New and Emerging Evidence

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National Academy for State Health Policy
October 23, 2017
New and Emerging Evidence

Lots on the way:

1) Uterine Fibroids
2) Contralateral Prophylactic Mastectomy and Breast Cancer
3) Using Technology to Deliver Multi-Disciplinary Care to Individuals with Parkinson Disease in Their Homes
4) Group Exercise to Prevent Walking Difficulty in At-Risk Older Adults
5) Depression Care among Low-Income Patients
6) Preventing Venous Thromboembolism
7) Shared Decision Making in the Emergency Department: Chest Pain Choice
8) **Glucose Monitoring in Non-Insulin Treated Diabetes**
9) Improving Childhood Obesity Outcomes
10) Peritoneal Dialysis or Hemodialysis for Kidney Failure
11) Reducing Health Disparities in Appalachians with Multiple Cardiovascular Disease Risk Factors
New and Emerging Evidence

12) Treating Peripheral Arterial Disease
13) Treatment Choices among Minorities with Lupus
14) Intravenous vs. Oral Antibiotic Therapy for Serious Bacterial Infections
15) Hospital-PCMH Collaboration within an ACO to Improve Care Transitions
16) Community Health Worker/Mobile Chronic Care Team Strategy
17) Transitional Care for Individuals with Serious Mental Illness
18) Corticosteroids versus Anti-TNF Alpha Therapy for Inflammatory Bowel Disease
19) Broad vs. Narrow Spectrum Antibiotics for Acute Respiratory Tract Infections in Children
20) Decision-Support Tool for Adult Consumers with Mental Health Needs and their Care Managers
21) Navigation for Disadvantaged Women with Depression
22) Self-Care Management of Cancer Symptoms
23) Surveillance Imaging Modalities in Breast Cancer Survivors
New and Emerging Evidence

24) Literacy-Adapted Psychosocial Treatments for Chronic Pain
25) Supplemental Oxygen for Pulmonary Fibrosis
26) Shared Decision Making in Parents of Children with Head Trauma: Head CT Choice
27) Developmental Trajectories of Children with Cerebral Palsy
28) Patient-Defined Treatment Success and Preferences in Stage IV Lung Cancer Patients
29) Chronic Kidney Disease in Zuni Indians
30) Use of a Web-Portal by Patients with Complex Chronic Conditions
31) Optimal Patient-Centered Care for US Trauma Care Systems
32) Promoting Informed Decisions about Lung Cancer Screening
33) Decision Aid for Therapeutic Options in Sickle Cell Disease
34) Telehealth Self-Management Program in Older Adults Living with Heart Failure in Health Disparity Communities
35) Ovarian Cancer Patient-Centered Decision Aid
New and Emerging Evidence

36) Smoking Cessation Versus Long-Term Nicotine Replacement among High-Risk Smokers
37) A Comparison of Non-Surgical Treatment Methods for Patients with Lumbar Spinal Stenosis
38) Risk Stratification for Improving Primary Care for Back Pain
39) Addressing HIV Treatment Disparities Using a Self-Management Program and Interactive Personal Health Record
40) A Toolbox Approach to Obesity Treatment in Primary Care
41) Mobile Application for Improving Symptoms and Adherence to Oral Chemotherapy in Patients with Cancer
42) Shared Decision-Making Tool for Stent Selection in PCI
43) Navigator Guided e-Psychoeducational Intervention for Prostate Cancer Patients and Their Caregivers
44) Peer-Facilitated Support Group and Cognitive Behavioral Therapy for Hoarding Disorder
New and Emerging Evidence

45) Long Term Outcomes of Lumbar Epidural Steroid Injections for Spinal Stenosis
46) **Decision Making in Localized Prostate Cancer**
47) Health Plan Initiative to Mitigate Chronic Opioid Therapy Risks
48) Burnout in Mental Health Care
49) Integrated Care and Patient Navigators for Latinos with Serious Mental Illness
50) Increasing CRC Screening Among Hispanic Primary Care Patients
51) Comparing Effectiveness of Treating Depression With and Without Comorbidity to Improve Fetal Health
52) Community Engagement to Address Depression Outcomes Disparities
53) Advance Care Planning for Perioperative Cancer Patients and Families
54) Behavioral Health Homes for Adults with Serious Mental Illness
55) Decision Aid for Ventricular Assist Device Placement
56) Improving QOL in Latina Breast Cancer Survivors and Their Caregivers
Content and Resources Arranged by Topic

Cardiovascular Disease

No. 1 cause of death
800,000 deaths each year
$320 BILLION in healthcare costs and lost productivity annually

Source: Centers for Disease Control and Prevention

To address this problem, PCORI has funded 11 comparative clinical effectiveness research studies and related projects to help patients and those who care for them make better-informed decisions about their options for preventing, diagnosing, and treating cardiovascular disease.

PCORI Answers Critical Questions

Evidence gaps can make it difficult to know which approach to cancer care will work best given a particular patient’s needs. PCORI funds studies that seek to help patients, clinicians, and others answer various questions they might have about treatment options, such as:

Patient: I want to avoid having another deep vein blood clot. Which of the many blood-thinning drugs would be most safe and effective for me over the long term?

