Using Patient-Centered Outcomes Research In Practice:

Building Capacity for PA Dissemination
Faculty

William Lawrence, MD, MS
Senior Clinical Advisor, Office of the Deputy Executive Director for Patient-Centered Research Programs
Patient-Centered Outcomes Research Institute (PCORI)
Washington, DC

Viet Le, MPAS PA-C FACC FAHA
Associate Professor of Research/Preventive Cardiology PA
Intermountain Health
Salt Lake City, UT
Learning Objectives

At the conclusion of this activity, participants should be able to:

• Define patient centered outcomes research (PCOR) and comparative effectiveness research (CER)

• Compare and contrast how PCOR and CER research designs differ to traditional research designs

• Access and assess PCOR and CER relevant to the patients under their care

• Incorporate PCOR and CER results into patient care activities
About Patient-Centered Outcomes Research Institute (PCORI)

• An independent research institute authorized by Congress in 2010 and governed by a 23-member Board of Governors representing the entire healthcare community

• Funds comparative clinical effectiveness research (CER) that engages patients and other stakeholders throughout the research process

• Seeks answers to real-world questions about what works best for patients based on their circumstances and concerns
PCORI’s Broad and Complex 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
Why is PCORI’s Work Needed?

• For all the advances it produces, traditional healthcare research has not answered many questions patients face

• People want to know which preventive, diagnostic, or treatment option is best for them

• Patients and their clinicians need information they can understand and use
How is PCORI Research Different?

• We aim to produce evidence that can be easily applied in real-world settings

• We focus on answering questions most important to patients and those who care for them

• We engage patients, caregivers, clinicians, insurers, employers, and other stakeholders throughout the research process
PCORI Funds Comparative Clinical Effectiveness Research (CER)

- Generates and synthesizes evidence comparing benefits and harms of at least two different methods to prevent, diagnose, treat, and monitor a clinical condition or improve care delivery
- Measures benefits in real-world populations
- Describes results in subgroups of people
- Helps consumers, clinicians, purchasers, and policy makers make informed decisions that will improve care for individuals and populations
- Informs a specific clinical or policy decision

*Note: We do not fund cost-effectiveness research*

Adapted from *Initial National Priorities for Comparative Effectiveness Research*, Institute of Medicine of the National Academies
PCORI Fund Patient-Centered Outcomes Research (PCOR)

PCOR is a relatively new form of CER that...

• Considers patients’ needs and preferences, and the outcomes most important to them
• Investigates what works, for whom, under what circumstances
• Helps patients and other healthcare stakeholders make better-informed decisions about health and healthcare options
Implementing PCOR – Outcomes Important to Patients

The PA’s Path to Patient-Centered Care
Traditional Health “Care” Approach

Disease Focused
• Has the patient had the appropriate initial or ongoing screening/surveillance?
• Is the patient on guideline directed medications?
• Which medications have the most benefit?
• Is the patient eligible for invasive interventions?
• Has the patient received counseling on diet and lifestyle?
• Has the patient seen or been referred to appropriate specialists?
• Has the patient been scheduled for follow-up?

Patient Focused - PCOR
• Given my personal characteristics, conditions, and preferences, what should I expect to happen to me?
• What are my options? What are the potential benefits and harms of those options?
• What can I do to improve the outcomes that are most important to me?
• How can clinicians and the healthcare systems they work in help me make the best decisions about my health and health care?
Diabetes Mellitus – Why We Treat

Medical Rationale
387 million people across the world have diabetes, 90% of those are Type II and lead to significant complications, medical sequelae

• Reduce or Avoid patient-level development of co-morbid conditions: cardiovascular events, nephropathy, neuropathy, retinopathy
• Follow guidelines-directed care
• Improve population and community health

Patient Concerns
• How will/can I afford the foods I am recommended to eat? Will I like the foods? Are they available at the stores I frequent?
• What foods should I eat? How do I prepare/cook healthy foods?
• Can I afford the medications?
• What side effects will I experience from medications?
• Will the medications harm me?
• What problems might occur if I don’t treat? Will this shorten my life? Will I lose limbs or nerve feelings?
• Will treatment be inconvenient?
Reviewing the Evidence for Treatment: Traditional Medical Literature Scan

How does the SGLT2i class compare to GLP-1RA for reduction of A1c and major adverse cardiovascular events (MACE)?

