Board of Governors Meeting

In-Person and via Teleconference/Webinar

May 13, 2019
9:00 AM – 1:00 PM ET
Welcome and Introductions

Grayson Norquist, MD, MSPH
Chairperson, Board of Governors

Joe Selby, MD, MPH
Executive Director
<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00 AM</td>
<td>Call to Order and Welcome</td>
</tr>
<tr>
<td>9:00 – 9:10</td>
<td>Consider for Approval: Consent Agenda</td>
</tr>
<tr>
<td>9:10 – 10:00</td>
<td>Executive Director’s Report &amp; Q2 Dashboard Review</td>
</tr>
<tr>
<td>10:00 – 10:15</td>
<td>Research Portfolio Exploration Series: Portfolio Overview</td>
</tr>
<tr>
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<td>Research Portfolio Exploration Series: Focus on Telehealth Portfolio</td>
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<td>Consider for Approval: Funds to Support Implementation of the PCORnet Common Data Linkage Method</td>
</tr>
<tr>
<td>11:45 – 12:30</td>
<td>Dissemination and Implementation Update: Overview and Project Focus</td>
</tr>
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<td>12:30 – 1:00</td>
<td>Public Comment Period</td>
</tr>
<tr>
<td>1:00 PM</td>
<td>Wrap up and Adjournment</td>
</tr>
</tbody>
</table>
Consent Agenda Items

Grayson Norquist, MD, MPH
Chairperson, Board of Governors
Motion for Consent Agenda Items

That the Board approve:

• Minutes from the April 16, 2019 PCORI Board of Governors Meeting
• Amended Governance Committee Charter with provisions addressing:
  • The process by which a Vice-Chair is named, and
  • Voting by written consent on audit matters to be consistent with DC nonprofit law
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
Executive Director’s Report

Joe Selby, MD, MPH
Executive Director
Upcoming Discussions for Future Board Meetings

• During the Board Planning Session in March, the Board began thinking about the year ahead with reauthorization on the horizon.

• The Board identified several topics for discussion at upcoming board meetings over the course of the year to start planning for “PCORI 2.0” including:
  
  • Revitalizing, enhancing and making our stakeholder-driven topic generation process more transparent.
  
  • Exploring our research portfolios as one way to generate the next round of targeted research topics. *This exploration series kicks off today with a look at the telehealth portfolio.*
  
  • Enhancing our focus and activities to promote worthy research findings with dissemination and implementation activities. *This discussion begins today.*
PCORI’s Topic Pipeline for Focused Research:
Process for Topic Capture, Generation, and Prioritization

Landscape of Key Priority Topics

Topics proactively identified via landscape review, with the purpose of identifying new areas of targeted research in high burden areas.

Analysis of Current Portfolio for Remaining Gaps

Topics proactively identified from portfolio findings for possible infill opportunities.

Ongoing Input from Stakeholders, Applicants

Topics proactively identified through:
- Focused outreach to stakeholders
- Collaboration with other funders

Triage & Initial Prioritization

Topic Development

Topic Refinement

Commit Funding to Focused Research

- Topic Briefs
- Evidence Maps
- Systematic Reviews
A new, regular series in the coming year is an exploration of various portfolios of PCORI-funded projects. With the series we’ll be taking stock, delving into the current set of funded projects in PCORI’s portfolio and beginning to think about how we can continue to shape it for research that matters most to patients and stakeholders.
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Dashboard Review: Second Quarter of FY-2019

Joe Selby, MD, MPH
Executive Director
PCORI Board of Governors Dashboard
Second Quarter FY-2019 (As of 3/31/2019)

Citations in UpToDate®

- Budgeted: $232M for FY-2019
- Actual: Q1 Q2

Operational Expenses

- Budgeted: $82M for FY-2019
- Actual: Q1 Q2

Research Project Performance

- % of Research Projects On Track
- Q2 2018 Meeting Target
- Q4 2018 Not Meeting Target
- Q1 2019 Needs Board Attention
- Q2 2019 Target in Development

Dashboard Key

- Median Time to Complete Peer Review (Grey = 75th Percentile)
- Controlling for Date and Journal of Publication
- Controlling for Increasing Results Over Time

Results Published in Literature

- CER Results and Other Results Published in the Literature

Altmetric: Attention to PCORI Results

- % of CER Results Publications in Top 10% of Attention

Speed of PCORI Peer Review

- Median Time to Complete Peer Review (Grey = 75th Percentile)

Results Viewed on PCORI.org

- Average Pageviews of Results Posted to PCORI.org

Front Door Requests in PCORnet

- Requests Submitted to PCORnet

Inputs

Process

Outputs

Uptake

Use

Impact

Citations in Systematic Reviews, Guidelines, & Policy Documents

- Q3 Q4 Q1 Q2

New Studies Underway in PCORnet

- Projects

Front Door Requests Submitted to PCORnet

- Requests

Other Examples of Uptake

- CER Results and Other Results Published in the Literature
- Projected for 2019
- Target in Development

PCORI Board of Governors Dashboard
Second Quarter FY-2019 (As of 3/31/2019)
Goal 1: Increase Information for Health Decision-Making
For Women with Urinary Incontinence, Behavioral Therapies are More Effective than Drugs Alone

Summary: Urinary incontinence (UI) can affect a woman’s physical, psychological, and social well-being and can impose substantial lifestyle restrictions. Nonpharmacologic approaches to managing UI mostly aim to strengthen the pelvic floor, or change behaviors that influence bladder function. Pharmacologic treatments typically address bladder and urethral function.

PCORI and AHRQ partnered to commission a systematic review update for comparing the effectiveness and harms of pharmacologic and nonpharmacologic interventions to improve or cure stress, urgency, or mixed UI in nonpregnant women.

Reviewers included 84 randomized trials that evaluated 14 categories of interventions. Nonpharmacologic and pharmacologic interventions were more likely than no treatment to improve UI outcomes. Behavioral therapy, alone or in combination with other interventions, is generally more effective than pharmacologic therapies alone in treating both stress and urgency UI.

A reasonable approach is to start with behavioral modifications. If that’s unsuccessful, then move on to medications or procedures. But this is a quality-of-life issue, not a life-threatening problem... go through all the options and let the patient decide.

-Dr. Peter C. Jeppson, MD
Senior Researcher, Urogynecologist
University of New Mexico

Quote from: Nicholas Bakalar, “For Urinary Incontinence, Try Behavioral Treatments or Drugs, or Both,” The New York Times. Mar 22, 2019. (link)
Goal 1: Increase Information for Health Decision-Making
Among Nonsurgical Treatments for UI, Behavioral Therapies Have Lowest Associated Risks

Summary: For women with Urinary Incontinence (UI), there are numerous nonsurgical treatments available, and each are associated with risk of adverse events (AEs). This companion article reports on the harms associated with treatment options.

Nonpharmacologic Therapies: 52 studies reported on AEs in studies of nonpharmacological interventions. Behavioral therapies and neuromodulation have low risk of AEs.

Pharmacologic Therapies: 102 studies reported on AEs in studies of pharmacological interventions. Anticholinergics and alpha agonists have high rates of dry mouth and constitutional effects such as fatigue and gastrointestinal complaints. BTX (botulinum toxin injection) is associated with urinary tract infections and voiding dysfunction. Periurethral bulking agents are associated with erosion and voiding dysfunction. These AE risks should be considered when selecting appropriate UI treatment options.

The choice of which treatment option is best for a particular woman with UI will vary depending on her symptoms, the severity of those symptoms, her history of prior treatments, treatment goals, preferences, and values regarding the types of treatments she is willing to undergo, and also the AE risks she is willing to assume.

PCORI Study

| Study Title: Nonsurgical Treatments for Urinary Incontinence in Women: A Systematic Review Update
| Organization: Memorandum of Understanding with Agency for Healthcare Research and Quality (AHRQ); Study conducted by Evidence-based Practice Center at Brown University

Results Publication


Altmetric Score:
Too early to assess (published 5/7/19)
Results from a PCORI-funded study on antibiotic therapies for serious bacterial infections in children were taken up into the 2018 Infectious Diseases Society of America (IDSA) Clinical Practice Guideline for the Management of Outpatient Parenteral Antimicrobial Therapy (OPAT).

The study found that oral antibiotics are as effective as intravenous antibiotics, with fewer complications. Three CER results publications from the study were cited in the guideline update:

“...There is mounting evidence that oral therapy can be substituted for OPAT without compromising cure rates. Safety is enhanced by avoiding OPAT-related complications for certain clinical conditions where OPAT has traditionally been the preferred treatment mode. The evidence supporting this practice includes studies comparing oral vs parenteral therapy for osteomyelitis, perforated appendicitis, and complicated pneumonia. As a result, ensuring that OPAT is only prescribed for patients where an equivalent oral therapy is not available is a high priority for pediatric ID specialists and pediatric antimicrobial stewardship programs.”

