Introducing PCORnet and the Greater Plains Collaborative:
The National Patient-Centered Clinical Research Network and Our Role

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Marshfield Clinic, January 22, 2014
Outline

- **PCORnet** standard introduction
- **Greater Plains Collaborative** introduction and approaches
- **Babel** demo if time
Our national clinical research system is well-intentioned but flawed

- High percentage of decisions not supported by evidence*
- Health outcomes and disparities are not improving
- Current system is great except:
  - Too slow
  - Too expensive
  - Unreliable
  - Doesn’t answer questions that matter most to patients
  - Unattractive to clinicians & administrators

We are not generating the evidence we need to support the healthcare decisions that patients and their doctors have to make every day.

Both researchers and funders now recognize the value in integrating clinical research networks.

- Linking existing networks means clinical research can be conducted more effectively.
- Ensures that patients, providers, and scientists form true “communities of research”.
- Creates “interoperability” – networks can share sites and data.
PCORnet embodies a “community of research” by uniting systems, patients & clinicians.
What will PCORnet do for research?
PCORnet’s goal

PCORnet seeks to improve the nation’s capacity to conduct clinical research by creating a large, highly representative, national patient-centered network that supports more efficient clinical trials and observational studies.
PCORnet’s vision

PCORnet will support widespread capability for the US healthcare system to learn from research, meaning that large-scale research can be conducted with greater speed and accuracy within real-world care delivery systems.
Overall objectives of PCORnet: achieving a single functional research network

- **Create** a secure national research resource that will enable teams of health researchers, patients, and their partners to work together on researching questions of shared interest.

- **Utilize** multiple rich data sources to support research, such as electronic health records, insurance claims data, and data reported directly by patients.

- **Engage** patients, clinicians & health system leaders throughout the research cycle from idea generation to implementation.

- **Support** observational and interventional research studies that compare how well different treatment options work for different people.

- **Enable** external partners to collaborate with PCORI-funded networks.

- **Sustain** PCORnet resources for a range of research activities supported by PCORI and other sponsors.
PCORnet organizational structure

PCORnet STEERING COMMITTEE

Members represent:
- Each Clinical Data Research Network
- Each Patient-Powered Research Network
- Patients
- HHS agencies:
  - NIH
  - FDA
  - AHRQ
  - CDC
  - CMS
  - ONC
  - ASPE
- Medical product and device manufacturers
- PCORI and Coordinating Center

PCORnet Executive Committee

11 CLINICAL DATA RESEARCH NETWORKS

18 PATIENT-POWERED RESEARCH NETWORKS

TASK FORCES
- GOVERNANCE
- DATA PRIVACY
- ETHICS & REGULATORY
- DATA STANDARDS & SECURITY
- HEALTH SYSTEMS INTERACTIONS
- PATIENT & CONSUMER ENGAGEMENT
- PATIENT GENERATED OUTCOMES
- CLINICAL TRIALS
- RARE DISEASES
- BIOREPOSITORIES
- OBESITY
29 CDRN and PPRN awards were approved on December 17th by PCORI’s Board of Governors.

This map depicts the number of PCORI funded Patient-Powered or Clinical Data Research Networks that have coverage in each state.
CDRN Partners
Goals for Each Clinical Data Research Network (CDRN)

_create a research-ready dataset of at least 1 million patients that is:
- **Secure** and does not identify individual patients
- **Comprehensive**, using data from EHRs to describe patients’ care experience over time and in different care settings

_involve patients, clinicians, and health system leaders in all aspects of creating and running the network

_develop the ability to run a clinical trial in the participating systems that fits seamlessly into healthcare operations

_identify at least 3 cohorts of patients who have a condition in common, and who can be characterized and surveyed_
CDRN highlights

- Networks of academic health centers, hospitals & clinical practices
- Networks of non-profit integrated health systems
- Networks of Federally Qualified Health Centers (FQHCs) serving low-income communities
- Networks leveraging NIH and AHRQ investments (CTSAs)
- Inclusion of Health Information Exchanges
- Wide geographical spread
- Inclusion of under-served populations
- Range from 1M covered lives to 28M
PPRN Partners

pcornet
The National Patient-Centered Clinical Research Network
Goals for each Patient-Powered Research Network (PPRN)

- Establish an activated patient population with a condition of interest (Size >50 patients for rare diseases; >50,000 for common conditions)
- Collect patient-reported data for ≥80% of patients in the network
- Involve patients in network governance
- Create standardized database suitable for sharing with other network members that can be used to respond to “queries” (ideas for possible research studies)
**PPRN highlights**

- Participating organizations and leadership teams include patients, advocacy groups, clinicians, academic centers, practice-based research networks
- Strong understanding of patient engagement
- Significant range of conditions and diseases
- Variety in populations represented (including pediatrics, under-served populations)
- 50% are focused on rare diseases
- Varying capabilities with respect to developing research data
- Several PPRNs have capacity to work with biospecimens
The PCORnet opportunity: making a real difference for patients and their families

Until now, we have been unable to answer many of the most important questions affecting health and healthcare.