Figure 1. The risk reduction in three-point MACE in GLP-1RA and SGLT2i trials. MACE: major adverse cardiovascular events; GLP-1RA: glucagon-like peptide 1 receptor agonists; SGLT2i: sodium-glucose cotransporter 2 inhibitors.

Reviewing the Evidence for Treatment:

How does the SGLT2i class compare to GLP-1RA for reduction of A1c and major adverse cardiovascular events (MACE)?

This data may help the PA to understand the impact of these therapies on A1c and MACE.

However, may not translate well to educating the patient and addressing what may be top concerns for the patient.

Figure 1. The risk reduction in three-point MACE in GLP-1RA and SGLT2i trials. MACE: major adverse cardiovascular events; GLP-1RA: glucagon-like peptide 1 receptor agonists; SGLT2i: sodium-glucose cotransporter 2 inhibitors.

Pragmatic Diabetes Treatment Question

Will daily glucose monitoring lead to lower glucose levels in patients with diabetes and not using insulin?

Potential Benefit

• Knowledge of glucose levels may help direct diet and inform medication titration/addition, and provide additional value to A1c obtained every 3-6 months

• Improve patient DM self-efficacy (confidence in managing their own chronic illness), DM-related quality of life, DM treatment satisfaction, patient-provider communication

• Lower hypoglycemia frequency and health care utilization

Patient Burden

• Cost of purchasing glucometer and recurring costs of purchase and replacement of testing strips and sharps

• Remembering to complete self-monitoring of blood glucose daily

• Understand results and know what to do based on the results (e.g., nothing, change diet intake, increase medications, etc.)
The Monitor Trial

Patients randomized from 15 North Carolina Primary Care Practices
N=450

1. No self monitoring blood glucose
   N=150

1. Once-daily testing with immediate glucose readings
   N=150

2. Enhanced tailored automated patient feedback
   N=150

Primary Endpoint
1. Glycemic Control
2. Health-Related Quality of Life

Findings
NO DIFFERENCE in
1. Glycemic control
2. HRQOL – including hypoglycemia frequency, health care utilization, or insulin initiation

Translating the Data to Patient-Centered Care

Patient: “I have diabetes. Does this mean I have to test my blood sugar everyday?”

Clinician: “Not all patients with the diagnosis of diabetes benefit from daily glucose monitoring. In fact, a study of those not on insulin found that daily monitoring did not improve sugar control, add any benefit to quality of life, or decrease health care use.”

Provide Patient Education From PCORI

Blood Sugar Testing to Manage Type 2 Diabetes in Patients Who Don’t Need Insulin (pcori.org)

Diets: Which Evidence-Based Diet Works Best?

- We recommend “healthy lifestyle” to our patients which includes diet and activity for many different types of chronic diseases or to reduce risk. However, with so many evidence-based diets, which one works best for which disease, patient population?

**Example of Recommended Diets:**

- Dietary Approaches to Stop Hypertension (DASH)
- Mediterranean Diet
- MyPlate
- Centers for Disease Control and Prevention National Diabetes Prevention Program’s Calorie Counting (CC)
# Comparative Effectiveness Trial - Diets

**Overweight, low income, mostly Latinx**  
N=261

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>MyPlate</td>
<td>131</td>
</tr>
<tr>
<td>Calorie Counting (CC)</td>
<td>130</td>
</tr>
</tbody>
</table>

**Primary PCO Endpoint**  
Satiation and Satiety

**Primary Measurement Endpoints**  
Waist circumference and body weight

## Findings
Both groups reported improved satiation and satiety scores. Weight circumference also decreased in both. MyPlate participants had improved (lower) systolic blood pressure compared to CC group.

## ADDITIONAL FINDINGS
MyPlate is a simpler diet with similar outcomes. It also had improved reduction of central adiposity that continued beyond 6 months from study start.

Translating the Data to Patient-Centered Care

Clinician: “Following a healthy diet is important for reducing your longer-term risk for disease, improve your overall health, and may help with weight control.”

Patient: “Will it be hard to follow? What one lowers my weight more?”

Clinician: “A study of two diets, MyPlate and Calorie Counting showed they both reduce weight. However, the MyPlate diet is a simpler one to follow and may provide more central (abdominal) circumference (size) reduction.”

