnosis record in the period of 01/01/2016 to 12/31/2016 |     |
|-------------------------------------------|---------------------------------------------------------------------------------------|-----|
|                                           | N                                                                                     | %   |
| <b>Total N</b>                            | 51,700,580                                                                            |     |
| <b>By Sex (N, % of patients)</b>          |                                                                                       |     |
| Female                                    | 26,640,930                                                                            | 52% |
| Male                                      | 25,055,544                                                                            | 48% |
| Other*                                    | 4,025                                                                                 | 0%  |
| <b>By Age (N, % of patients)</b>          |                                                                                       |     |
| 0-20                                      | 14,557,945                                                                            | 28% |
| 21-44                                     | 13,584,120                                                                            | 26% |
| 45-64                                     | 13,304,004                                                                            | 26% |
| 65-74                                     | 6,079,062                                                                             | 12% |
| 75+                                       | 4,175,445                                                                             | 8%  |
| <b>By Hispanic (N, % of patients)</b>     |                                                                                       |     |
| Yes                                       | 7,304,324                                                                             | 14% |
| No                                        | 34,510,804                                                                            | 67% |
| Other*                                    | 9,885,449                                                                             | 19% |
| <b>By Race (N, % of patients)</b>         |                                                                                       |     |
| American Indian or Alaska Native          | 395,476                                                                               | 1%  |
| Asian                                     | 1,797,590                                                                             | 3%  |
| Black/African American                    | 7,465,379                                                                             | 14% |
| Native Hawaiian or Other Pacific Islander | 212,397                                                                               | 0%  |
| White                                     | 31,748,430                                                                            | 61% |
| Other*                                    | 10,081,266                                                                            | 19% |
| <b>By Payor</b>                           | <b>Percent (%) distribution reported by the Network</b>                               |     |
| Private                                   | 45%                                                                                   |     |
| Medicaid                                  | 18%                                                                                   |     |
| Medicare                                  | 15%                                                                                   |     |
| Other Public                              | 12%                                                                                   |     |
| Self-pay/None                             | 9%                                                                                    |     |
| No Information                            | 1%                                                                                    |     |



# PCORnet HPRN Demographics (March 2018)

|                                           | Patients with at least one diagnosis record in the period of 01/01/2016 to 12/31/2016 |     |
|-------------------------------------------|---------------------------------------------------------------------------------------|-----|
|                                           | N                                                                                     | %   |
| <b>Total N</b>                            | 23,512,123                                                                            |     |
| <b>By Sex (N, % of patients)</b>          |                                                                                       |     |
| Female                                    | 12,686,471                                                                            | 54% |
| Male                                      | 10,825,620                                                                            | 46% |
| Other*                                    | 32                                                                                    | 0%  |
| <b>By Age (N, % of patients)</b>          |                                                                                       |     |
| 0-20                                      | 5,181,521                                                                             | 22% |
| 21-44                                     | 6,682,534                                                                             | 28% |
| 45-64                                     | 7,146,258                                                                             | 30% |
| 65-74                                     | 2,670,806                                                                             | 11% |
| 75+                                       | 1,831,004                                                                             | 8%  |
| <b>By Hispanic (N, % of patients)</b>     |                                                                                       |     |
| Yes                                       | 56,248                                                                                | 0%  |
| No                                        | 2,775,612                                                                             | 12% |
| Other*                                    | 20,680,263                                                                            | 88% |
| <b>By Race (N, % of patients)</b>         |                                                                                       |     |
| American Indian or Alaska Native          | 7,011                                                                                 | 0%  |
| Asian                                     | 35,920                                                                                | 0%  |
| Black/African American                    | 437,414                                                                               | 2%  |
| Native Hawaiian or Other Pacific Islander | 41,054                                                                                | 0%  |
| White                                     | 2,254,212                                                                             | 10% |
| Other*                                    | 20,736,512                                                                            | 88% |
| <b>By Payor (% of patients)</b>           | <b>Percent (%) distribution reported by the Network</b>                               |     |
| Private                                   | 82%                                                                                   |     |
| Medicaid                                  | 0%                                                                                    |     |
| Medicare                                  | 18%                                                                                   |     |
| Other Public                              | 0%                                                                                    |     |
| Self-pay/None                             | 0%                                                                                    |     |
| No Information                            | 0%                                                                                    |     |



# PCORnet Demonstration Study Updates

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# PCORnet Bariatric Study

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**PI: David Arterburn, MD, MPH**

Kaiser Permanente Washington Health Research Institute



# Comparative Effectiveness of Bariatric Procedures Among Adolescents: PCORnet Bariatric Study

Thomas Inge, R. Yates Coley; Lydia Bazzano, Stavra Xanthakos, Kathleen McTigue, David Arterburn, Neely Williams; Rob Wellman; Karen J. Coleman, Anita P. Courcoulas, Nirav Desai, Jane Anau; Roy Pardee; Sengwee Toh, Cheri D. Janning, Andrea Cook, Jessica Sturtevant, Casie Horgan, Ava Zebrick, and Marc P. Michalsky

## Background

Severe obesity adversely affects the health and well-being of adolescents. Bariatric surgery has been used for treatment of severe obesity in adolescents but most studies have been small and limited in follow up.

