How to work with the PCORI Research Network – From EMR data-only protocols to pragmatic clinical trials

Objectives:

1. Describe the general organization of the PCORnet and PaTH research networks
2. Review the various types of research currently being done within PCORnet/PaTH
3. Learn why and how you might collaborate with PCORnet/PaTH for your own research
Agenda

- The PCORnet and PaTH Research Networks: *Network Structures and Research Supported* (Dan Ford)
- The PCORnet Common Data Model (CDM): *Strengths and Weaknesses* (Harold Lehmann)
- How to Work with Us: *Collaborating with PCORnet/PaTH for your own research* ("GK" Gauvey-Kern)
- A Researcher’s Experience Using PCORnet/PaTH (Wendy Bennett)
- Q & A
The PCORnet and PaTH Research Networks

Daniel Ford, MD, MPH
PI for PCORnet/PaTH at Johns Hopkins; Director of ICTR
Three things to know about PCORnet:

**Patient-Partnered**
Patients, and those who love and care for them, are integral to ALL PHASES OF PCORNET-ENABLED RESEARCH.

**Data-Driven**
Data accessible via PCORnet draws from millions of EHRs with growing links to patient-reported and payor data, all consolidated using a common data model.

**Broadly Connected**
PCORnet connects you to thousands of clinicians and researchers who are committed to answering important questions that will improve patient lives.
PCORnet is a “network of networks” that harnesses the power of partnerships.

Clinical Research Networks (CRNs) + Health Plan Research Networks (HPRNs) + Patient Partners + Coordinating Center = A national infrastructure for people-centered clinical research.
PCORnet – Partner Networks

- ADVANCE Network
- CAPriCORN
- GPC
- REACHnet
- PRACnet
- PaTH
- INSIGHT - NYC
- PEDSnet
- STAR
- OneFlorida
- INSIGHT - NYC
- PEDSnet
- STAR
- OneFlorida
PCORnet - Data on a national scale

Those encounters with 70 million people result in data available throughout the nation in all types of communities. This map represents data from the PCORnet-partnered Clinical Research Networks.
The PaTH Network

The PaTH CDM includes > 14 million people with diversity in age, geography, and race/ethnicity (# or %)

<table>
<thead>
<tr>
<th>Institution*</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>GHS</td>
<td>2,082,953</td>
</tr>
<tr>
<td>JHU</td>
<td>3,227,975</td>
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<tr>
<td>OSU</td>
<td>1,326,701</td>
</tr>
<tr>
<td>Pitt</td>
<td>3,769,209</td>
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<tr>
<td>PSCoM</td>
<td>1,188,031</td>
</tr>
<tr>
<td>TUHS</td>
<td>1,199,151</td>
</tr>
<tr>
<td>UMI</td>
<td>1,958,971</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>14,752,991</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>17 and younger</td>
<td>15%</td>
</tr>
<tr>
<td>18-44 years</td>
<td>34%</td>
</tr>
<tr>
<td>45-64 years</td>
<td>25%</td>
</tr>
<tr>
<td>65+ years</td>
<td>26%</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black/African American</td>
<td>13%</td>
</tr>
<tr>
<td>White</td>
<td>69%</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>4%</td>
</tr>
<tr>
<td>Other</td>
<td>14%</td>
</tr>
</tbody>
</table>
How can PCORnet help you?

PCORnet enables answers to questions like...

<table>
<thead>
<tr>
<th>Site Selection and Cohort Identification</th>
<th>Descriptive Analytics</th>
<th>Data Characterization and Quality Assessments</th>
<th>Exposure and Outcome Assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are patients who switched to a new heart failure medication achieving better symptom outcomes than their former treatment?</td>
<td>How do three popular bariatric procedures fare in an assessment of long-term comparative effectiveness?</td>
<td>Which aspirin dose offers the right balance of effectiveness and minimal risk of bleeding?</td>
<td>How do health systems compare across three well-established measures of quality in pediatric populations?</td>
</tr>
</tbody>
</table>
Accomplishments to Date

○ Data Only Protocols
  • Long term outcomes for 40,000 individuals who had bariatric surgery

○ Observational Protocols
  • Quality of life for patients with atrial fibrillation

○ Pragmatic Randomized Clinical Trials
  • ADAPTABLE – Aspirin dose in patients with CVD
Network Structure: Levels of Engagement

- **PCORNNet** – National PCORI funded research network that includes nine clinical data research networks (CRNs) and a coordinating center ([https://pcornet.org/](https://pcornet.org/))

- **PaTH** – One of the nine CRNs based at U Pittsburgh and includes Johns Hopkins ([https://www.pathnetwork.org/](https://www.pathnetwork.org/))
  - Pittsburgh, Penn State, Temple, Geisinger, Ohio State, Michigan