Full Citation: 2018 Infectious Diseases Society of America Clinical Practice Guideline for the Management of Outpatient Parenteral Antimicrobial Therapy. *Clinical Infectious Diseases*, Volume 68, Issue 1, 1 January 2019, Pages e1–e35, [https://doi.org/10.1093/cid/ciy745](https://doi.org/10.1093/cid/ciy745)

Study Title: Comparative Effectiveness of Intravenous vs. Oral Antibiotic Therapy for Serious Bacterial Infections

Principal Investigator: Ron Keren, MD, MPH, The Children's Hospital of Philadelphia
Goal 3: Influence the Way Research is Done
Publications on How Research is Done at PCORI

- Performed **self-assessment of practice and policies against Lancet recommendations** to benchmark our current practice and identify areas for improvement


- Review of trial transparency policy among US noncommercial funders
  - 6 of 9 (67%) **of top US funders, including PCORI, have a publicly available written policy addressing clinical trial registration, summary results sharing, and individual patient data sharing**
  - Fewer US funders require specific actions (11%-56%) or monitor compliance (56%-67%)

Q2 Focus on PCORI Peer Review

Q1 Dashboard Changes

Q2 PCORI Peer Review & PCORnet

Q3 Recruitment, Modifications, Progress of Projects

Q4 End of Year Summary
Peer Review’s Stages of Review and Revision

Multiple checks ensure that the final report is clear, complete, and scientifically sound

**Pre-Peer Review**
- Pre-Review editor reviews for clarity & DFRR structure
- Program Officer reviews for completeness
- The PI may need to revise before peer review can start

**External Peer Review**
- External peer reviewers provide comments
- Associate editor sends a synthesis letter of peer review comments.
- PI responds to comments within 2 months
- Associate editor may request additional changes until they determine that the DFRR has met Peer Review expectations

**PCORI’s Final Review**
- PCORI Director of Peer Review and Scientific Publications provides final review for clarity
- This step may repeat until the Director of Peer Review approves the report on behalf of PCORI
Studies in PCORI Peer Review Process or Completed PCORI Peer Review
N=285, as of Q2-19

15
In Process:
Research Period Complete; Drafting DFRR or undergoing Pre-Review Edits

9
In Process:
Undergoing PCORI Peer Review

48
In Process;
Final edits underway

31
PCORI Peer Review Complete;
Summaries being developed

182
Results Posted;
PCORI Peer-Reviewed results posted to PCORI.org

*Does not include Pilots, Systematic Reviews, Infrastructure, or D&I awards (50 Pilots and 4 Systematic Reviews are complete, with results posted to PCORI.org)
**Speed of PCORI Peer Review**

**Q2-19 Update**

- **Target:** 6 months from acceptance of the Draft Final Research Report (DFRR) to acceptance of Final Research Report (FRR).

- **Time for PCORI Peer Review to-date:**
  - 213 completed as of Q2-19
    - Median time in Peer Review: 8.3 months (average 9.0 m)
    - Fastest to-date: 3.4 months; Slowest to-date: 19.8 months

**Time to Complete Peer Review**

N= 213 Studies

- Target: <6 mo.
The pre-peer review phase was initiated because many DFRRs were coming in not following DFRR instructions, or poorly developed. This has changed with increased focus on the instructions and reminders from program staff. More reports are coming in ready for peer review – no need for revisions before going external reviewers (dark blue).
In 2 years, we have cut the median amount of time reports spend in peer review by half: 7 months from start to finish.
PCORI’s authorizing law requires that we make research findings available no longer than 90 days after PCORI Peer Review is complete.

This includes the time it takes to translate findings into lay and scientific text.

All abstracts to-date have been posted within 90 days of completion of PCORI Peer Review.

Time for Posting of Abstracts:
- 182 completed as of Q2-19
  - Median time to post: 86 days (average 84 days)

Target: 100% within <90 days
Comprehensive Final Research Reports Are Being Posted to the Website

The Final Research Report (FRR) is a comprehensive, full final report of the funded study, usually equivalent to the length and content of 3-5 journal articles.

- Up to 152 final reports may be posted by the end of FY-2019
- Average time from acceptance to posting: about 10 months
- The new FRR search function & presentation makes the reports easier to find

Number of Final, Accepted Reports (FRRs) Posted to the Website, by Quarter

- Q2-18: 8
- Q3-18: 4
- Q4-18: 9
- Q1-19: 16
- Q2-19: 13

Coming soon: Measures of attention to FRRs

Examining Health Outcomes for People Who Are Transgender

The objective of this study was to examine (1) the incidence of acute cardiovascular events and cancers and the prevalence of mental health conditions among transgender and gender nonconforming people, and (2) perceived benefits of gender-affirming therapies such as hormones or surgery among transgender people.

Project page: [Examining Health Outcomes for People Who Are Transgender](https://example.com)
Principal Investigator: Michael Goodman, MD, MPH
Organization: Emory University
Original project title: Comparative Risks and Benefits of Gender Reassignment Therapies
HSR&D ID: HSRP20143115


View the Final Research Report
Promoting Our Model of Peer Review in JAMA and Accompanying Blog Post

PCORI-Funded Trials Publish Their Results as Quickly or Faster Than Studies Typically Do

% CER Results Published in Peer-Reviewed Journal Relative to PCD

Benchmark Max: 60% at 60 mo.

Benchmarks Based on:

Version: 4/23/19
Cohort: PCORI’s first 4 cycles (135 trials)
PCORI’s Process Results in Complete and Earlier Availability of Results in the Public Domain

% CER Results Publicly Available (Publication or Posted Abstract) Relative to PCD

Field Benchmark

Public Availability of PCORI Results

Benchmark
Max: 60% at 60 mo.

Public Availability of PCORI Results 100% at 30 mo.

Benchmarks Based on:
• C Riveros, A Dechartres, et al. Timing and Completeness of Trial Results Posted at ClinicalTrials.gov and Published in Journals. Plos One, Dec 2013.

Version: 4/23/19
Cohort: PCORI’s first 4 cycles (135 trials)
Q2 Focus on PCORnet

1) Data improvements
2) New projects and prospects
PCORnet 2.0
What Data are Available from CRNs (Most recent assessment)

- In 2019, PCORnet 2.0 Clinical Research Networks (CRNs) accessed 30.8 million patient records who had at least one diagnosis record.

- Response received from all 9 PCORnet 2.0 Clinical Research Networks (43 sites)

<table>
<thead>
<tr>
<th>Patients with at least one diagnosis record in the period 7/1/2017 - 6/30/2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Unique Patients</td>
</tr>
<tr>
<td>By Age (N, % of patients)</td>
</tr>
<tr>
<td>0-20</td>
</tr>
<tr>
<td>21-44</td>
</tr>
<tr>
<td>45-64</td>
</tr>
<tr>
<td>65-74</td>
</tr>
<tr>
<td>75+</td>
</tr>
<tr>
<td>By Sex (N, % of patients)</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>By Race (N, % of patients)</td>
</tr>
<tr>
<td>Black or African American</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>By Hispanic (N, % of patients)</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>
In 2019, PCORnet’s two **Health Plan Research Networks (HPRNs)** accessed data on 24.6 million patients with a least one diagnosis record.

<table>
<thead>
<tr>
<th>Number of Unique Patients</th>
<th>24,574,856</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>By Age (N, % of patients)</strong></td>
<td></td>
</tr>
<tr>
<td>0-20</td>
<td>5,316,011</td>
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<tr>
<td>21-44</td>
<td>6,960,375</td>
</tr>
<tr>
<td>45-64</td>
<td>7,547,717</td>
</tr>
<tr>
<td>65-74</td>
<td>3,099,768</td>
</tr>
<tr>
<td>75+</td>
<td>2,216,196</td>
</tr>
<tr>
<td><strong>By Sex (N, % of patients)</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>11,262,575</td>
</tr>
<tr>
<td>Female</td>
<td>13,312,277</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
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<tr>
<td><strong>By Race (N, % of patients)</strong></td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td>524,904</td>
</tr>
<tr>
<td>White</td>
<td>2,634,055</td>
</tr>
<tr>
<td>Other</td>
<td>21,415,897</td>
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<tr>
<td><strong>By Hispanic (N, % of patients)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>67,523</td>
</tr>
<tr>
<td>No</td>
<td>3,262,523</td>
</tr>
<tr>
<td>Other</td>
<td>21,244,810</td>
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## PCORnet 2.0
### Data Available on Selected Conditions (CRNs)