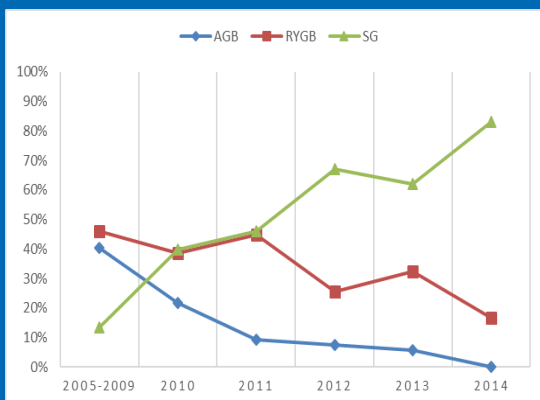
## Methods

Adolescents (age <20 years) who underwent a primary bariatric procedure at 41 contributing health systems participating in 11 Clinical Data Research Networks (CDRN) of National Patient-Centered Clinical Research Network (PCORnet) sites from 2005-2015 were identified. Propensity score regression was used to estimate the percent change in BMI at 1 and 3 years for patients undergoing sleeve gastrectomy (SG), Roux-en-Y gastric bypass (RYGB), and laparoscopic adjustable gastric banding (AGB). 95% confidence intervals and p-values were estimated for procedures with more than 25 patients at each time period; otherwise descriptive estimates were calculated.

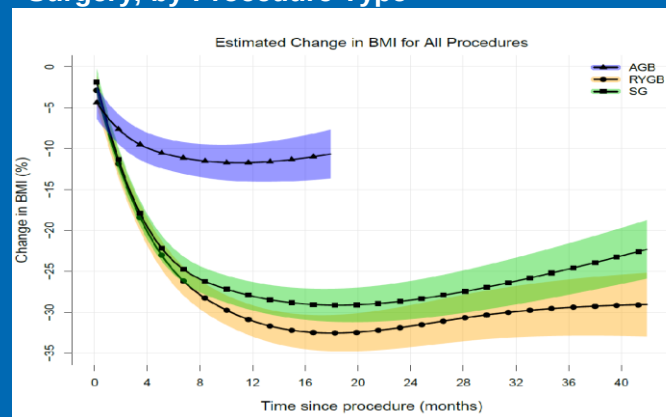
## Cohort Characteristics

- **Age:** Mean (SD), 17.3 (1.6) years; age 12-15, 14%; age 16-17, 29%; age 18-19, 57%
- **Sex:** % Male:Female, 21:79
- **Race/Ethnicity:** 66% White, 25% Black, 17% Hispanic
- **Baseline BMI:** mean (SD) 49.8kg/m<sup>2</sup> (7.8)
- **Baseline BMI Categories:** 35-39, 5%; 40-49, 52%; 50-59, 32%; >60, 11%

## Procedure Prevalence

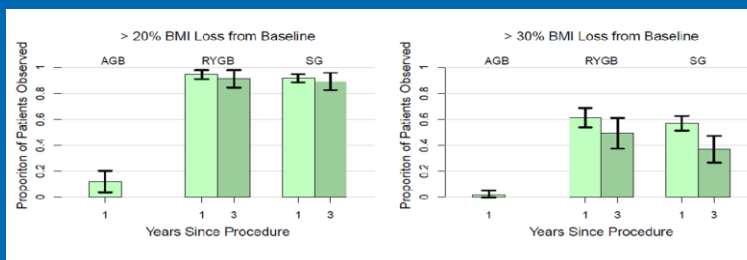


## Percentage Change in Body Mass Index after Bariatric Surgery, by Procedure Type\*



\*This plot shows the estimated change in BMI for the average patient. The confidence intervals for RYGB and SG overlap here even though the difference was significant at 1 year because these curves also take into account uncertainty in the effect of other variables. Sample sizes were insufficient for AGB to model 3 years of follow-up.