Doctor: My 85-year-old father is having heart trouble after suffering a stroke. What long-term blood-thinning drug for heart disease is best and least likely to cause bleeding? Should I consider a medication to lower his blood pressure?

Patient: I have breast cancer and plan to undergo chemotherapy. How do I know that my doctor has all the information he needs when discussing treatment options, so that we take into account all my health issues?

Patient: I have a family history of cancer and plan to undergo treatment. How often do I need to undergo mammograms?

Cancer Study Spotlights

Breast Cancer Screening: Annual versus Personalized

National guidelines call for middle-aged women to get annual mammograms, even though they have different risks for developing breast cancer. This study compared annual screening versus screening related to individual risk levels.

Results Highlights for Patients and Researchers

Early-stage prostate cancer can be treated in different ways. Two recent PCORI-funded researchers produced new information on the effects of treatments and can help patients navigate their treatment decisions.

Informed Decisions about Lung Cancer Screening

Annual lung cancer screening for smokers could save 20,000 lives, but it may also lead to some harms. This study compared the impact and outcomes and found that some smokers may benefit from an informational video aimed at standard patient educational materials.

Pain Care and Opioids

Chronic pain costs an estimated $600 billion in lost productivity and wages, medical expenses, and disability payments in the U.S.

Source: Centers for Disease Control and Prevention

To address this problem, PCORI has funded 59 comparative clinical effectiveness research studies and related projects to help patients and those who care for them make better-informed decisions about their options for preventing, diagnosing, and treating chronic pain while reducing inappropriate use or overuse of opioids.

PCORI Answers Critical Questions

Evidence gaps can make it difficult to know which pain treatments work best while reducing the risks associated with long-term opioid use, given a patient’s needs. PCORI funds studies that seek to help patients, clinicians, and others answer questions they might have about treatment options, such as:

Patient: After having so many stories of people who struggled with opioid addiction, I’m reluctant to use these drugs for my back pain. Would non-opioid medications work as well as pain drugs for me?

Patient: I don’t find non-opioid medications very helpful. When I don’t understand what my doctor is talking about when prescribing my chronic pain, what would help me get more involved in making choices about my pain care?

Patient: I have many patients with chronic pain who have trouble going about their day-to-day business. Other than prescribing them opioids, what other strategies could prevent that have proven effective in reducing pain?

Tackling Chronic Pain While Reducing Opioid Use

This study found that a clinical plan to encourage safe opioid prescriptions for pain experienced in lowering patients’ scores.

Chronic Pain Treatment without Opioids

This study compared how well cognitive behavioral therapy and mindfulness meditation were in managing pain and enabling people to reduce or discontinue opioid use.

Non-Opioid Therapies for Chronic Low Back Pain

This study compared how well cognitive behavioral therapy and mindfulness meditation were in managing pain and enabling people to reduce or discontinue opioid use.
Fact Sheets Highlight Activities and Portfolios

**PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE**

**RESEARCH SPOTLIGHT ON**

**Cancer**

There are more than 100 kinds of cancer, each with a distinct pathology and a unique list of causes and environmental triggers. People facing a cancer diagnosis often face decisions over which treatments to pursue, each with its own risks and benefits. This choice is often made with little to no assistance, with most patients being given their individual circumstances and potential outcomes. This highlights the need for patients to make informed decisions, guided by the latest research and evidence-based practices.

**1.69 MILLION**

people in the United States were diagnosed with cancer in 2016

(Source: Centers for Disease Control and Prevention)

**87.8**

is estimated to be the number of people who will die from cancer in 2016

(Source: American Cancer Society)

**Research Addressing Questions That Matter**

PCORI funds comparative clinical effectiveness research (CER) to determine which healthcare options work best for which patients, based on their needs and preferences. CER produces evidence that helps people make better-informed healthcare choices.

**STUDY SPOTLIGHT**

**Patient-Centered Information for Decision Making in Localized Prostate Cancer**

This study analyzed quality of life changes over three years among prostate cancer patients who received either radical prostatectomy (surgery), external beam radiation therapy, or active surveillance. It found that those who had either surgery or radiation reported more adverse effects. However, quality of life levels remained among all patients after three years. More information may be found at www.pcnr.org/Prostate.

**PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE**

**RESEARCH SPOTLIGHT ON**

**Cardiovascular Disease**

Heart disease remains one of the leading causes of death in the nation, with many efforts to prevent cardiovascular conditions. When heart disease and stroke are treated, it can result in reduced risk and increased quality of life. This heart disease and stroke cost the nation $320 billion in healthcare costs and productivity in 2011, according to the US Department of Health and Human Services.

**Heart disease is the**

#1 cause of death in the United States, killing 614,348 people in 2018.

(Source: Centers for Disease Control and Prevention)

**Research Addressing Questions That Matter**

PCORI funds comparative clinical effectiveness research (CER) to determine which healthcare options work best for which patients, based on their needs and preferences. CER produces evidence that helps people make better-informed healthcare choices.