<table>
<thead>
<tr>
<th></th>
<th>Anxiety</th>
<th>Alzheimer's</th>
<th>Breast Cancer</th>
<th>Asthma</th>
<th>Heart Failure</th>
<th>Heart Failure and Diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Number of Unique Patients</td>
<td>2,625,750</td>
<td>99,409</td>
<td>1,736,474</td>
<td>290,267</td>
<td>689,730</td>
<td>295,007</td>
</tr>
<tr>
<td>By Age (N, % of patients)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-20</td>
<td>473,676</td>
<td>18%</td>
<td>327</td>
<td>0%</td>
<td>749,134</td>
<td>43%</td>
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<tr>
<td>21-44</td>
<td>881,623</td>
<td>33%</td>
<td>278</td>
<td>0%</td>
<td>397,115</td>
<td>23%</td>
</tr>
<tr>
<td>45-64</td>
<td>798,635</td>
<td>30%</td>
<td>5,524</td>
<td>6%</td>
<td>370,224</td>
<td>21%</td>
</tr>
<tr>
<td>65-74</td>
<td>287,998</td>
<td>11%</td>
<td>16,479</td>
<td>17%</td>
<td>142,416</td>
<td>8%</td>
</tr>
<tr>
<td>75+</td>
<td>205,417</td>
<td>8%</td>
<td>77,542</td>
<td>78%</td>
<td>87,500</td>
<td>5%</td>
</tr>
<tr>
<td>By Sex (N, % of patients)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>885,267</td>
<td>34%</td>
<td>33,647</td>
<td>34%</td>
<td>718,827</td>
<td>41%</td>
</tr>
<tr>
<td>Female</td>
<td>1,740,325</td>
<td>66%</td>
<td>65,751</td>
<td>66%</td>
<td>1,017,583</td>
<td>59%</td>
</tr>
<tr>
<td>Other</td>
<td>95</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>22</td>
<td>0%</td>
</tr>
<tr>
<td>By Race (N, % of patients)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td>308,945</td>
<td>12%</td>
<td>12,225</td>
<td>12%</td>
<td>442,770</td>
<td>26%</td>
</tr>
<tr>
<td>White</td>
<td>1,949,909</td>
<td>74%</td>
<td>70,475</td>
<td>71%</td>
<td>940,478</td>
<td>54%</td>
</tr>
<tr>
<td>Other</td>
<td>366,896</td>
<td>14%</td>
<td>16,668</td>
<td>17%</td>
<td>353,226</td>
<td>20%</td>
</tr>
<tr>
<td>By Hispanic (N, % of patients)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>276,898</td>
<td>11%</td>
<td>10,835</td>
<td>11%</td>
<td>291,435</td>
<td>17%</td>
</tr>
<tr>
<td>No</td>
<td>2,116,159</td>
<td>81%</td>
<td>79,311</td>
<td>80%</td>
<td>1,291,711</td>
<td>74%</td>
</tr>
<tr>
<td>Other</td>
<td>232,680</td>
<td>9%</td>
<td>9,200</td>
<td>9%</td>
<td>153,303</td>
<td>9%</td>
</tr>
</tbody>
</table>

Data Source: PCORnet 2.0
## PCORnet 2.0
Data Available on Selected Conditions (HPRNs)

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</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>N (%)</td>
<td>N</td>
<td>N %</td>
<td>N</td>
<td>N %</td>
<td>N</td>
</tr>
<tr>
<td>3,535,088</td>
<td>133,638</td>
<td>1,499,805</td>
<td>264,107</td>
<td>751,358</td>
<td>360,987</td>
<td></td>
</tr>
</tbody>
</table>

### By Age (N, % of patients)

<table>
<thead>
<tr>
<th>Age Range</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-20</td>
<td>419,312</td>
<td>12%</td>
<td>18</td>
<td>0%</td>
<td>345,787</td>
<td>23%</td>
<td>66</td>
<td>0%</td>
</tr>
<tr>
<td>21-44</td>
<td>1,164,821</td>
<td>33%</td>
<td>171</td>
<td>0%</td>
<td>353,813</td>
<td>24%</td>
<td>14,173</td>
<td>5%</td>
</tr>
<tr>
<td>45-64</td>
<td>1,193,722</td>
<td>34%</td>
<td>4,361</td>
<td>3%</td>
<td>466,443</td>
<td>31%</td>
<td>112,224</td>
<td>43%</td>
</tr>
<tr>
<td>65-74</td>
<td>457,502</td>
<td>13%</td>
<td>20,543</td>
<td>15%</td>
<td>209,742</td>
<td>14%</td>
<td>78,331</td>
<td>30%</td>
</tr>
<tr>
<td>75+</td>
<td>341,864</td>
<td>10%</td>
<td>109,860</td>
<td>82%</td>
<td>137,285</td>
<td>9%</td>
<td>65,238</td>
<td>25%</td>
</tr>
</tbody>
</table>

### By Sex (N, % of patients)

<table>
<thead>
<tr>
<th>Sex</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>1,198,272</td>
<td>34%</td>
<td>47,813</td>
<td>36%</td>
<td>585,924</td>
<td>39%</td>
<td>2,237</td>
<td>1%</td>
</tr>
<tr>
<td>Female</td>
<td>2,336,815</td>
<td>66%</td>
<td>85,825</td>
<td>64%</td>
<td>913,881</td>
<td>61%</td>
<td>261,870</td>
<td>99%</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

### By Race (N, % of patients)

<table>
<thead>
<tr>
<th>Race</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black or African American</td>
<td>72,277</td>
<td>2%</td>
<td>11,337</td>
<td>9%</td>
<td>48,411</td>
<td>3%</td>
<td>13,264</td>
<td>5%</td>
</tr>
<tr>
<td>White</td>
<td>561,104</td>
<td>16%</td>
<td>59,901</td>
<td>45%</td>
<td>184,030</td>
<td>12%</td>
<td>58,773</td>
<td>22%</td>
</tr>
<tr>
<td>Other</td>
<td>2,901,707</td>
<td>82%</td>
<td>62,400</td>
<td>47%</td>
<td>1,267,364</td>
<td>85%</td>
<td>192,070</td>
<td>73%</td>
</tr>
</tbody>
</table>

### By Hispanic (N, % of patients)

<table>
<thead>
<tr>
<th>Hispanic</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>12,741</td>
<td>0%</td>
<td>1,786</td>
<td>1%</td>
<td>5,511</td>
<td>0%</td>
<td>1,030</td>
<td>0%</td>
</tr>
<tr>
<td>No</td>
<td>644,717</td>
<td>18%</td>
<td>72,867</td>
<td>55%</td>
<td>239,799</td>
<td>16%</td>
<td>74,000</td>
<td>28%</td>
</tr>
<tr>
<td>Other</td>
<td>2,877,630</td>
<td>81%</td>
<td>58,985</td>
<td>44%</td>
<td>1,254,495</td>
<td>84%</td>
<td>189,077</td>
<td>72%</td>
</tr>
</tbody>
</table>

### By Hispanic (N, % of patients)

<table>
<thead>
<tr>
<th>Hispanic</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>12,741</td>
<td>0%</td>
<td>1,786</td>
<td>1%</td>
<td>5,511</td>
<td>0%</td>
<td>1,030</td>
<td>0%</td>
</tr>
<tr>
<td>No</td>
<td>644,717</td>
<td>18%</td>
<td>72,867</td>
<td>55%</td>
<td>239,799</td>
<td>16%</td>
<td>74,000</td>
<td>28%</td>
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<tr>
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<td>1,254,495</td>
<td>84%</td>
<td>189,077</td>
<td>72%</td>
</tr>
</tbody>
</table>
PCORnet 2.0
Density of Lab Data

Median Number of Distinct Lab Tests

<table>
<thead>
<tr>
<th>DataMart Refresh (eligible DataMarts)</th>
<th>Lab Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov 2016 (n=45)</td>
<td>9</td>
</tr>
<tr>
<td>Jul 2017 (n=42)</td>
<td>140</td>
</tr>
<tr>
<td>Jan 2018 (n=45)</td>
<td>146</td>
</tr>
<tr>
<td>Jul 2018 (n=46)</td>
<td>185</td>
</tr>
<tr>
<td>Jan 2019 (n=47)</td>
<td>202</td>
</tr>
</tbody>
</table>

Eligible DataMarts: PCORnet 2.0 DataMarts which populate the LAB_RESULT_CM table
PCORnet 2.0
Completeness of Selected Lab Tests

Percentage of DataMarts Capturing Specific Lab Tests

- Serum Creatinine
- Hemoglobin A1c
- eGFR
- Serum White Blood Cells

Eligible DataMarts: PCORnet 2.0 DataMarts which populate the LAB_RESULT_CM table.
Use Case: A study to evaluate whether an approved biosimilar is interchangeable with its reference product.

DataMarts must capture the specific drug names that can distinguish a biosimilar from its reference product. Here we show the % of dataMarts that capture specific product names for at least 80% of prescriptions.
PCORnet 2.0
Availability of Recent Data

Average Encounter Data Latency
(goal ≤ 4 months)

Latency in months

DataMart refresh (eligible DataMarts)

Eligible DataMarts: PCORnet 2.0 DataMarts which include inpatient, ambulatory, and/or Emergency Department encounters and do not use date obfuscation.
Many of the research studies using PCORnet are externally funded or co-funded. For Q2-19, **there are 6 new externally-funded studies in PCORnet**.
The Front Door is the access point for potential investigators, patient groups, health systems, and sponsors to reach PCORnet resources and infrastructure. It is managed by the PCORnet Coordinating Center.

Front Door Requests in PCORnet are being tracked, including data network requests, network collaborator requests, study designation requests, and consultations.

PCORnet Front Door Activity

Front Door Requests

- 2016*: 18
- 2017*: 15
- Q3-18: 19
- Q4-18: 24
- Q1-19: 17
- Q2-19: 22

*Average per quarter
PCORnet
Inquiries from Potential Funders of Research

• Increasing diversity of funding sources pursued

• PCORI Partnerships to Conduct Research within PCORnet (PaCR) opportunity is increasing other funder’s awareness of opportunities for co-funding

![Front Door Request by Potential Funding Source](chart)

- Federal
- Foundation
- Industry
- PCORI
- Not Indicated
INVESTED (INfluenza Vaccine to Effectively Stop CardioThoracic Events and Decompensated heart failure)

- Randomized trial to compare high dose trivalent influenza vaccine versus standard dose quadrivalent vaccine in high-risk cardiovascular patients

- PCORnet sites leverage electronic identification methods and cross-network collaborations to enroll

- In Year 02, PCORnet had fewest sites (n=21), but delivered most patients per site (on average). And in Year 03, PCORnet sites tied for the highest enrollment rate!