## Proportions of Adolescent Patients Undergoing RYGB, SG, and AGB with Weight Loss of >20% and >30% at 1 and 3 years, by Procedure



## Conclusions

The PCORnet Bariatric Study analyzed electronic health record data for the largest sample of adolescents undergoing bariatric surgery to date. Adolescents undergoing SG and RYGB experienced greater declines in BMI at 1- and 3-year follow-up time points, while AGB was significantly less effective for BMI reduction for participants who chose this procedure.

## Acknowledgements

The PCORnet® Study reported in this presentation was conducted using PCORnet®, the National Patient-Centered Clinical Research Network, an initiative funded by the Patient-Centered Outcomes Research Institute (PCORI). The study was funded by PCORI through PCORI Award OBS-1505-30683. The views presented in this [work, publication, article, report, etc.] are solely the responsibility of the author(s) and do not necessarily represent the views of the other organizations participating in or collaborating with PCORnet® or of the Patient-Centered Outcomes Research Institute (PCORI).

# Case Management Programs and their Effectiveness in Managing High-Risk Patients

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**PI: Maureen Smith, PhD, MD, MPH**

University of Wisconsin-Madison



# Rationale

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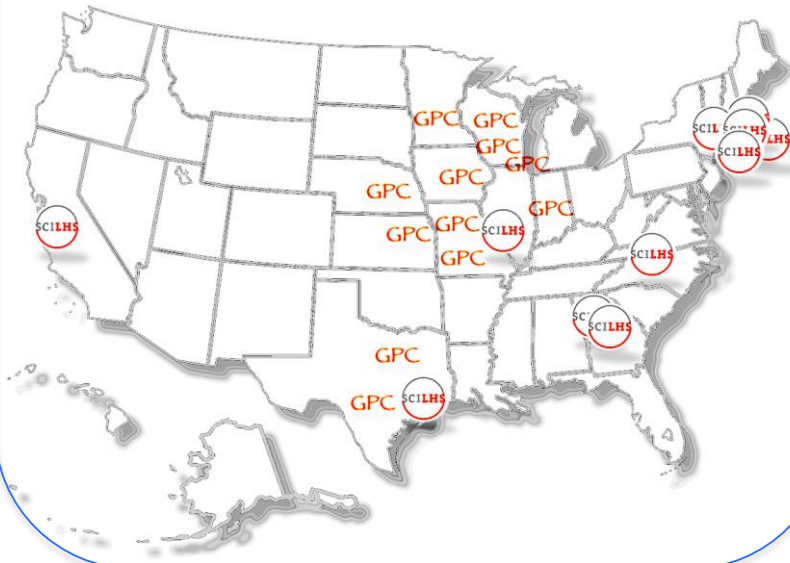
Health system leaders of the PCORnet Clinical Data Research Networks (CDRNs) recognized an urgent need to **improve identification and management** of high healthcare utilization



# Aims

## Aim 1: Characterize Case Management (Survey of 20 health systems)

- **Benchmark:** Compare programs providing case management



## Aim 2: Evaluate Effectiveness of Case Management (CDM + claims + registry data from 3 health systems)

- **Benchmark:** Compare patients enrolled in case management
- **Evaluate:** Evaluate effectiveness of case management programs

