PCORNNet and the PaTH Clinical Data Research Network

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Outline

• Debunking the RCT
• Introducing the Learning Health System
• Using Clinical Data for Research
• PCORNet
• The PaTH Clinical Data Research Network
• Examples of PCORNet and PaTH studies
• Opportunities for Penn State researchers
(i.e., randomized controlled trials)

DEBUNKING THE RCT
The Holy Grail of Evidence Based Medicine

RANDOMIZED
CONTROLLED TRIALS
Do RCTs work?

Well, they sure work out well for me.
Our national clinical research system is well-intentioned but flawed

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

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

INTRODUCING THE LEARNING HEALTH SYSTEM
Silos
• How research has traditionally been done

• A learning health system: research informs clinical practice, and clinical practice informs research
USING CLINICAL DATA FOR RESEARCH
big data
What is Big Data?

• Data that is BIG in volume, velocity, and variety
• EHR data for typical middle-aged person = size of the collected works of Shakespeare
• Patient reported outcomes, mobile sensors, social networks
• Data ≠ Knowledge

hemoglobin A1c = 8.2%
The National Patient-Centered Clinical Research Network

PCORNET
We face many important, unanswered questions about health care.

But our current research system is not set up to answer these questions in the most useful and efficient way.

We need to link patients, clinicians, health systems, and researchers as partners.

And harness health data to foster knowledge that can lead to better care.

Together, partners can decide what questions to study and how to use the data.

And get answers more quickly to the health and healthcare questions that matter most.

A collaborative national resource using the power of partnerships and health data for better research.

That’s the vision of PCORI's Patient-Centered Clinical Research Network.
We face many important, unanswered questions about health care.

- “What type of chemo is best for a breast cancer patient diagnosed at age 82?”
- “My son was diagnosed with ADHD. What risks does he face if he goes on meds?”
- “What can my hospital do to reduce readmission rates?”
- “How can I help my patient with chronic back pain decide on the best treatment?”
But our current research system is not set up to answer these questions in the most **useful** and **efficient** way.
We need to link patients, clinicians, health systems, and researchers as partners.
And harness health **data** to foster **knowledge** that can lead to **better care**.
Together, **partners** can decide what questions to study and how to use the data.
And get **answers** more quickly to the health and healthcare questions that matter most.
A collaborative national resource using the power of partnerships and health data for better research.

PCORnet is an initiative of the Patient-Centered Outcomes Research Institute
With sites and partners in every state...

...And protection of patients’ privacy and data security.
That’s the vision of **pcornet**
The National Patient-Centered Clinical Research Network
PCORnet embodies a “community of research” by uniting systems, patients & clinicians.

PCORnet: A national infrastructure for patient-centered clinical research
Introducing PCORnet:
The National Patient-Centered Clinical Research Network

This map depicts the number of PCORI-funded Patient-Powered or Clinical Data Research Networks that have coverage in each state.
# Penn State PaTH Team

## Site PI
- **Cynthia Chuang, MD, MSc**
  - Professor of Medicine and Public Health Sciences (Division of General Internal Medicine)

## Site Co-PI
- **Wenke Hwang, PhD**
  - Associate Professor of Public Health Sciences (Division of Health Services Research)

## Clinical Research
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  - Professor of Medicine (Division of Pulmonary, Allergy, and Critical Care)

## Clinical Champions*
- **Edward Fox, MD**
  - Professor of Orthopaedics and Rehabilitation Medicine
- **Andrew Fox, MD**
  - Assistant Professor of Medicine and Public Health Sciences
- **Ann Rogers, MD**
  - Associate Professor, Director: Penn State Surgical Weight Loss Program
- **Christopher Sciamanna, MD, MPH**
  - Professor of Medicine and Public Health Sciences (Division of General Internal Medicine)

## Clinical Leaders
- **Jennifer Kraschnewski, MD, MPH**
  - Assistant Professor of Medicine and Public Health Sciences (Division of General Internal Medicine)
- **Gerald Naccarelli, MD**
  - Professor of Medicine (Heart and Vascular Institute)

## Clinical CHAMPIONS*
- **Sanjoy Bhattacharjee, MS**
  - Data Warehouse and Decision Support Team
- **Rai Dzomba, MS, PhD**
  - Assistant Professor of Public Health Sciences
- **Khaleel Iskandarani, MPH**
  - Research Data Analyst
- **David Mack, BS**
  - Data Warehouse and Decision Support Team
- **Darrell Walter**
  - Director, Data Warehouses and Decision Support Team

## Project Manager
- **Jody McCullough**
  - PaTH Research Project Manager

## Research Staff
- **Kayla Confer, MS**
  - Research Assistant
- **Anne Dinmook, BA**
  - Project Manager (Division of Pulmonary, Allergy, and Critical Care)
- **Jessica Garber, BS**
  - Research Assistant

## Patient Partners
- **Jim Carne**
  - IPF
- **Bob Meehan**
  - FNP/C
- **Ray Hulings**
  - AFib
- **Millie Morris**
  - Weight
- **Tom Maioli**
  - AFib
- **Julie Tice**
  - Weight

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*Revised: 2/05/2015*
• Established institutional relationships
• PaTH Network Protocol Review Committee and Centralized IRB
• Data Use Agreements
• Common Data Model
• PaTH i2b2 → Central Desktop
• Established 3 initial study cohorts aided by patient partners
• Patient-reported outcomes
• Biorepositories
EXAMPLES OF PCORNET AND PATH STUDIES
Targeted Interventions to Prevent Chronic Low Back Pain in High Risk Patients: A Multi-Site Pragmatic RCT

Anthony Delitto, PhD, PT
Professor, Department of Physical Therapy
University of Pittsburgh

PCORI Pragmatic Clinical Studies and Large Simple Trials to Evaluate Patient-Centered Outcomes
$14M (5 years)
Integrating Patient-Centered Exercise Coaching into Primary Care to Reduce Fragility Fractures

Christopher Sciamanna, MD, MPH
Professor of Medicine and Public Health Sciences
Penn State College of Medicine

PCORI Pragmatic Clinical Studies and Large Simple Trials to Evaluate Patient-Centered Outcomes
$14M (5 years)
A Patient-Centered PaTH to Addressing Diabetes: Impact of State Health Policies on Diabetes Outcomes

Jennifer Kraschnewski, MD, MPH
Assistant Professor of Medicine and Public Health Sciences
Penn State College of Medicine

PCORI National Experiments Network: A Collaborative Initiative
$2.3M (5 years)
• ADAPTABLE—the Aspirin Study
• Bariatric surgery
• Antibiotic Use in Infants and Obesity
THE QUESTION: Clinicians often prescribe aspirin to prevent strokes and heart attacks in people living with heart disease. Research has yet to determine the best dose to use, since aspirin can cause serious side effects – like bleeding – in some people.

- Pragmatic clinical trial—81mg vs. 325 mg
- ADAPTABLE will include ~20,000 patient living with heart disease from 8 CDRNs
• Bariatric surgery is becoming more commonly performed in the U.S.

• Research Question: Which of the three most commonly performed procedures results in best patient outcomes?

• PCORnet observational research study
• Previous research has shown a link between use of antibiotics and increased risk for obesity in children

• Studying relationship between antibiotic use in first 2 years of life and weight gain in later childhood

• PCORnet observational research study will include ~600,000 patients
• **www.pathnetwork.org**

• **Contact Penn State PaTH Team**
  – Cynthia Chuang (Penn State PaTH PI)
  – Jody McCullough (Penn State PaTH Project Manager)

• **Questions?**