<table>
<thead>
<tr>
<th>Network</th>
<th>Number of Sites</th>
<th>YEAR 3 Enrollment</th>
<th>Daily Median Enrollment Rate Per Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>54</td>
<td>822</td>
<td>.09</td>
</tr>
<tr>
<td>Non-VA US</td>
<td>60</td>
<td>691</td>
<td>.07</td>
</tr>
<tr>
<td>PCORnet</td>
<td>25</td>
<td>306</td>
<td>.09</td>
</tr>
<tr>
<td>VA</td>
<td>33</td>
<td>445</td>
<td>.08</td>
</tr>
<tr>
<td>ALL</td>
<td>172</td>
<td>2264</td>
<td>.07</td>
</tr>
</tbody>
</table>

The INVESTED trial is funded by the National Heart, Lung and Blood Institute, ClinicalTrials.gov NCT02787044.
PROVIDE-HF (Patient Reported Outcomes inVestigation following Initiation of Drug therapy with Entresto (Sacubitril/Valsartan) in Heart Failure)

• A non-interventional prospective cohort study of 400 chronic HF patients.

• **Patient reported primary outcome** to determine impact on physical limitations, symptoms, self-efficacy, social interference, and quality of life.

• PCORnet enhanced recruitment techniques enabled this study to **complete enrollment ahead of schedule**! The final study query to capture outcomes scheduled for late summer 2019!

PROVIDE-HF is funded by Novartis
ADAPTABLE (Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness)

- PCORnet demonstration project to compare daily dose of 81mg or 325mg aspirin.
- PCORnet sites leverage the Common Data Model to identify patients and outcomes. Patient stakeholders (ADAPTORS) drive success!
- Enrollment rates far exceed other trials in this area. The project has achieved 92% of its enrollment goal to date (>14,000 of 15,000)!
PCORnet
Select Future Opportunities for the Network

• PREVENTABLE (PRagmatic EValuation of evENTs And Benefits of Lipid-lowering in oldEr adults)
  • NIH (NIA, NHLBI, NINDS) application with budget of $60.5M submitted February 1st (Review in May 2019)
  • Response led by Mid-South (PIs: Alexander, Hernandez, Williamson, Ambrosius)
  • All 7 eligible PCORnet networks (~40 sites) participating*
  • Front Door prep-to-research query informed feasibility, approach, and site selection

AIM 1: Determine the role of a moderate-intensity statin in preventing dementia and prolonging disability-free survival in patients 75 years and older without clinically evident coronary heart disease, including those with frailty, impaired physical function, mild cognitive impairment, polypharmacy, and multi-morbidity.

AIM 2: Determine the role of moderate-intensity statin in preventing hospitalization for myocardial infarction/acute coronary syndrome, stroke, heart failure, revascularization or cardiovascular-related death, and preventing either mild cognitive impairment or dementia.

AIM 3: Test the safety and tolerability of statins in older adults and collect 17,000 bio-specimens to advance precision health.

*Neither PEDSnet nor ADVANCE have sufficient numbers of the eligible population
PCORI Board of Governors Dashboard
Second Quarter FY-2019 (As of 3/31/2019)

**Funds Committed**

- **Budgeted**: $232M for FY-2019
- **Actual**: Q1, Q2

**Operational Expenses**

- **Budgeted**: $82M for FY-2019
- **Actual**: Q1, Q2

**Research Project Performance**

- **% of Research Projects On Track**
- **Percent**: Q3, Q4, Q1, Q2

**Altmetric: Attention to PCORI Results**

- **% of CER Results Publications in Top 10% of Attention**
- **%**: Q3, Q4, Q1, Q2

**Speed of PCORI Peer Review**

- **Median Time to Complete Peer Review (Grey = 75th Percentile)**
- **Months**: Q3, Q4, Q1, Q2

**Results Viewed on PCORI.org**

- **Average Pageviews of Results Posted to PCORI.org**
- **Page Views**: Q3, Q4, Q1, Q2

**Dashboard Key**

- **Q2 2018**
- **Q4 2018**
- **Q1 2019**
- **Q2 2019**
- **Meeting Target**
- **Not Meeting Target**
- **Needs Board Attention**
- **Target in Development**

**Results Published in Literature**

- **Articles**: 20, 17, 26, 22
- **CER Results and Other Results Published in the Literature**: Q3, Q4, Q1, Q2

**Uptake into UpToDate®**

- **Cumulative: 27 Citations**
- **Citations in UpToDate® point-of-care decision tool**: Q4, Q1, Q2

**Other Examples of Uptake**

- **New Studies Underway in PCORnet**
- **Projects**: Q3, Q4, Q1, Q2

**Front Door Requests in PCORnet**

- **Requests**: Q3, Q4, Q1, Q2
Discussion Questions

• Do our FY-2019 Dashboard and associated background materials cover the topics that are most important for the Board to review?
• Do you have questions about our Q2 in-depth focus on PCORnet?
• Do you have questions about our Q2 in-depth focus on PCORI Peer Review?
• What questions do you have for our upcoming Q3-19 in-depth focus on Recruitment, Modifications, and Progress of Projects?
Research Portfolio Exploration
Series:
Portfolio Overview

Joe Selby, MD, MPH
Executive Director
Exploring PCORI’s Portfolio of CER Studies

- First, a *brief overview* of some basic dimensions of PCORI’s CER portfolio
  - To set the *context*
  - Find out *what else you might like to know* about our portfolio
    - We will prepare these analyses for future meetings

- Then, an *in-depth look* at one of our topic portfolios – Telehealth
  - The first of many planned topic presentations, with others already in the queue
    - Opioids, Multiple Sclerosis, Mental Health, Cancer

- *What other topic portfolios would you like to learn about?*
  - We will prepare in-depth looks for future meetings
Overall Research Portfolio (including Methods Research)
21 cycles funding 622 studies for a total of $1.95B

- **Broad PFAs**
  - 17 cycles
  - 493 studies
  - $902 M

- **Pragmatic PFAs**
  - 11 cycles
  - 43 studies
  - $493 M

- **Targeted PFAs**
  - 28 topics
  - 86 studies
  - $557 M
Clinical Conditions in CER Studies
Number & Funding by Condition Category

By Number of Studies (n=464)

- Mental/Behavioral Health: 128
- Cancer: 87
- Neurological Disorders: 77
- Cardiovascular Diseases: 69
- Multiple/Comorbid,...: 58
- Nutritional and Metabolic...: 51
- Respiratory Diseases: 43
- Functional Limitations...: 34
- Infectious Diseases: 31
- Rare Disease: 31
- Muscular and Skeletal...: 30
- Reproductive and...: 28
- Trauma/Injury: 21

By Funding (Board-Approved $)

- Mental/Behavioral Health: $521 M
- Cancer: $340 M
- Neurological Disorders: $331 M
- Cardiovascular Diseases: $302 M
- Multiple/Comorbid,...: $242 M
- Nutritional and Metabolic...: $170 M
- Respiratory Diseases: $166 M
- Functional Limitations...: $124 M
- Infectious Diseases: $141 M
- Rare Disease: $93 M
- Muscular and Skeletal...: $126 M
- Reproductive and...: $101 M
- Trauma/Injury: $122 M

A study may be counted across more than one category.
### Populations of Interest in CER Studies
#### Number & Funding by Population

**Total CER funding**: $1.52 billion

- **LGBT**: $40 M
- **Veterans**: $98 M
- **Individuals with Disabilities**: $151 M
- **Individuals with Rare Disease**: $93 M
- **Low Health Literacy/Numeracy**: $227 M
- **Rural**: $368 M
- **Children**: $367 M
- **Urban**: $343 M
- **Older Adults**: $364 M
- **Individuals with Multiple Health Conditions**: $497 M
- **Low Income**: $724 M
- **Women**: $686 M

**By Number of Studies (n=464)**

- **Racial/Ethnic Minorities**: 307
- **Low Income**: 204
- **Women**: 159
- **Older Adults**: 137
- **Individuals with Multiple Health Conditions**: 116
- **Urban**: 104
- **Children**: 103
- **Rural**: 85
- **Low Health Literacy/Numeracy**: 69
- **Individuals with Rare Disease**: 31
- **Individuals with Disabilities**: 30
- **Veterans**: 19
- **LGBT**: 11

**By Funding (Board Approved $)**

- **Racial/Ethnic Minorities**: $1226 M
- **Low Income**: $724 M
- **Women**: $686 M
- **Older Adults**: $664 M
- **Individuals with Multiple Health Conditions**: $497 M
- **Urban**: $367 M
- **Children**: $343 M
- **Rural**: $368 M
- **Low Health Literacy/Numeracy**: $227 M
- **Individuals with Rare Disease**: $93 M
- **Individuals with Disabilities**: $151 M
- **Veterans**: $98 M
- **LGBT**: $40 M

*Note: A study may be counted across more than one category.*
Over half of PCORI CER studies are led by a principal investigator with a medical degree, including the following specialties:

- Internal Medicine: 49 PIs
- Surgery: 29 PIs
- General Pediatrics: 29 PIs
- Hematology/Oncology: 28 PIs
- Psychiatry: 27 PIs
- Emergency Medicine: 20 PIs
- Neurology: 19 PIs
- Family Medicine: 14 PIs
- Pulmonology: 12 PIs

Lead PIs may be counted across more than one category. Chart shows specialties with 12 or more PIs.
CER Portfolio

CER Distribution by Study Design

- RCTs: 76%
- Quasi-Experimental: 6%
- Observational: 18%

Study Design by number of awards

- RCTs: 85%
- Quasi-Experimental: 3%
- Observational: 12%

Study Design by Funding amount ($)
Total: $1.8B
CER Study Outcomes
Themes

- Health Status and Well-Being: 365
- Clinical: 349
- Health Behaviors: 307
- Service Delivery Level: 301
- Evaluation of Care: 263
- Outcomes related to research: 161
- Decision Making: 119
- Knowledge and Understanding: 108
- Communication: 71
- Support: 47
- Skills Acquisition: 45
- Societal and Governmental: 31

Studies often measure outcomes across more than one theme.
PCORI Funds Research on High-Cost, High-Impact Health Conditions

<table>
<thead>
<tr>
<th>National Per Capita Expenditure</th>
<th>Condition</th>
<th>Number of PCORI Studies</th>
<th>PCORI Investment</th>
</tr>
</thead>
<tbody>
<tr>
<td>$32,027</td>
<td>Stroke</td>
<td>15</td>
<td>$63 M</td>
</tr>
<tr>
<td></td>
<td>Heart Failure</td>
<td>15</td>
<td>$70 M</td>
</tr>
<tr>
<td></td>
<td>Hepatitis (Chronic Viral B and C)</td>
<td>8</td>
<td>$59 M</td>
</tr>
<tr>
<td></td>
<td>Chronic Obstructive Pulmonary Disease</td>
<td>17</td>
<td>$89 M</td>
</tr>
<tr>
<td></td>
<td>Schizophrenia/Other Psychotic Disorders</td>
<td>11</td>
<td>$22 M</td>
</tr>
<tr>
<td></td>
<td>Chronic Kidney Disease</td>
<td>18</td>
<td>$72 M</td>
</tr>
<tr>
<td></td>
<td>Asthma</td>
<td>16</td>
<td>$51 M</td>
</tr>
<tr>
<td></td>
<td>Atrial Fibrillation</td>
<td>4</td>
<td>$8 M</td>
</tr>
<tr>
<td></td>
<td>Alzheimer's Disease/Dementia</td>
<td>13</td>
<td>$78 M</td>
</tr>
<tr>
<td></td>
<td>Depression</td>
<td>47</td>
<td>$196 M</td>
</tr>
<tr>
<td></td>
<td>Cancer</td>
<td>85</td>
<td>$336 M</td>
</tr>
<tr>
<td></td>
<td>Ischemic Heart Disease</td>
<td>22</td>
<td>$108 M</td>
</tr>
<tr>
<td></td>
<td>Osteoporosis</td>
<td>1</td>
<td>$14 M</td>
</tr>
<tr>
<td></td>
<td>HIV/AIDS</td>
<td>9</td>
<td>$28 M</td>
</tr>
<tr>
<td></td>
<td>Arthritis</td>
<td>15</td>
<td>$50 M</td>
</tr>
<tr>
<td></td>
<td>Diabetes</td>
<td>32</td>
<td>$75 M</td>
</tr>
<tr>
<td></td>
<td>Hypertension</td>
<td>12</td>
<td>$54 M</td>
</tr>
<tr>
<td></td>
<td>Hyperlipidemia</td>
<td>7</td>
<td>$27 M</td>
</tr>
<tr>
<td></td>
<td>Autism Spectrum Disorders</td>
<td>2</td>
<td>$4 M</td>
</tr>
</tbody>
</table>

PCORI has funded **260** CER studies examining what works best in care for the **19 highest cost conditions** in the United States^.

[^]: High-cost clinical conditions identified by the Centers for Medicare and Medicaid Services for 2015.

A study may be counted across more than one condition category.
Future Portfolio Exploration

• Thanks to the diligent work of teams that contribute to information services, we now have much more information available for each aspect of our funded research portfolio – for example, detail about the outcomes being studied in funded projects, as well as growing info on applications that were not funded.

• *What questions do you have* about PCORI’s portfolio of funded studies?

• What should we prepare to focus on in *future portfolio explorations*?
Overview of PCORI’s Telehealth Portfolio: Reflections of a Changing Delivery System

Penny Mohr, MA
Senior Advisor, Emerging Technology and Healthcare Delivery Innovation Research Initiatives
Overview

• Background
• Overview of the Telehealth Portfolio
• Putting Our Findings into Context
• Looking Ahead
• Background
• Overview of the Telehealth Portfolio
• Putting Our Findings into Context
• Looking Ahead
What is Telehealth?

Telehealth

• The use of medical information exchanged **from one site to another** via **electronic communications** to improve a patient’s clinical health status. Voice only interactions are excluded

Telemedicine

• Telemedicine seeks to improve a patient's health by permitting **two-way, real time or asynchronous interactive** communication between the **patient, and the physician or practitioner** at the distant site. It allows health professionals to **evaluate, diagnose, and treat** patients at a distance

mHealth

• The use of **mobile and wireless devices** to improve health outcomes and healthcare services at a distance from the health care provider. Includes **unidirectional** communication (e.g., text message support)
Why PCORI Attracted Telehealth

Research Gaps in Telehealth Reflect Our Mission

- **Robust Comparative Studies**
  - Head-to-head comparisons of functionality/integration

- **Measurement of Patient-Centered Outcomes**
  - Function, symptoms, and health-related quality of life.

- **Understanding Variation Across Diverse Populations and Settings.**
  - Addressing individual differences and barriers to implementation and dissemination

- **Engaging Stakeholders in the Design**
  - User-centered design can help surmount barriers to adoption and sustainability (integration into the workflow; acceptability to patients)

Telehealth Affords Patient-Centered Care

- **Delivery where and when care is needed**
- **Personalization of the interface**
  - Low health literacy /Limited English proficiency
  - Cultural preferences


States with the year of enactment:

States with proposed legislation:
- In 2018, Kansas, Massachusetts, Pennsylvania, and South Dakota

*Coverage applies to certain health services.
Growth in Outpatient Telehealth Services in Private Insurance

Source: Harvey JB et al. Utilization of Outpatient Telehealth Services in Parity and Non-Parity States, 2010-2015. Telemedicine and eHealth Published online 30 May 2018; https://doi.org/10.1089/tmj.2017.0265
A Trend Towards Expanded Coverage

- Medicare Advantage Plans
  - Eliminates geographic restrictions
  - Allows payment for services in the home
- Physician Fee Schedule
  - Expands coverage for remote monitoring
  - Pays for Brief Virtual Visits
  - Expands coverage for inter-professional consults
- Expands coverage for addiction treatment

- All but one state pays for live video
  - Expansion by some states to eliminate originating site restrictions and include more specialties
- 11 states pay for store and forward
- 20 states pay for remote monitoring
- Allows remote prescribing for opioid treatment
• Background

• Overview of the Telehealth Portfolio

• Putting Our Findings into Context

• Looking Ahead
PCORI’s Telehealth, Telemedicine, and mHealth Portfolio

Telehealth
(preventative, promotive and curative delivered at a distance)
74 Projects

Telemedicine
(consultative, curative)
23 Projects

mHealth
(use of mobile devices in medical care)
56 Projects

$352 MILLION SUPPORTING 84 COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH STUDIES IN TELEHEALTH

As of April 2019
Projects may be classified as more than one type
When Will Results from Telehealth Studies Likely Be Available?

Average duration of telehealth projects (N=84): 3.7 years
Telehealth Projects by Study Design

Nearly all studies are RCTs

- Individual Randomized Controlled Trials (N=59) - 70%
- Cluster Randomized Controlled Trials (N=22) - 26%
- Observational Studies (N=3) - 4%

As of April 2019
While most studies are moderate size, a significant number are very large.
STUDY PROFILE
Comparative Effectiveness of Early Integrated Telehealth Versus In-Person Palliative Care for Patients with Advanced Lung Cancer

What This Study Does
• Compares the effectiveness of early integration of palliative care delivered via telemedicine versus in-person visits for advanced lung cancer patients living in remote areas

Design
• Individual RCT (1,250 patients and 987 caregivers)
• 20 institutions in 17 states

Key Outcomes
• Quality of life, satisfaction with care, healthcare utilization

Engagement
• Patients, caregivers, clinicians, telemedicine experts, health systems leaders, payers, and health policy experts will be engaged throughout this study

Jennifer Temel, MD
Massachusetts General Hospital

Palliative Care Targeted Funding Announcement, awarded August 2017
## Number of Telehealth Projects by Primary Disease/Condition