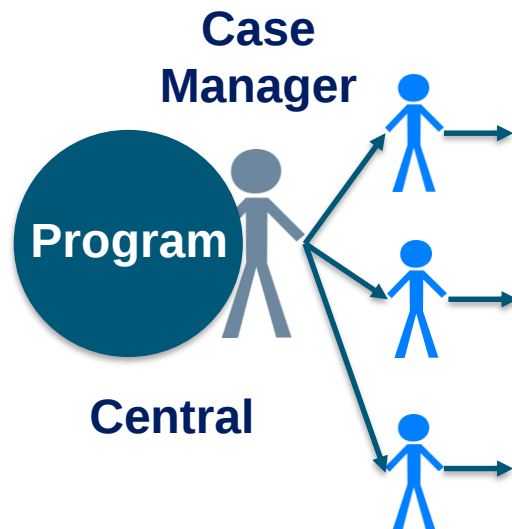


# Aim 1: Benchmark Case Management Programs

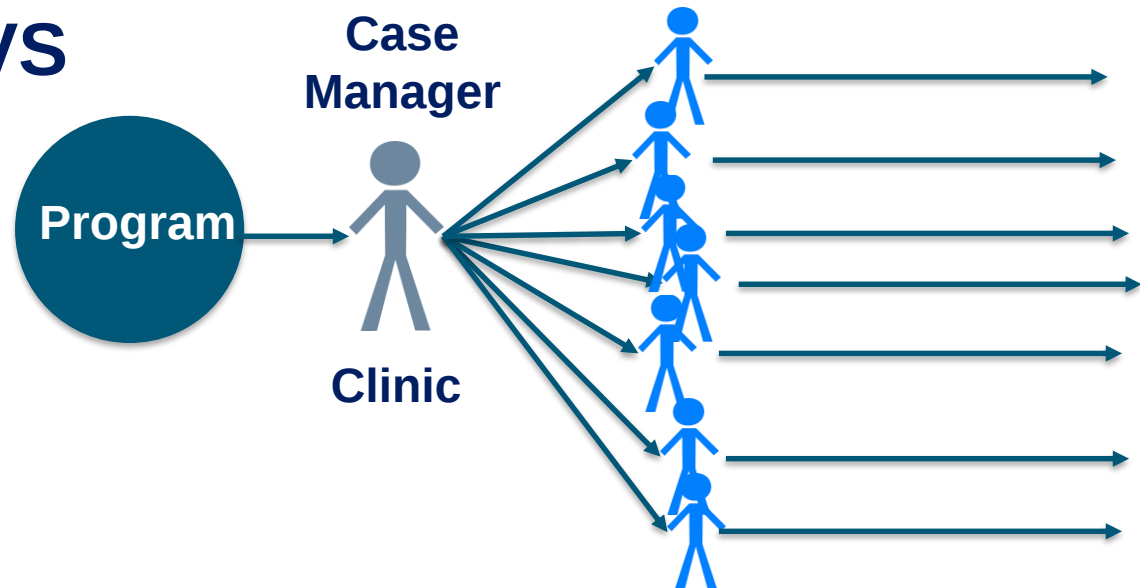
Programs report similar activities/personnel but widely varying staffing/caseloads

- ✓ Low panel size (Min=16)
- ✓ Short duration (<6 mo.)
- ✓ High intensity (weekly)
- ✓ Not onsite

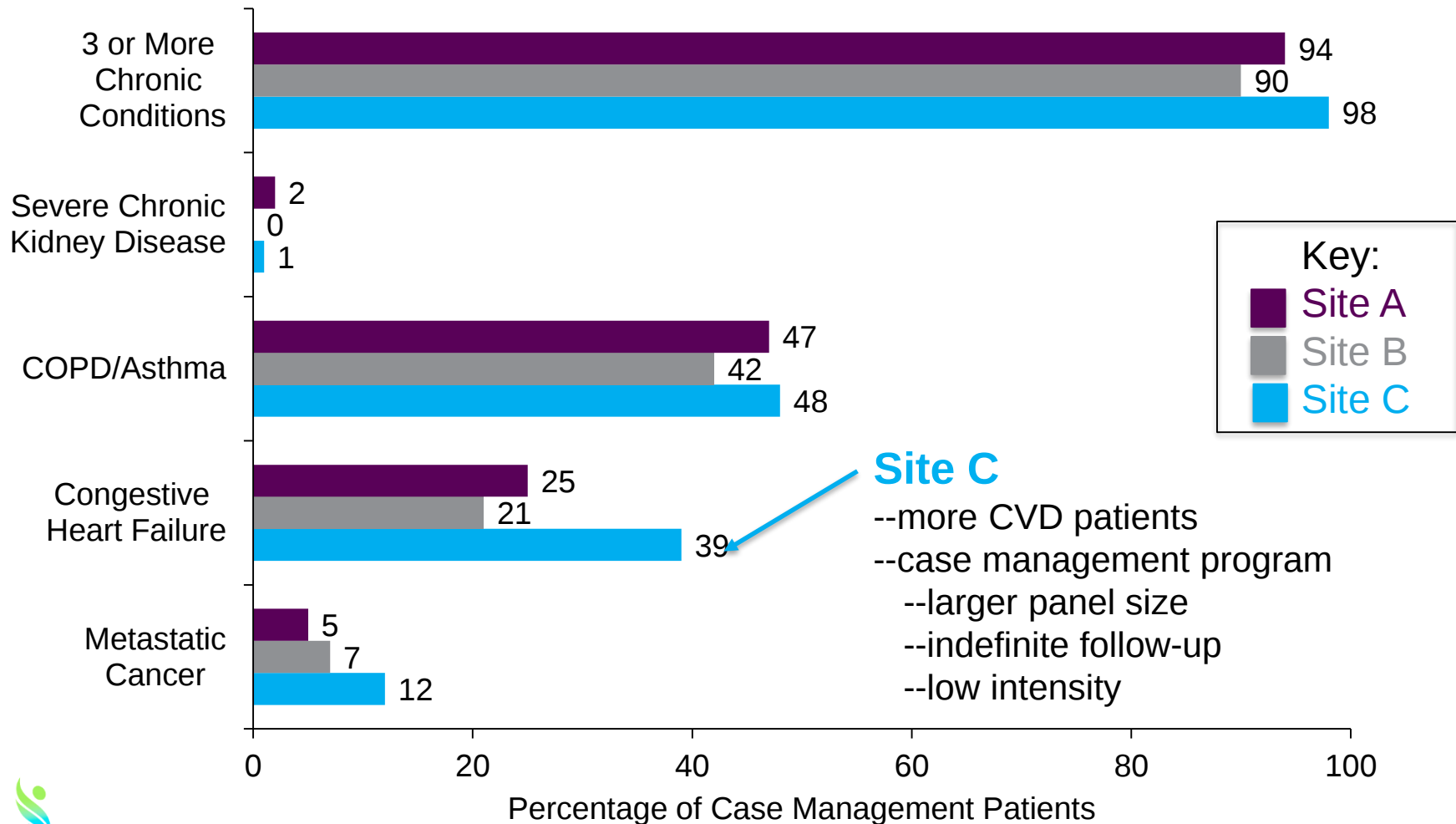
- ✓ Large panel size (Max=2,500)
- ✓ Long duration (>6 mo. to indefinite)
- ✓ Mostly low intensity (annually)
- ✓ Integrated onsite