Discuss Results of PCORI Funded CER Trial

Randomized Comparative Effectiveness Trial of 2 Federally Recommended Strategies to Reduce Excess Body Fat in Overweight, Low-Income Patients: MyPlate.gov vs Calorie Counting | Annals of Family Medicine (annfammed.org)

Getting Research Into Practice
PCORI-Funded AHRQ Systematic Reviews

• **Systematic Reviews** use methodologically rigorous methods to produce a synthesis of the evidence

• **Primary Use:** Inform guidelines and evidence-based clinical practice

• **Nominating Partners:** Guideline writing organizations

• **Agency for Healthcare and Research (AHRQ)/PCORI Collaboration**
From Evidence Synthesis to Evidence-Based Guidelines

Source: https://ascopubs.org/doi/10.1200/JCO.20.03465
Shared Decision Making (SDM)

...where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences (Elwyn, et al. BMJ. 2010; 341: c5146.)
Providing Evidence and Supporting Decisions

**JAMA | Original Investigation**

**Association Between Radiation Therapy, Surgery, or Observation for Localized Prostate Cancer and Patient-Reported Outcomes After 3 Years**

Daniel A. Barocas, MD, MPH; JoAnn Alvarez, MA; Matthew J. Resnick, MD, MPH; Tatsuki Koyama, PhD; Karen E. Hoffman, MD, MHSc, MPH; Mark D. Tyson, MD; Ralph Conwill, BS; Dan McCollum, BS; Matthew R. Cooperberg, MD, MPH; Michael Goodman, MD, MPH; Sheldon Greenfield, MD; Ann S. Hamilton, PhD, MA; Mia Hashibe, PhD, MPH; Sherrie H. Kaplan, PhD, MS, MPH; Lisa E. Paddock, PhD, MPH; Antoinette M. Stroup, PhD; Xiao-Cheng Wu, MD, MPH; David F. Penson, MD, MPH

**JAMA Internal Medicine | Original Investigation**

**Effectiveness of an Intervention Supporting Shared Decision Making for Destination Therapy Left Ventricular Assist Device The DECIDE-LVAD Randomized Clinical Trial**

Larry A. Allen, MD, MHS; Colleen K. McIlvnamen, DNP, ANP; Jocelyn S. Thompson, MA; Shannon M. Dunlay, MD, MS; Shane J. LaRue, MD, MPH; Eldrin F. Lewis, MD, MPH; Chetan B. Patel, MD; Laura Blue, DNP, ANP; Diane L. Fairclough, PhD; Erin C. Leister, MS; Russell E. Glasgow, PhD; Joseph C. Cleveland Jr., MD; Clifford Phillips; Vicie Baldridge; Mary Norine Walsh, MD; Daniel D. Matlock, MD, MPH
Getting SDM Into Practice

Improving Shared Decision Making for Men with Prostate Cancer That Has Not Spread

Expanding a Shared Decision Making Program for Patients Considering LVAD Treatment

Finding Data to Support Implementation of Patient-Centered Approaches, Shared Decision Making

PCORI in the Literature | PCORI

Refine Results:

- Article Type
  - Paper Resulting From PCORI-Funded Research Study with results
    - (2522)
  - CER Results (357)
  - Other Results (2164)
  - Paper Resulting From PCORI-Funded Research Study conducted using...
    - (153)

JAMA

- Direct Oral Anticoagulants vs Low-Molecular-Weight Heparin and Recurrent VTE in Patients With Cancer

JAMA NETWORK OPEN

- Health Insurance Coverage and Postpartum Outcomes in the US: A Systematic Review
Dissemination and Implementation (D&I) of Results

• We are committed to extending the pathway from PCORI-funded research through dissemination and implementation – to assure that research findings are used to improve health care and health

  • Enhancing awareness of evidence useful to people and organizations as they make health decisions
  • Speeding the integration of this evidence into practice
Evidence Updates

Comparing Two Common Types of Weight Loss Surgery

Weight loss surgery, also called bariatric surgery, helps people with obesity lose weight. A recent study compared the benefits and harms of two common types of weight loss surgery.