As of April 2019

<table>
<thead>
<tr>
<th>Disease/Condition</th>
<th>Number of Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental/Behavioral Health</td>
<td>15</td>
</tr>
<tr>
<td>Nutritional and Metabolic Disorders</td>
<td>12</td>
</tr>
<tr>
<td>Cardiovascular Diseases</td>
<td>10</td>
</tr>
<tr>
<td>Cancer</td>
<td>8</td>
</tr>
<tr>
<td>Neurological Disorders</td>
<td>7</td>
</tr>
<tr>
<td>Kidney Disease</td>
<td>5</td>
</tr>
<tr>
<td>Rare Diseases</td>
<td>5</td>
</tr>
<tr>
<td>Infectious Diseases</td>
<td>4</td>
</tr>
<tr>
<td>Respiratory Diseases</td>
<td>3</td>
</tr>
<tr>
<td>Multiple/co-morbid Chronic Conditions</td>
<td>2</td>
</tr>
<tr>
<td>Muscular and Skeletal Disorders</td>
<td>2</td>
</tr>
<tr>
<td>Other or Non-Disease Specific</td>
<td>2</td>
</tr>
<tr>
<td>Reproductive and Perinatal Health</td>
<td>2</td>
</tr>
<tr>
<td>Trauma/Injury</td>
<td>2</td>
</tr>
<tr>
<td>Allergies and Immune Disorders</td>
<td>1</td>
</tr>
<tr>
<td>Ear, Nose and Throat Diseases</td>
<td>1</td>
</tr>
<tr>
<td>Functional Limitations and Disabilities</td>
<td>1</td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td>1</td>
</tr>
<tr>
<td>Skin Diseases</td>
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</tr>
<tr>
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Number of Telehealth Projects by Primary Disease/Condition

N=84 projects

- Mental/Behavioral Health: 15
- Nutritional and Metabolic Disorders: 12
- Cardiovascular Diseases: 10
- Cancer: 8
- Neurological Disorders: 7
- Kidney Disease: 5
- Rare Diseases: 5
- Infectious Diseases: 4
- Respiratory Diseases: 3
- Multiple/co-morbid Chronic Conditions: 2
- Muscular and Skeletal Disorders: 2
- Other or Non-Disease Specific: 2
- Reproductive and Perinatal Health: 2
- Trauma/Injury: 2
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- Ear, Nose and Throat Diseases: 1
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As of April 2019
Number of Telehealth Projects by Primary Disease/Condition

As of April 2019
### Purpose of telehealth intervention

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Promote Self Management</strong></td>
<td>51</td>
</tr>
<tr>
<td><strong>Educate</strong></td>
<td>46</td>
</tr>
<tr>
<td><strong>Address Disparities</strong></td>
<td>40</td>
</tr>
<tr>
<td><strong>Improve Access to Primary and Speciality Care</strong></td>
<td>36</td>
</tr>
<tr>
<td><strong>Remote Monitoring</strong></td>
<td>17</td>
</tr>
</tbody>
</table>

Projects may be classified as more than one type.


As of April 2019.
Our Telehealth Projects Target Underserved Populations

40 STUDIES
Are utilizing telehealth to address disparities by addressing at least 1 of the populations of interest

$173 MILLION
The total research investment towards telehealth studies that address disparities

40 STUDIES
Are utilizing telehealth to address disparities by addressing at least 1 of the populations of interest

$173 MILLION
The total research investment towards telehealth studies that address disparities

N=40, as of April 2019. Categories are not mutually exclusive.
PCORI telehealth projects incorporate diverse modalities

**Mobile phones or tablets**
- 56 Studies
- (22 use tailored messaging)

**Remote monitoring through wireless devices**
- 17 Studies

**Store and forward**
- 6 Studies

**Interactive live video**
- 31 Studies

**Web portals (accessed through multiple devices)**
- 62 Studies

*Categories are not mutually exclusive*
Outcomes for Telehealth Studies

The focus is on improving patient/caregiver well being


Projects may be classified as more than one type
As of April 2019.
What This Study Did

• Evaluated the feasibility, effectiveness, and satisfaction associated with tele-healthcare visits for patients with Parkinson’s Disease

Design

• RCT (200 patients)
• 20 sites in 16 states

Key Findings

• Telehealth was feasible
• High levels of satisfaction
• No differences in quality of life, quality of care, or caregiver strain for telehealth versus control

Engagement

• Parkinson’s Foundation, patient advisory board members, and steering committee

Earl Ray Dorsey, MD, MBA
University of Rochester, Rochester, NY
Study Aims

- Expand intervention to include multidisciplinary care and address comorbid conditions (anxiety, depression, dementia)
- Implement the intervention through a funded statewide (NY) telemedicine program that will provide care to 500+ individuals with Parkinson’s disease

What This Study Does

- Expands reach to rural areas, racial/ethnic minorities, low income, elderly
- Builds national capacity (training neurologists and allied healthcare workers in telehealth and comorbid disease management)

Engagement

- Patients and caregivers, Parkinson Disease Care NY, Finger Lake Health Systems Agency, local home health care, nursing homes in upstate NY
- International Parkinson and Movement Disorders Society, American Academy of Neurology, American Telemedicine Association, West Health Institute, Michael J Fox Foundation/Parkinson’s Action Network

Earl Ray Dorsey, MD, MBA
University of Rochester, Rochester, NY
Network Goals

• Patient engagement, community integration and education
• Healthcare decisionmaking
• Research opportunities
• Personal longitudinal health and healthcare tracking

Membership

• 18,261 adult patients with Crohn’s disease and ulcerative colitis, collectively referred to as inflammatory bowel disease

mHealth Component

• Incorporation of data imported from mHealth apps and wearable devices
• Captures patient-generated data for research
Evidence Map on mHealth for Self-Management of Chronic Disease

https://www.pcori.org/evidence-maps/results-strength-evidence-mHealth-systematic-reviews-1


99 Included Assessing Strength of Evidence

19 PCORI Studies

Gaps being addressed:
- Vulnerable populations
- Pediatric populations
- Measuring patient-centered outcomes
Advancing the State of Evidence for Decisionmakers About Telehealth
PCORI Stakeholder Workshop (May 24, 2018)

Key message: patient/clinician experience and context are critical

- Need to understand long-term adherence
  - Patient and provider experience that contributes to adoption/lack of interest and sustained use or discontinuation
  - Tracking use and outcomes beyond the study period

- Report out contextual factors that make the telehealth component work
  - Type of support personnel needed
  - How they interact with the care team
  - Type of training needed
  - Requirements for integration with the EHR

Included 22 participants representing patients, clinicians, payers, health systems, policymakers, and telehealth advocacy
Establishing Investigator Communities

Number of studies=36
Addressing Disparities

Number of studies=29
mHealth for Self-Management of Chronic Disease

Number of studies=15
Challenges of Implementing Multi-site Telemedicine Trials
Engagement Award: Community-Driven Evidence Dissemination

- **Disseminating PCOR on Telehealth to State Health Policymakers to Maximize its Relevance & Impact**
  - National Academy for State Health Policy (NASHP)
- NASHP is convening an interbranch, interagency workgroup of state health policy makers to disseminate PCOR findings on telehealth and explore in depth the policy and contextual issues affecting implementation
  - Create opportunities for policymakers to learn directly from their peers’ experiences implementing telehealth
  - Share the necessary contextual information for policymakers to most effectively understand, and when appropriate, to implement actionable telehealth research
- Deliverables include an in-person convening at the NASHP 2019 Annual Conference, four posts on the NASHP blog, a topic brief, and a webinar
  - All promoted via NASHP’s newsletter
• Background
• Overview of the Telehealth Portfolio
• Putting Our Findings into Context
• Looking Ahead
Remaining Gaps

- Head-to-head trials of mobile apps (Veazie et al., 2018)
- Cancer treatment (not symptom management) (Totten et al., 2016)
- Maternal and child health (Totten et al., 2016)
- Children and adolescents; Management of serious pediatric conditions (Totten et al., 2016; Reston et al., 2018)

Sources:


The Telehealth Research Synthesis Team

Cathy Gurgol
Anum Lakhia
Metti Duressa
Soknorntha Prum
Sindhura Gummi
Adam Bloom-Paicopolos

Heather Edwards
Emily Lazowick
Emily Russell
Jessica McCreary
Holly Ramsawah
Kristin Carman
Greg Martin
Bill Lawrence
Robert Treadway
Questions?
BREAK

We will return at 11:30 am ET

Join the conversation on Twitter via @PCORI
PCORnet: Implementing a Common Linkage Method

Kathleen Troeger, MPH
Chair, Research Transformation Committee

Maryan Zirkle, MD, MS, MA
Senior Program Officer
Identifying a Common Linkage Method in PCORnet

History & Evolution of Linkage

- **August 2016:** Long history of seeking to obtain more complete data in PCORnet given the enormous value add when several disparate sources of data can be linked together at the level of an individual participant in a secure and private way, called privacy-preserving record linkage (PPRL)

- **August 2018:** Over time PCORnet community realized the need for more efficient, privacy-preserving approach to record linkage in lieu of the many one-off linkages conducted on a project by project basis

- **October 2018:**
  - PCORI Approved FY2019 Commitment Plan: $10M for infrastructure to support integration and linkage of additional sources of data in PCORnet
  - PCORnet community set out to identify a Common Linkage Method (PPRL) that all partners use to perform their linkages

- **December 2018-March 2019:** A robust search and review process identified a vendor and an approach to supply the Common Linkage Method for all networks and all projects

- **April 2019:** The PCORI RTC recommends that the Board approve the use of up to $2.0M in funds to implement a Common Linkage Method in PCORnet
Implementing a Common Linkage Method in PCORnet: Who plays a role in implementation of the linkage method and what will each entity do?