VS

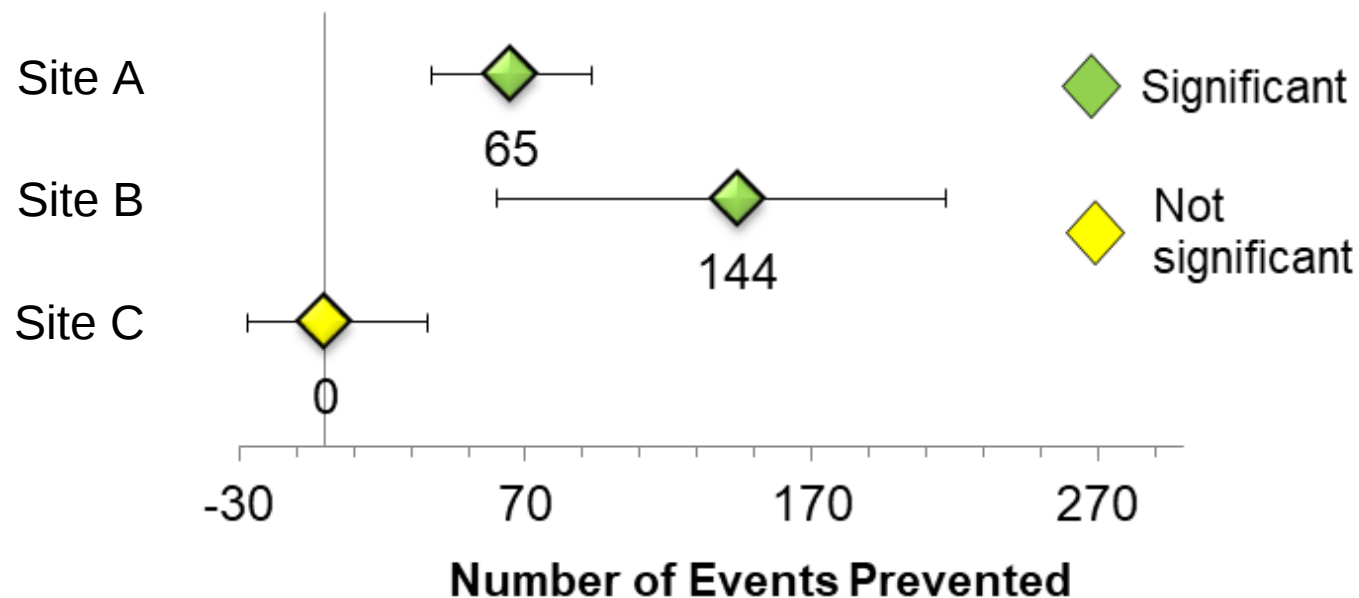


## Aim 2: Benchmark Case Management Patients



## Aim 2: Evaluate Case Management

Case management **associated with fewer emergency department and inpatient events** over 12 months of follow-up\*



\*Estimated number of events prevented for every 100 patients enrolled in case management similar to those in our analyses



# Conclusions

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- Case management programs
  - Program characteristics vary widely across sites
  - Programs varied in association with event rates
    - 2 sites had lower event rates
    - 1 site did not differ in event rates
- Next steps
  - Understand key characteristics of effective programs
  - Improve the match between programs and patients
- Health systems can benefit by leveraging PCORnet data
  - Ability to **benchmark** against other health systems
  - Conduct rapid streamlined **evaluation**