By combining the knowledge and insights of patients, caregivers, and researchers in a revolutionary network with carefully controlled access to rich sources of health data, we will be able to respond to patients’ priorities and speed the creation of new knowledge to guide treatment on a national scale.
The “Greater Plains Collaborative”
Funded in March

- KS, the University of Kansas Medical Center (KUMC)
- MO, Children’s Mercy Hospital
- IA, University of Iowa Healthcare
- WI, the University of Wisconsin-Madison, the Medical College of Wisconsin, and Marshfield Clinic
- MN, the University of Minnesota Medical Center
- NE, the University of Nebraska Medical Center
- TX, the University of Texas Health Sciences Center at San Antonio and the University of Texas Southwestern Medical Center.
- Selected in July to submit full proposal in September, award in December, funding January?
  - $7 million total costs over 18 months
The “Greater Plains Collaborative”
Size, Goals, Structure

- 11.8 Million Covered Lives
- 13 hospitals, 430 clinics, 1800 primary care providers, 7600 specialists

- Establish Governance
- Measure EHR Meaningful Use standardization and align for 3 use cases:
  - Breast Cancer
  - ALS (Lou Gerhig’s Disease)
  - Obesity (Pediatric Inpatient Focus)

- Develop Patient Reported Outcome Measure Methods
- Develop Comparative Effectiveness Research Trial infrastructure embedded in EHRs
- Enhance Patient Recruitment
- Support Biospecimen Requests

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Legend:
Black items are current site processes/systems.
Green items are data sources which might be piloted at each site, but not deployed across the network.
Red items are new components deployed at each site across the network.
Blue items are components deployed centrally.
Purple lines show the feedback processes to configure sites for PROM, CER, and coordinating amongst biospecimen repositories.

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The “Greater Plains Collaborative”
Epic EHR Sites: Clarity Data Resources

• “Fish” through Clarity Data Dictionary, site workflows and Epic build to identify the datasets
• Map Epic EHR data to vocabulary standards in synchronization with Meaningful Use requirements

Meaningful Use Terminology Mapping Guide
Based on the final rule for Stage 2 of Meaningful Use

Last Revised: July 8, 2013
The “Greater Plains Collaborative”
Support for interoperation

• Research data integration and management tooling: i2b2
• Information model: Star schema
• Domain ontology/code sets:
  – Demographics, Clinical findings/biometrics, Lab findings, Radiology findings, Diagnoses, Allergies, Procedures, Orders - procedure/medications, Medications/pharmaceuticals administered, Registry data
• Value sets for coded data
Demographics (80% stage 2): HL7/OMB code set
Family history, past medical history, smoking status, clinical observations: SNOMED CT
Problem list/diagnoses (80% of patients): SNOMED CT, ICD*
Structured lab results (55% stage 2): Lab LOINC
E-prescribing (50% formulary check stage 2): RxNORM
Medications: RxNORM
Immunizations (Immunization registries): CVX, MVX
Procedures (summary of care): CPT, HCPCS
Documents (summary of care): LOINC
The “Greater Plains Collaborative”  
Epic EHR Sites: Vocabulary Deployment

<table>
<thead>
<tr>
<th>Domain</th>
<th>Ontology/Code sets</th>
<th>Value sets</th>
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</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
<td>HL7/OMB</td>
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<tr>
<td>Diagnoses</td>
<td>SNOMED CT; ICD-9-CM; ICD-10-CM (IMO)</td>
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<tr>
<td>Clinical findings</td>
<td>SNOMED CT (Clinical LOINC)</td>
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<td>Lab findings</td>
<td>Lab LOINC</td>
<td>SNOMED CT</td>
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<td>Allergies</td>
<td>SNOMED CT; RXNORM</td>
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<tr>
<td>Procedures</td>
<td>CPT, HCPCS, SNOMED CT</td>
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<tr>
<td>Medication orders</td>
<td>RXNORM</td>
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Available in most implementations  
Must be mapped per Epic  
Requires extension of Epic data model
**Goal:** lifetime data density; data standardization and interoperability between systems and networks

**Figure 3.1.** Comprehensive and complete data example from KUMC: heat map of percentage of proposed data elements from the HER and billing sources recorded in six month intervals surrounding the data of breast cancer diagnosis specified by the hospital tumor registry.
Web based for user. Just another tab in the browser.