Findings

- A PCORI-funded study found that people lost more weight with gastric bypass than with sleeve. But more people who had gastric bypass needed additional surgeries and hospitalizations than those who had sleeve.
- Among patients with type 2 diabetes, about the same number of people no longer had to take medicine for their diabetes with both surgeries. However, more people with sleeve had their diabetes reverse.

Comparing the Benefits and Harms of Bariatric Procedures

A recent study documented differences in the benefits and harms of two common types of bariatric surgery. The findings can help clinicians and patients work together to make informed decisions regarding patient care.1, 2

1. Obesity is associated with a range of comorbidities including type 2 diabetes mellitus (T2DM). Bariatric surgery may be a viable treatment for patients with a body mass index (BMI) of 35 or greater who are unable to lose weight through diet and exercise alone. However, outcomes vary across procedures.
2. A PCORI-funded study compared the benefits and harms of the two most common types of weight loss surgery: Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG). The study included a third type of surgery, adjustable gastric banding. Because this surgery is no longer commonly used, the results are not included in this Evidence Update.

Findings

- A PCORI-funded study found that both procedures resulted in weight loss and remission of T2DM for the majority of patients. Overall, RYGB had better overall weight loss results and a more significant impact on minimizing T2DM remission and improving glycemic control compared with SG. However, SG was also associated with a higher risk of adverse outcomes such as additional abdominal surgeries and hospitalization.
- Type 2 Diabetes Outcomes
  - RYGB and SG resulted in clinically comparable T2DM remission rates throughout the five-year period following surgery.2 Remission is defined as HbA1c under 6.5% after six months without a diabetes medication prescription. More T2DM remission occurred within two years of surgery. The risk of relapse was 25% lower in patients who had RYGB compared with patients who had SG.
  - Percent of Patients Experiencing Type 2 Diabetes Remission and Relapse
    - RYGB: 88% (66%)
    - SG: 81% (48%)

https://www.pcori.org/impact/evidence-updates
Interested in PCOR? How to Get Involved

PCORI website
www.pcori.org
for research funding opportunities
Getting involved: Engagement in the Research Literature

Engagement in Health Research Literature Explorer

About this Literature Explorer

Example of Engagement in Health Research

Displaying 1 - 25 of 892 results

MEDICAL CARE
Implementation of Complex Interventions: Lessons Learned From the Patient-Centered Outcomes Research Institute Transitional Care Portfolio

JOURNAL OF SUBSTANCE ABUSE TREATMENT
Extended release injectable naltrexone before vs. after release: A randomized trial of opioid substitution treatment patients

Refine Results:

Search journal Articles

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Getting Involved With PCORI

Engagement

The Value Of Engagement

Engagement in Health Research Literature

Influencing The Culture Of Research

Engagement Award Program

Engagement Resources

Engage With Us

PCORI Ambassador Program

Become A Peer Reviewer

Become A Merit Reviewer

Suggest A Patient-Centered Research Question

Participate in PCORI Events

Engage with Us

Patient and stakeholder input is critical to our success and in helping ensure that our work is truly patient centered. We are committed to continuously seeking input from the public to guide what we do.

Through public comment periods, opportunities to review research

Questions about Public and Patient Engagement?

For questions about how PCORI-funded projects meaningfully engage patients and the public in research or how healthcare stakeholders can engage

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PA Engagement

I am a Patient Engagement Officer (PEO) for the Intermountain site of the Greater Plains Collaborative (GPC) – gpcnetwork.org

GPC represents a network of 13 medical centers (see picture)

This collaborative allows for aggregation of patient data (34 million patients), to research disease, therapies, disparities, etc. and compare effectiveness of therapies and approaches
Summary

• PCOR/CER aims to generate effectiveness information focusing on informing decisions
  • Take known and existing therapies and understand which are more applicable and effective under a patient-centered lens
  • Intentionally invite patient perspectives into study designs, treatment choices, and including outcomes that are most important to them

• Getting research into practice:
  • Getting the evidence into the hands of those who need it (In a form they understand!)
  • Intervention to speed the adoption of the evidence into practice
Contact Information

William Lawrence – wlawrence@pcori.org

- 202.827.7700
- info@pcori.org
- www.pcori.org
- @pcori
- /PCORInstitute
- PCORI
- /pcori

Viet Le – Viet.Le@imail.org

- 801.245.9355
- @VietHeartPA