## Select PCORnet Queries

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# Queries in PCORnet

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- 42 query packages have been released to date
- Broadly address:
  - Common conditions (diabetes, respiratory conditions, selected malignancies, myocardial infarction, stroke, rheumatoid arthritis, ulcerative colitis, hypertension, renal disease, influenza and pneumonia)
  - Behavioral health, pain, and mental illness
  - Pediatric conditions
  - Infectious diseases
  - Cancer (breast, colorectal, lung, esophageal, ovarian, pancreatic, prostate, malignant breast cancer and mastectomy)
  - Chronic kidney disease (CKD)
  - Autoimmune disorders
  - Rare diseases



# Query Requests

- Query requests come from:
  - Funders wanting more information to plan a study (industry, federal)
  - Internal and external investigators preparing for a funding opportunity
  - Collaborative Research Groups (CRGs) within PCORnet seeking to better understand a target population of interest
- Visit [PCORnet.org/frontdoor](https://www.pcornet.org/frontdoor) to initiate a request



# What to expect from a query request

## Initial Assessment (~ 3 weeks)



## Query Specifications (3-6 weeks\*\*)



\* Meeting between DRN OC and requestor as needed  
\*\* Dependent on information provided, query complexity, etc.

Turnaround times are based on business days and could potentially be extended based on number of queries currently under review.

DRN OC: Distributed Research Network Operations Center

## Query Distribution, Report (~ 6 weeks)



# Select Query Requests

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- The following queries highlight the diversity of queries in PCORnet
  1. *Statin Prescribing, New Statin Prescription, Statins and Cytochrome p450 Enzyme Inhibitors, Statin Discontinuation*
  2. *Heart Failure with Preserved Ejection Fraction*
  3. *Comorbidities of Individuals with Schizophrenia or Schizoaffective Disorder*
  4. *Multiple Sclerosis*
  5. *Population Characteristics among Individuals with Diagnosis of HIV*



# Statin Exposure, Incidence, Discontinuation

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- Purpose
  - Describe patients who had:
    - Statin prescription
    - Statin prescription in conjunction with diagnosis of CKD, diabetes or hypothyroidism
    - Statin prescription without prior statin prescription
    - Statin and cytochrome p450 enzyme inhibitor prescription with cardiovascular disease (CVD)
    - Statin prescription with no following statin prescription



# Statin Exposure, Incidence, Discontinuation Results

|                        | Statin Prescription |     | No Statin |     | Statin with no prior statin |     | Concurrent p450 enzyme inhibitor |     |
|------------------------|---------------------|-----|-----------|-----|-----------------------------|-----|----------------------------------|-----|
| Total Patients         | 526,327             |     | 1,196,533 |     | 207,866                     |     | 32,036                           |     |
| <b>By Sex</b>          |                     |     |           |     |                             |     |                                  |     |
| Male                   | 205,199             | 39% | 439,233   | 37% | 82,524                      | 40% | 12,181                           | 38% |
| Female                 | 321,104             | 61% | 757,229   | 63% | 125,318                     | 60% | 19,781                           | 62% |
| Other                  | 0                   | 0%  | 0         | 0%  | 0                           | 0%  | 0                                | 0%  |
| <b>By Hispanic</b>     |                     |     |           |     |                             |     |                                  |     |
| Yes                    | 39,003              | 7%  | 75,560    | 6%  | 12,617                      | 6%  | 2,510                            | 8%  |
| No                     | 408,345             | 78% | 939,898   | 79% | 166,910                     | 80% | 24,286                           | 76% |
| Other                  | 78,958              | 15% | 181,022   | 15% | 28,261                      | 14% | 5,060                            | 16% |
| <b>By Race</b>         |                     |     |           |     |                             |     |                                  |     |
| Black/African American | 43,974              | 8%  | 87,262    | 7%  | 16,787                      | 8%  | 2,248                            | 7%  |
| White                  | 406,951             | 77% | 938,791   | 78% | 162,766                     | 80% | 25,339                           | 79% |
| Other                  | 75,344              | 14% | 181,022   | 15% | 28,261                      | 14% | 4,308                            | 13% |
| <b>By Comorbidity</b>  |                     |     |           |     |                             |     |                                  |     |
| Diabetes               | 145,497             | 28% | 134,435   | 11% | 45,947                      | 22% | 9,275                            | 29% |
| Hypothyroidism         | 83,151              | 16% | 131,091   | 11% | 28,468                      | 14% | 6,025                            | 19% |
| CKD                    | 89,023              | 17% | 93,167    | 8%  | 21,374                      | 10% | 6,070                            | 19% |
| Any Comorbidity        | 239,325             | 45% | 296,936   | 25% | 75,678                      | 36% | 15,652                           | 49% |