All data stays on the server so there’s no data release and risk of re-identification due to a lost file.

i2b2 Plugin invokes a program that creates a Rda file in their directory on the server.
Identified data server
i2b2 compatible
star schema
Staged
source data
De-identified server
i2b2 compatible
star schema
De-identification process
secure FTP/ETL
Application server
RStudio Server
plots, statistics
Hive
rgate
R scripts
RStudio IDE web client
Another tab in browser
Investigator's client
One tab in browser
RStudio Server
Source System files
(EMR dump, UHC CDB extract)
Staged
source data
monthly refresh ETL
i2b2 compatible
star schema
3513 patients had a UHC-defined septicemia diagnosis

2912 patients were an Emergency Admission

2861 patients age were 18 years or older

2722 patients had an exposure to an Antibiotic in the encounter

1839 had ED Triage documentation during the encounter

1836 had the Sepsis Screen Used during the encounter

1223 had 2 SIRS criteria, organ dysfunction and suspicion/treatment of infection

717 MD notified

1244 patients had 1st antibiotic admin within 24 hours (1474 encounters)

Average time to sepsis screening 2.9 hours, median 49 minutes

Note: 28 patients who lacked an ED departure time were excluded from further analysis

Average time in ED is 7.9 hours, median 7.1

i2b2 could define cohort

Cohorts above line defined with i2b2

Cohorts below line further refined with R

cohort refinement with R

261 had 1st antibiotic admin before sepsis screening (277 encounters)

1040 had 1st antibiotic admin after sepsis screening (1197 encounters)

993 had 1st antibiotic admin given in ED (1140 encounters)

316 had 1st antibiotic admin not in ED (334 encounters)

Average time spent in ED is 8.7 hours, median 7.6

Average time spent in ED is 6.7 hours, median 6.6
Density Plots: Time from Arrival to First Antibiotic

**Broad Spectrum versus Vancomycin**

**Lag when given outside Emergency Room**

**Lag in Broad Spectrum after Vancomycin**

**Administration relative to RN Sepsis Screen**

- **Drug**
  - broad
  - vanc

- **When**
  - in.ed
  - not.in

- **Admin**
  - before
  - after
Incorporating Patient Reported Outcomes and PPRNs?: REDCap Integration and Data Delivery

- **REDCap registries into i2b2** allows intuitive exploration
  - Researchers may need less abstraction as data is extracted from the EMR.

- **i2b2 into REDCap**: inherit security model, graphical/export tools
Current Challenges

• Activating a large diverse network
  – Marshaling local talents while meeting deadlines
  – Getting people engaged act as team

• Establishing Legal/Regulatory Foundation
  – IRB Reciprocity, Data Sharing Agreement, Memorandum of Agreement and Operating Procedures (modeled on MARCH)

• Reconciling Mini-Sentinel and Data Sharing
  – Central PCORI needs versus GPC needs (eg. tumor registry) and supporting PCORNet investigators bottom up
  – Analysis Framework and shipping data to researchers

• Integrating Research into the Patient/Clinical Workflow
  – Will be a new frontier at many places like KUMC/Epic
  – Challenges deploying across multiple EHR environments
So... why the “Greater Plains Collaborative”?...

Greater Plains Collaborative Objective

- Lek: gather in the the Spring on a Booming Ground to attract other Greater Prairie Chickens
- If you dance by yourself, you’re not attracting researchers interested in generalizable results
- GPC: CTSAs create ideal habitat for clinical researchers to come and study our state’s populations and develop methods to improve our communities health outcomes
- Data, IRB, and governance in place so we can enable Comparative Effectiveness Research trials and Patient Reported Outcome collection
Want to see what people have? Babel!

- [http://babel.gpcnetwork.org/i2b2/webclient](http://babel.gpcnetwork.org/i2b2/webclient)

- Email Dan or I if you want access
  - dconnolly@kumc.edu  rwaitman@kumc.edu
References

• GPC Contract Milestones and Proposal: http://informatics.gpcnetwork.org/trac/Project/attachment/wiki/PMO/Copy%20of%20Global%20Milestones%20CDRNs_12192013rwv7_Reviewed%20022222014WaitmanAdjusts02252014.xlsx

• PCORNet: http://pcornet.org

• GPC Development: http://informatics.gpcnetwork.org

• GPC: http://www.gpcnetwork.org

• Babel, GPC warehouses: https://babel.gpcnetwork.org

• PCORI: http://www.pcori.org/funding-opportunities/pcornet-national-patient-centered-clinical-research-network/

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