- **Johns Hopkins PCORnet/PaTH program** – Site specific program within the Institute for Clinical and Translational Research (ICTR)
Johns Hopkins PCORnet/PaTH Team

- Daniel Ford, MD, MPH – PaTH Johns Hopkins PI and Director of ICTR
- Harold Lehmann, MD, PhD – PaTH Co-PI and Informatics Director
- Megan “GK” Gauvey-Kern, MS – PCORnet/PaTH Program Director
Common Data Model (CDM): Strengths and Weaknesses

Harold Lehmann, MD, PhD
Co-I and Informatics Lead for PCORnet/PaTH at Johns Hopkins
The Path to PaTH: Extract, Transform, Load (ETL)

- Epic Transactional (Chronicles)
  - 5 million patients
- Epic Clarity
  - 5 million patients
- Other
- PaTH CDM
  - 2.7 million patients
- PaTH Covid CDM
  - 250K patients

Investigators
PCORnet
Computable Phenotypes

- “Atomic” data: What the computer can examine
  - Numbers, enumerated values (codes)
  - Inclusion criteria
  - Exclusion criteria

- Time
  - Enter the cohort
  - Leave the cohort
  - Event
What We Now Bring In

PCORnet Common Data Model v6.0 Tables and Constraints

- **DEMOGRAPHIC**
  - PATID

- **VITAL**
  - PATID
  - VITALID
  - MEASURE_DATE
  - VITAL_SOURCE

- **PRO_CM**
  - PATID
  - PRO_CM_ID
  - PRO_DATE

- **MED_ADMIN**
  - PATID
  - MEDADMINID
  - MEDADMIN_START_DATE

- **ENROLLMENT**
  - PATID
  - ENR_START_DATE
  - ENR_BASIS

- **ENCOUNTER**
  - PATID
  - ENCOUNTERID
  - ADMIT_DATE
  - ENC_TYPE

- **DISPENSING**
  - PATID
  - DISPENSINGID
  - DISPENSE_DATE
  - NDC

- **PROSGN**
  - PATID
  - PROSGNID
  - PROSGN_DATE

- **OBS_CLIN**
  - PATID
  - OBSCLINID
  - OBSCLIN_START_DATE

- **PCORNET_TRIAL**
  - PATID
  - TRIALID
  - PARTICIPANTID

- **LAB_RESULT_CM**
  - PATID
  - LAB_RESULT_CM_ID
  - RESULT_DATE

- **DEATH**
  - PATID
  - DEATH_SOURCE

- **OBS_GEN**
  - PATID
  - OBSGENID
  - OBSGEN_START_DATE

- **CONDITION**
  - PATID
  - CONDITIONID
  - CONDITION
  - CONDITION_TYPE
  - CONDITION_SOURCE

- **DEATH_CAUSE**
  - PATID
  - DEATH_CAUSE
  - DEATH_CAUSE_CODE
  - DEATH_CAUSE_TYPE
  - DEATH_CAUSE_SOURCE

- **HASH_TOKEN**
  - PATID

- **LAB_HIST**
  - LABHISTORYID
  - LAB_LOINC

- **IMMUNIZATION**
  - PATID
  - IMMUNIZATIONID
  - VX_CODE
  - VX_CODE_TYPE
  - VX_STATUS

- **LDS_ADDRESS_HISTORY**
  - PATID
  - ADDRESSID
  - ADDRESS_USE
  - ADDRESS_TYPE
  - ADDRESS_PREFERRED

- **ENCOUNTER**
  - PATID
  - ENCOUNTERID
  - ADMIT_DATE
  - ENC_TYPE

- **DIAGNOSIS**
  - PATID
  - DIAGNOSISID
  - DX
  - DX_TYPE
  - DX_SOURCE

- **PROCEDURES**
  - PATID
  - PROCEDURESID
  - PX
  - PX_TYPE

New to v6.0
New ETL: Coded ("atomic") data

- Chief complaint
- Surgical procedures not "ordered"
- Patient Reported Outcomes that are collected clinically
- Study data from other sources
New work (NLP, REDCap)

- Notes
  - “Natural Language Processing” (NLP)
  - Convert Text to “atomic” data

- Patient Reported Outcomes not collected clinically
  - Or, not reliably collected: Epic
  - Not clinically collected: REDCap
New Linkages: Remember “Hash Token”?