# Statin Exposure, Incidence, Discontinuation Results

|                           | Statin Prescription |     | Statin prescription with CVD<br>in year after prescription |     | Statin prescription and no<br>future statin prescription |     |
|---------------------------|---------------------|-----|------------------------------------------------------------|-----|----------------------------------------------------------|-----|
| Total Patients            | 526,327             |     | 99,722                                                     |     | 202,890                                                  |     |
| <b>By Sex</b>             |                     |     |                                                            |     |                                                          |     |
| Male                      | 205,199             | 39% | 46,180                                                     | 46% | 80,739                                                   | 40% |
| Female                    | 321,104             | 61% | 53,528                                                     | 54% | 122,128                                                  | 60% |
| Other                     | 0                   | 0%  | 0                                                          | 0%  | 0                                                        | 0%  |
| <b>By Hispanic</b>        |                     |     |                                                            |     |                                                          |     |
| Yes                       | 39,003              | 7%  | 5,876                                                      | 6%  | 11,836                                                   | 6%  |
| No                        | 408,345             | 78% | 77,595                                                     | 78% | 161,335                                                  | 80% |
| Other                     | 78,958              | 15% | 16,145                                                     | 16% | 29,641                                                   | 15% |
| <b>By Race</b>            |                     |     |                                                            |     |                                                          |     |
| Black/African<br>American | 43,974              | 8%  | 7,469                                                      | 7%  | 16,028                                                   | 8%  |
| White                     | 406,951             | 77% | 80,305                                                     | 81% | 159,318                                                  | 79% |
| Other                     | 75,344              | 14% | 11,831                                                     | 12% | 27,481                                                   | 14% |
| <b>By Comorbidity</b>     |                     |     |                                                            |     |                                                          |     |
| Diabetes                  | 145,497             | 28% | 34,768                                                     | 35% | 44,928                                                   | 22% |
| Hypothyroidism            | 83,151              | 16% | 19,262                                                     | 19% | 26,929                                                   | 13% |
| CKD                       | 89,023              | 17% | 26,737                                                     | 27% | 22,566                                                   | 11% |
| Any Comorbidity           | 239,325             | 45% | 56,677                                                     | 57% | 73,808                                                   | 36% |



# Heart Failure with Preserved Ejection Fraction

- Purpose
  - Describes patients with a diagnosis of heart failure with preserved ejection fraction (HFpEF) during 2014-2016.
    - Also examined by presence of diagnosis for:
      - Diabetes
      - Hypertension
      - Myocardial infarction
      - Coronary artery bypass graft (CABG) or primary coronary intervention (PCI)
      - Stroke or transient ischemic attack (TIA)
      - Atrial fibrillation or flutter
    - And examined by presence of hospitalization or medications including:
      - ACE inhibitor
      - Angiotensin receptor blocker
      - Sacubitril-valsartan
      - Beta blocker
      - Loop diuretic
      - Thiazide diuretic
      - Digoxin
      - Insulin
      - SGLT2 inhibitors



# Heart Failure with Preserved Ejection Fraction Results

|                        | HFpEF   |     |
|------------------------|---------|-----|
| Total Patients         | 359,025 |     |
| <b>By Sex</b>          |         |     |
| Male                   | 154,026 | 43% |
| Female                 | 204,936 | 57% |
| Other                  | 0       | 0%  |
| <b>By Age</b>          |         |     |
| 0-24                   | 3,467   | 1%  |
| 25-44                  | 12,367  | 3%  |
| 45-64                  | 88,382  | 25% |
| 65-88                  | 220,314 | 61% |
| 89+                    | 33,965  | 9%  |
| <b>By Hispanic</b>     |         |     |
| Yes                    | 18,105  | 5%  |
| No                     | 277,051 | 77% |
| Other                  | 63,786  | 18% |
| <b>By Race</b>         |         |     |
| Black/African American | 63,159  | 18% |
| White                  | 252,018 | 70% |
| Other                  | 43,727  | 12% |



# Heart Failure with Preserved Ejection Fraction Results

|                                                        | HFpEF   |     |
|--------------------------------------------------------|---------|-----|
| Total Patients                                         | 359,025 |     |
| <b>By Comorbidity (5 years prior to HFpEF)</b>         |         |     |
| Diabetes                                               | 177,779 | 50% |
| Hypertension                                           | 326,963 | 91% |
| Myocardial Infarction                                  | 41,621  | 12% |
| CABG/PCI                                               | 26,004  | 7%  |
| Stroke/TIA                                             | 38,238  | 11% |
| Afib/Flutter                                           | 165,924 | 46% |
| <b>By In-Patient Hospitalization for Heart Failure</b> |         |     |
| 180 days prior to HFpEF                                | 140,241 | 39% |
| 1 year prior to HFpEF                                  | 158,311 | 44% |
| 5 years prior to HFpEF                                 | 195,459 | 54% |
| 1 year after HFpEF                                     | 156,632 | 44% |