<table>
<thead>
<tr>
<th>Networks/Sites</th>
<th>Selected Vendor</th>
<th>Coordinating Center (CC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expand/amend existing infrastructure:</td>
<td></td>
<td>Expand existing infrastructure and develop new approaches:</td>
</tr>
<tr>
<td>• Common Data Model (CDM)</td>
<td></td>
<td>• Queries</td>
</tr>
<tr>
<td>• IRB approvals</td>
<td></td>
<td>• Query architecture</td>
</tr>
<tr>
<td>• Data Sharing/Use Agreement Integration (DSUA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remote implementation of software:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• CRN/HPRNs &amp; DCRI/HPHCI</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Enables privacy –preserving record linkage</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Functions take place behind each institutions firewall and encrypt all information necessary to ensure privacy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ongoing technical support</td>
<td></td>
</tr>
</tbody>
</table>
Implementing a Common Linkage Method in PCORnet: Linkage in Action: Overlap Analysis

Clinical Research Networks (CRNs)/Health Plan Research Networks (HPRNs)

- NW X Sites
  - Privacy-preserving record linkage (PPRL) software to enable secure linkage
- NW Y Sites
- NW Z Sites

Transforming Data

CDM

Coordinating Center

Query Architecture

Query release and response

- Encrypted Data

Query

- Secure Firewall

CRN sites/HPRNs

Selected Vendor

Coordinating Center

PPRL software to enable secure linkage

<table>
<thead>
<tr>
<th>HASH_ID</th>
<th>Record at &gt;1 CRN</th>
<th>Record at HPRN</th>
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</thead>
<tbody>
<tr>
<td>1234</td>
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<td>5678</td>
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<td>1</td>
</tr>
<tr>
<td>9012</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>
Implementing a Common Linkage Method in PCORnet: What is the estimated budget?

- Approved FY2019 Commitment Plan included the use of $10M to enhance the integration and linkage of additional sources of data in PCORnet and/or support network expansion.

- Implementation of a Common Linkage Method in PCORnet would significantly increase the capacity to readily link disparate sources of data (e.g., claims data) for use in future PCORnet studies.

- Request approval for up to $2.0M in funds to support the activities needed to implement a Common Linkage Method in PCORnet.

### APPROVED FY2019 PCORnet Commitment Plan

<table>
<thead>
<tr>
<th>Activity</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY2019 Health Plans and/or Additional Data Networks</td>
<td>$10.0M</td>
</tr>
<tr>
<td>Common Linkage Method Implementation</td>
<td>(up to $2.0M)</td>
</tr>
<tr>
<td>FY2019 Health Plan and/or Additional Data Networks (Balance)</td>
<td>$8.0M</td>
</tr>
</tbody>
</table>
Board Vote

Call for a Motion to:
- Approve up to $2 million to fund infrastructure development for implementation of a common linkage method in PCORnet.

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
Personalizing Treatment: Realizing the Benefits of Diabetes Risk Prediction

Jean Slutsky, PA, MSPH
Chief Engagement and Dissemination Officer

John Cuddeback, MD, PhD
Chief Medical Informatics Officer
American Medical Group Association
PCORI’s Mandate

“The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis...

... and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services...”

— from PCORI’s authorizing legislation
PCORI’s Dissemination & Implementation Program

• The D&I Program is charged with heightening awareness of the results of PCORI-funded research, and with advancing efforts to put these findings into practice to improve healthcare delivery and health outcomes.

  o Transparent reporting and public release of findings
  o Increasing awareness of these findings among the “right people”
  o Promoting systems for doctors, patients, and others to use the evidence to help with real life decisions and improve care
Snapshot of Funded D&I Awards

Completed Funding Cycles: **10**

Funded Awards: **25**

Total PCORI investment: **$29M**

Project budgets: **$500K to $2.2M**

Implementation Sites: in **32 states**
D&I Awards by Priority Area for the Original PCORI-Funded Research

- **AD**: 20%
- **CDR**: 20%
- **IHS**: 17%
- **Methods**: 17%
- **APDTO**: 25%

- **Communication and Dissemination Research**: 20%
- **Addressing Disparities**: 25%
- **Methods/Pilots**: 17%
- **Assessment, Prevention, Diagnosis, and Treatment Options**: 17%
- **Improving Healthcare Systems**: 25%
**Goal:** To facilitate the uptake and integration of evidence from PCORI-funded studies into real-world practice, in the context of other relevant evidence

- **Limited Competition: Implementation of PCORI-Funded PCOR Results PFA**
  - Provides PCORI investigator teams the opportunity to propose next steps to put their findings into practice (up to $1M in direct costs per project)

- **Implementation of Effective Shared Decision Making Approaches in Practice Settings PFA**
  - Promotes the implementation and systematic uptake of shared decision making in practice settings (up to $1.5M in total costs per project)

- **Implementation of Findings from PCORI’s Major Research Investments PFA**
  - Provides a broad applicant pool the opportunity to propose strategies to put evidence from specific, high-priority PCORI initiatives into practice, in the context of related evidence (up to $2.5M in total costs per project)
Improving Diabetes Prevention Based on Predicted Benefits of Treatment (PI: David Kent, MD; Tufts Medical Center)

PCORI STUDY:

• Analyzed individual patient data from 32 studies, including the 2002 Diabetes Prevention Program (DPP) Study, to see how treatments affected different groups of people.
Improving Diabetes Prevention Based on Predicted Benefits of Treatment (PI: David Kent, MD; Tufts Medical Center)

Pre-diabetes affects ~84M people in the United States. In practice-based screening, for every person with a result in the diabetes range, 6 people are identified with pre-diabetes.

STUDY FOUND:
- Risk of developing diabetes varied dramatically across patients.
- Low-risk patients showed little benefit from intensive lifestyle modification or taking metformin; high-risk patients showed significant benefit from these interventions.

D&I PROJECT: (in progress)
- Incorporate the prediction model into clinical workflow in the EHR, so it can be used in shared decisions
- Partner with the American Medical Group Association to implement the EHR tool in 50 clinic sites at Mercy (St. Louis) and Premier Medical Associates (Pittsburgh)
Personalized Treatment: Realizing the Benefits of Diabetes Risk Prediction

John Cuddeback, MD, PhD

Project Partner

Chief Medical Informatics Officer
American Medical Group Association (AMGA)
Personalized Treatment: Realizing the Benefits of Diabetes Risk Prediction

Tufts Medical Center
Predictive Analytics and Comparative Effectiveness (PACE) Center
Boston

David Kent, MD, MS
Director, PACE Center
Prof. of Medicine, Neurology, Clinical & Translational Sci.
Director, Graduate Program in Clinical & Translational Sci.

Jason Nelson, MS
Sr. Statistician

Premier Medical Associates
Pittsburgh

Frank Colangelo, MD, MS
Chief Quality Officer

Mercy
St. Louis

Carolyn Koenig, MD
Chair, Quality Safety Value Med. Dir., Care Management Mercy East Community

Todd Stewart, MD
VP, Clinical Integrated Solutions Clinical Informatics Mercy Technology Services

AMGA
Alexandria, VA

Elizabeth Ciemins, PhD, MPH
Sr. Director, Research & Analytics

Jill Powelson, RN, DrPH, MBA
Sr. Director, Clinical Translation

Richard Stempniewicz
Chief Technology Officer
American Medical Group Association

Advocate

Volume → Value
Align payment incentives with population health

Educate Innovate

Help members redesign their delivery systems to manage population health

AMGA – 501(c)(6) non-profit trade association

AMGA Foundation – 501(c)(3)
Some AMGA Members
Translation Is a Simple, Linear Process (Not!)

Program Redesign: Areas of Focus

Program will identify optimal and efficient ways to overcome challenges in a clinical care settings, from identification of eligible patients to proper reporting.

Patient Identification
- Identifying eligible patients
- Incorporating clinical history into workflow

Interventions
- Informing patients about age-specific guidelines
- Reminding patients to schedule appts.
- Discussing optimal treatments with patients

Treatments
- Providing patient treatments at individual group practices

Documentation & Reporting
- Ensuring documentation of treatment
- Reporting of treatment properly within EMR
Overview

Diabetes Prevention Program Study (DPP)

Landmark clinical trial, 1996–2001
3,234 adults with BMI ≥ 24 and impaired fasting glucose
Incidence of diabetes at 3 years:
- Placebo 29%
- Taking metformin 22%
- Intensive lifestyle 14%

Population Risk Stratification Model

PCORI methods study:
- Heterogeneity of treatment effect
  David Kent, PI – Tufts PACE Center
  Reanalyzed 32 clinical trials—can we determine, using data available at the beginning of the trial, which patients will experience the greatest benefit?