- CMS Claims
- CRISP?
- Images?
Don’t Forget the Analysis of “Real World Data”

○ Think ahead
  • Negative controls
  • Instrumental variables

○ Make sure your analysts and statisticians can deal with EHR data
How to Work with Us – Collaborating with PCORnet/PaTH for your own research

Megan E. Gauvey-Kern, MS ~ “gk”
Program Director for PCORnet/PaTH at Johns Hopkins
Step 1: Start local

- If you are considering using the CDM for a research project, the first step is always to reach out to the Johns Hopkins PCORnet/PaTH team:
  - PCORnet@jhmi.edu and/or mgauvey1@jhmi.edu
  - Provide as much information about the proposed project as possible
Step 2: Meet with the JH team

- We’ll schedule a brief (30 min) meeting for you to discuss your proposed research with Harold Lehmann and “GK” Gauvey-Kern.
  - Answer any questions
  - Provide feedback on feasibility and pros/cons of using the CDM
  - Discuss options and next steps
Step 2a: Johns Hopkins-Only Studies

- e.g. pilot study that may want to expand beyond Johns Hopkins in the future
- If you decide you want to use the CDM only at Johns Hopkins, our team will continue to work with you directly.
Step 3: Studies beyond Johns Hopkins – Engaging the PaTH Network

- The Johns Hopkins team will connect you to the central PaTH team and help you through our research intake process
  - Complete intake form and presentation template
  - Present to the PaTH Future Research Topics group
  - Confirm sites, data requirements, PaTH services requested
  - We provide a cost estimate (budget/justification) and LOS

- Note: if you would like to engage PCORnet sites beyond PaTH, we will facilitate this as well.
Additional Features/Services

- Proposal Development
  - Prep-to-research queries
  - Identifying collaborators
    – Ideal sites, Site PIs, Patient Partners, etc.

- Regulatory
  - DUAs – PCORnet and PaTH already have DUAs in place for sharing most de-Identified data. Experience with DUAs for LDS, etc.
  - PaTH sIRB processes in place
  - Contracting
Key Take-Aways

○ **Start Local**
  - Always come to the Johns Hopkins PCORnet/PaTH team first (PCORnet@jhmi.edu)

○ **Start Early**
  - Recommend at least 5-6 weeks prior to deadlines, particularly when engaging multiple sites

○ **More than just data**
  - Wrap-around services (study development and implementation)
  - Established relationships, several years experience working together
A Researcher’s Experience Using PCORnet/PaTH

Wendy Bennett, MD, MPH
Johns Hopkins Researcher who Lead a PCORnet/PaTH Study
The Impact of Timing of Eating on Weight: A Multi-site Cohort Study using the Daily24 Mobile Application

- 6 month Cohort Study
- Aimed to assess association between timing of eating and weight over time using a mobile App called Daily24
- Participants identified and recruited from 3 PaTH sites using EHR-based computable phenotype
- Data collection involved EHR data, Online Survey, Daily24 mobile app
Electronic recruitment, consent and app downloading process

This is the Informed Consent Process.
You will learn more about the purpose of the research study and what will happen if you join. After learning more, you will be able to give your permission to join.

Your Progress
10%

Below is a summary of the Daily24 Informed Consent. Please click "Next Page" to download and view a full copy.

Audio

This is a research study. In this research, we want to determine whether the time of day people eat and sleep may affect their weight.

If you decide to join this study, the following things will happen:
You will complete an online survey at the beginning, the middle (3-months), and the end (6-months) of the study about eating and exercise habits, general health and technology use.
You will download the Daily24 mobile application to your phone and use it to record your meal and sleep times off and on for a 6 month period.
Selected health information and your weight at previous clinic visits will be extracted from your medical record and included in this study.

You have just a few more steps before joining the Daily24 study!

The first is to take a handful of online surveys about yourself, your eating and use of a cell phone. This process can take anywhere from 20-30 minutes to complete. A few things to keep in mind:

It is ideal to finish them in one sitting.

If at any point you must stop before finishing or you accidentally close your browser, do not worry! Your answers will be saved and you will receive an email within 10-15 minutes with a link that allows you to pick up where you left off when convenient.

Now, please CLICK SUBMIT below to begin the baseline surveys...

<< Previous Page
Submit

For the next six months of the study, we are asking you to focus on one initial month of tracking (POWER28) and 5 monthly POWER Weeks.

1 Power Month (Power28)
5 Power Weeks

6 Months

What is a Power28?
Key Strengths of study design using PCORnet/PaTH: Recruitment

- Low touch recruitment using EHR patient portal and emails → rapid recruitment over 6 months (>1000 participants) from 3 PaTH sites
  - Used MyChart at JH
  - Used Email at other 2 PaTH sites
- Designed “hand off” from 2 other sites to primary team following participant consent to enable streamlined approach
Key Strengths of study design using PCORnet/PaTH: Data Linkages


- Built cohort/dataset – available for multiple secondary analyses aligned with aims; data storage at the coordinating center
Thank You.

The Johns Hopkins PCORnet/PaTH Research Team

PCORnet@jhmi.edu

www.pcornet.org

www.pathnetwork.org

Find us on the Johns Hopkins ICTR website – updates coming soon