# Heart Failure with Preserved Ejection Fraction Results

|                                     | HFpEF   |     |
|-------------------------------------|---------|-----|
| Total Patients                      | 359,025 |     |
| <b>By Concurrent Medication Use</b> |         |     |
| ACE Inhibitors                      | 46,674  | 13% |
| Angiotensin Receptor Blockers       | 31,146  | 9%  |
| Sacubitril-valsartain               | 29      | 0%  |
| Spironolactone                      | 15,043  | 4%  |
| Beta Blockers                       | 111,620 | 31% |
| Loop Diuretics                      | 112,108 | 31% |
| Thiazide Diuretics                  | 12,735  | 4%  |
| Digoxin                             | 11,473  | 3%  |
| Insulin                             | 16,790  | 5%  |
| SGLT2 Inhibitors                    | 13      | 0%  |



# Comorbidities of Individuals with Schizophrenia or Schizoaffective Disorder

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- Purpose
  - Describe the Behavioral Health population of interest in PCORnet
- Description
  - Obtained counts of patients with Schizophrenia or Schizoaffective Disorder, both alone and with comorbidities, in 2016
  - Obtained counts of patients with Major Depressive Disorder, both alone and with comorbidities, in 2016
  - Comorbidities included COPD, dyskinesia, ischemic heart disease, diabetes, and hypertension



# Comorbidities of Individuals with Schizophrenia or Schizoaffective Disorder Results

|                            | Schizophrenia/<br>Schizoaffective<br>Disorder | Major<br>Depressive Disorder |
|----------------------------|-----------------------------------------------|------------------------------|
| Total Patients             | 82,121                                        | 1,023,496                    |
| <b>Comorbid Conditions</b> |                                               |                              |
| Dyskinesia                 | 616 (<1%)                                     | 770 (<1%)                    |
| Hypertension               | 22,280 (27%)                                  | 303,424 (30%)                |
| Diabetes                   | 12,564 (15%)                                  | 141,369 (14%)                |
| Ischemic Heart Disease     | 3,727 (5%)                                    | 72,930 (7%)                  |
| COPD                       | 1,899 (2%)                                    | 20,776 (2%)                  |



# Multiple Sclerosis

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- Purpose
  - Describe the Multiple Sclerosis population in PCORnet for use in support of a grant application
- Description
  - Obtain counts of patients with Multiple Sclerosis in 2015
  - Counts stratified by sex, age, race, and ethnicity



# Multiple Sclerosis Results

|                        | Multiple Sclerosis |     |
|------------------------|--------------------|-----|
| Total Patients         | 88,766             |     |
| <b>By Sex</b>          |                    |     |
| Male                   | 18,400             | 23% |
| Female                 | 62,466             | 77% |
| Other                  | 2                  | 0%  |
| <b>By Age</b>          |                    |     |
| 1-29                   | 4186               | 5%  |
| 30-39                  | 12,531             | 15% |
| 40-49                  | 18,970             | 23% |
| 50-59                  | 22,432             | 28% |
| 60-69                  | 16,889             | 21% |
| 70-89                  | 5,860              | 7%  |
| <b>By Hispanic</b>     |                    |     |
| Yes                    | 2,160              | 3%  |
| No                     | 62,036             | 77% |
| Other                  | 16,672             | 21% |
| <b>By Race</b>         |                    |     |
| Black/African American | 9,502              | 12% |
| White                  | 65,277             | 81% |
| Other                  | 6,089              | 8%  |



# Population Characteristics among Individuals with Diagnosis of HIV

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- Purpose
  - Describe the Health Disparities population of interest in PCORnet
- Description
  - Obtained counts of patients with HIV, both alone and with comorbidities, in 2013-2016
  - Comorbidities included anxiety, substance abuse, hepatitis C, mood disorder, and type 2 diabetes



# Population Characteristics among Individuals with Diagnosis of HIV Results

|                            | HIV           |
|----------------------------|---------------|
| Total Patients             | 195,982       |
| <b>Comorbid Conditions</b> |               |
| Anxiety                    | 186,984 (95%) |
| Substance Use              | 44,862 (23%)  |
| Hepatitis C                | 21,407 (11%)  |
| Mood Disorders             | 48,533 (25%)  |
| Diabetes                   | 28,947 (15%)  |



# Wrap Up and Adjournment

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**Kerry Barnett, JD**

Vice Chairperson, Board of Governors