Adapt for Use in Clinical Practice

PCORI D&I study: patient and provider focus groups
- Would this be useful?
- How to present the data?
Redisvelop model for real-world EHR data, at OptumLabs
- Missing data
- Fasting blood glucose values not labeled as fasting

Personalized Risk Estimates at the Point of Care

Clinical decision support (CDS) features of EHRs—designed for simple conditional logic
Emerging EHR interoperability standards enable cloud-hosted predictive models
Strong business case – avert or delay onset of type 2 diabetes

CDC: National DPP

CMS: Medicare DPP

Value-Based Payment

EHR Standards
AMGA Foundation: National Diabetes Campaign

Together2Goal

Improve care for 1 million people with type 2 diabetes by 2021
Results after Year 2

763,000 patients, aged 18–79, with improved care
  2/3 with net improvement in control on campaign measures
  1/3 have new Dx—identified through screening

319,000 additional patients with sustained control
on the bundle measure
AMGA Foundation: National Diabetes Campaign

**EMPOWER PATIENTS**
- Build an Accountable Diabetes Team
- Integrate Emotional & Behavioral Support
- Refer to Diabetes Self-Management Education & Support Programs

**IMPROVE CARE DELIVERY**
- Conduct Practice-Based Screening
- Adopt Treatment Algorithm
- Measure HbA1c Every 3-6 months
- Assess & Address Risk of Cardiovascular Disease
- Contact Patients Not at Goal & with Therapy Change within 30 Days

**LEVERAGE INFORMATION TECHNOLOGY**
- Use a Patient Registry
- Embed Point-of-Care Tools
- Publish Transparent Internal Reports
Together 2 Goal Launch: Member Survey

Which planks will you adopt?
Which will you not adopt?

31% said they \textit{wouldn’t} focus on screening.
They are already overwhelmed by the number of patients with type 2 diabetes...
...let alone prediabetes!
What Is Prediabetes?

Elevated blood sugar, but not high enough to indicate diabetes

- Fasting plasma glucose 100–125 mg/dL
- HbA1c 5.7–6.4 percent
- Oral glucose tolerance test, 2 hr 140–199 mg/dL

Elevated risk of progression to diabetes over 3 years—from DPP study

- No intervention (placebo) 28.9% over 3 years
84.1 million American adults — more than 1 out of 3 — have prediabetes

1 out of 3

9 out of 10 people with prediabetes don’t know they have it
5.1 million patients, 18–75, across 23 AMGA member organizations using Optum population health analytics
≥ 1 ambulatory visit with a PCP, endocrinologist, cardiologist, or nephrologist, July 2016 – June 2017,
no past evidence of diabetes (diagnosis or medication), not pregnant within the past 2 years

72.5\% were eligible for screening, by ADA criteria

Not screened: 1.7 million people
~ 600,000 people missed with prediabetes
~ 100,000 people missed with screening result in diabetes range

Screened in prior 2 years, no evidence of diabetes or prediabetes

Screened during study year – no evidence of diabetes or prediabetes

Prediabetes – 615,000 people

Screening result in diabetes range (6.0\%) – 102,000 people
What Is Prediabetes?

Elevated blood sugar, but not high enough to indicate diabetes

- Fasting plasma glucose 100–125 mg/dL
- HbA1c 5.7–6.4 percent
- Oral glucose tolerance test, 2 hr 140–199 mg/dL

Elevated risk of progression to diabetes over 3 years—from DPP study

- No intervention (placebo) 28.9% over 3 years
- Taking metformin absolute risk reduction: 7.1%
- Intensive lifestyle intervention absolute risk reduction: 14.2%
Heterogeneity of Treatment Effect

Quartiles of Risk

<table>
<thead>
<tr>
<th>Overall Risk</th>
<th>29%</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 High</td>
<td>45%</td>
</tr>
<tr>
<td>3 Moderate</td>
<td>20%</td>
</tr>
<tr>
<td>2 Moderate</td>
<td>12%</td>
</tr>
<tr>
<td>1 Low</td>
<td>7%</td>
</tr>
</tbody>
</table>

Absolute Risk Reduction Seen in DPP Study

http://www.pcori.org/research-in-action/moving-beyond-averages
Will a Predictive Model Be Useful?

Patient focus groups
- Most had family members with type 2 diabetes
- Intensely interested in their own personal risk for developing diabetes
- Quoted the ages at which family members were diagnosed

Provider focus groups
- Want to support/encourage patients—especially for lifestyle program
- Feel overwhelmed—need to prioritize
DPP Lifestyle Intervention

The lifestyle change program provides:

- A trained lifestyle coach
- CDC-approved curriculum
- Group support
- 16 weekly meetings with monthly follow-up

Supervised physical activity sessions
Individualized—“toolbox” of adherence strategies
Materials and strategies tailored to address ethnic diversity

Goal is 7% weight loss
Motivational techniques, “restarts”
Medicare now pays for the program
Will a Predictive Model Be Useful?

Patient focus groups
- Most had family members with type 2 diabetes
- Intensely interested in their own personal risk for developing diabetes
- Quoted the ages at which family members were diagnosed

Provider focus groups
- Want to support/encourage patients—especially for lifestyle program
- Feel overwhelmed—need to prioritize
- Multi-variable model is a better predictor than any individual parameter
  - In the lowest-risk quartile, about 15% of patients have A1c ≥ 6.0
  - In the highest-risk quartile, more than 25% of patients have A1c < 6.0
Are the Data Elements Available in the EHR?

<table>
<thead>
<tr>
<th>Model from DPP Study Data</th>
<th>Adapted Model for Use in EHR</th>
</tr>
</thead>
<tbody>
<tr>
<td>• HbA1c</td>
<td>• HbA1c</td>
</tr>
<tr>
<td>• Fasting glucose</td>
<td>• Fasting glucose</td>
</tr>
<tr>
<td>• Triglycerides</td>
<td>• Triglycerides</td>
</tr>
<tr>
<td>• History of elevated glucose</td>
<td>• Age</td>
</tr>
<tr>
<td>• Height</td>
<td>• Gender</td>
</tr>
<tr>
<td>• Waist circumference</td>
<td>• Race</td>
</tr>
<tr>
<td>• Waist:hip ratio</td>
<td>• BMI</td>
</tr>
<tr>
<td></td>
<td>• Smoking status</td>
</tr>
<tr>
<td></td>
<td>• Systolic blood pressure</td>
</tr>
<tr>
<td></td>
<td>• Hypertension diagnosis</td>
</tr>
<tr>
<td></td>
<td>• HDL cholesterol (&quot;good cholesterol&quot;)</td>
</tr>
</tbody>
</table>
Both have pre-diabetes. Who is at greatest risk for diabetes?

- 38-year-old female
- BMI 34
- HbA1c 5.8
- Systolic BP 153
- HDL 28
- Smoker?

- 44-year-old male
- BMI 22
- HbA1c 6.3
- Systolic BP 121
- HDL 100
- Former Smoker

HIGH RISK

LOW RISK
Predictive model results as displayed in EHR at Premier Medical Associates

**Low Risk Patient**

<table>
<thead>
<tr>
<th>Predicted Risk of Type 2 Diabetes at 3 Years</th>
<th>Treatment</th>
<th>Relative Risk Reduction (RRR)</th>
<th>Number Needed to Treat (NNT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.47%</td>
<td>Usual Care</td>
<td>Reference</td>
<td>N/A</td>
</tr>
<tr>
<td>4.38%</td>
<td>Metformin</td>
<td>20%</td>
<td>91.4</td>
</tr>
<tr>
<td>2.30%</td>
<td>DPP</td>
<td>58%</td>
<td>31.5</td>
</tr>
</tbody>
</table>

**High Risk Patient**

<table>
<thead>
<tr>
<th>Predicted Risk of Type 2 Diabetes at 3 Years</th>
<th>Treatment</th>
<th>Relative Risk Reduction (RRR)</th>
<th>Number Needed to Treat (NNT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>55.7%</td>
<td>Usual Care</td>
<td>Reference</td>
<td>N/A</td>
</tr>
<tr>
<td>24.5%</td>
<td>Metformin</td>
<td>56%</td>
<td>4</td>
</tr>
<tr>
<td>23.4%</td>
<td>DPP</td>
<td>58%</td>
<td>4</td>
</tr>
</tbody>
</table>
Of the 670 high-risk patients...

11 were On Metformin before 5/1/2018  (6%)
134 were Started on Metformin after 5/1/2018  (19%)

0 were Referred to a DPP before 5/1/2018  (0%)
297 were Referred to a DPP after 5/1/2018  (44%)
## Premier Medical Associates: May 2018 – Jan 2019

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Action Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>65%</td>
</tr>
<tr>
<td>Moderate</td>
<td>18%</td>
</tr>
<tr>
<td>Low</td>
<td>4%</td>
</tr>
</tbody>
</table>

During the project, 87 patients were identified as having diabetes, through timely screening.
Potential for Cost Savings

• Intermountain insurance plan saves $3,500 per person per year that development of diabetes is averted or delayed
  – $17,500 if diabetes is delayed for 5 years

• CMS Office of the Actuary estimates a savings of $2,650 over 15 months for Medicare beneficiaries participating in a DPP lifestyle program

• Cost of a DPP lifestyle program ~$600


Personalized Risk Estimates at the Point of Care

• Premier Medical Associates: Calculator add-in for Allscripts EHR
• Mercy
  – Preliminary build using EHR’s native clinical decision support logic—manual data entry
  – Alternative to building and validating full model in EHR—cloud-hosted version, using open interoperability standards
Personalized Risk Estimates at the Point of Care

Diabetes Prevention Program Study (DPP) → Population Risk Stratification Model → Adapt for Use in Clinical Practice → Personalized Risk Estimates at the Point of Care

Precision medicine without waiting for genomics
Public Comment Period

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

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