**STUDY SPOTLIGHT**

**Older vs. Newer Drugs for Preventing Recurring Blood Clots**

Patients who have a blood clot typically receive a blood thinning drug for three to six months. This study will compare two newer drugs, rivaroxaban and apixaban, to one another and to the older drug warfarin to evaluate each drug’s safety and effectiveness in preventing further clots in people who are at high risk for another. More information may be found at www.pcnr.org/Clots2019.

**STUDY SPOTLIGHT**

**Keeping Stroke Survivors Independently Longer**

Using the blood thinning drug warfarin results in patients living longer on average—but not longer among those who didn’t take the drug, this study also measured rates of major health problems, staying in their homes, and staying institutionalized in a healthcare facility. For the outcomes that mattered most to patients, achieving the researchers. More information may be found at www.pcnr.org/Stroke2019.

**PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE**

**RESEARCH SPOTLIGHT ON**

**Pain Care and Opioids**

Determining how to best treat pain is challenging for patients and clinicians. The alarming increase in opioid use and potentially fatal misuse has focused national attention on how to use these drugs appropriately and safely and treat opioid use disorders while also ensuring that people dealing with pain have a range of safe and effective treatment options available to them.

**100 MILLION**

adults in the United States are affected by chronic pain

(Source: National Academy of Medicine)

**33,000**

Americans died from opioid overdoses in 2015

(Source: Centers for Disease Control and Prevention)

**$600 BILLION**

Estimated total annual costs related to pain

(Source: National Institutes of Health)

**Addressing the Roots of the Opioid Crisis and Inadequate Pain Management**

PCORI funds comparative clinical effectiveness research (CER), which studies which healthcare options work best for which patients, based on their needs and preferences. PCORI-funded CER is filling the gap of evidence gaps in regards to both pain not related to cancer and opioid use disorders. The goal is not only to improve treatment for nociception-related pain and to prevent and treat opioid addiction but also to address the factors that cause these problems.

**PCORI-FUNDED CER STUDIES ARE DETERMINING WHAT’S MOST EFFECTIVE:**

- Managing acute and chronic pain
- Preventing unsafe prescribing of opioids
- Reducing reliance on opioids among people already using them
- Preventing opioid use disorders
- Treating opioid use disorders

**STUDY SPOTLIGHT**

**Alternative Therapies for Opioid-Treated Chronic Low Back Pain**

Many people with chronic low back pain as well as those who care for them are interested in alternatives to opioids, given the risks of addiction. This study is comparing how well two such alternative therapies—cognitive behavioral therapy and mindfulness meditation—work in easing pain and helping people reduce or discontinue opioid use. More details are at www.pcnr.org/After40989.

**PCORI | INFO@PCORI.ORG | FOLLOW US @PCORI**
Results of PCORI-funded Studies in Peer-reviewed Publications

- At least 60 articles have appeared in leading journals with results from PCORI-funded studies.
- Full text accessible for FREE as part of PCORI’s efforts to make results widely available.

Journal articles resulting from PCORI-funded research projects:

- FY2014: 56
- FY2015: 205
- FY2016: 190

As of May 2017
Public Reporting of Study Results

- PCORI release of findings
- Peer-reviewed publications that present results of PCORI-funded studies
- Initiatives to promote public access to peer-reviewed literature
- Reporting of results back to study participants
PCORI Public Release of Findings

Results posted to pcori.org

4 Results posted within next 90 days

9 Results to be posted within next 90 days

145 Results to be posted within next year
Engagement Case Study: Clinicians

American Urological Association

1:1 Engagement
- Invited to submit CER topics and questions
- PCORI funded two projects around prostate cancer decisions

Community Engagement
- Former AUA Board member and PCORI awardee Dave Penson, MD, participated in Hill Briefing

Dissemination and Implementation
- AUA served as key informant on evidence updates developed by PCOR Translation Center.
- AUA-branded evidence update to be disseminated via AUA to their membership

All activities lead to better science and better health outcomes
• Activities to disseminate results from PCORI-funded research on Current Treatments for Localized Prostate Cancer and Symptom-Related Quality of Life include:

  Evidence Updates for Clinicians and Patients
  Continuing Medical Education/Continuing Education
Resources for Putting Evidence to Use

Evidence for Decisions

PCORI provides Evidence Updates to highlight some of our important research findings. Feel free to print or download these materials for personal use.

Prostate Cancer

Early-stage prostate cancer can be treated in different ways. Two recent PCORI-funded research studies provide new information on the effects of treatments and can help patients navigate their treatment decisions.

- Prostate Cancer Evidence Update for Patients
- Prostate Cancer Evidence Update for Clinicians

Check back for Evidence Updates on additional topics in the coming months.

Interested in disseminating our Evidence Updates more broadly? Contact.

Putting Evidence to Work

In the past, it often has taken years for new evidence from clinical research to influence health care. And many times, these findings have failed to reach patients and families who could benefit from the information. Disseminating and promoting the uptake of research findings is part of PCORI’s legal mandate to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policymakers reach better-informed health decisions.

PCORI’s dissemination activities begin with the translation of all research findings into understandable summaries for posting on our website, with the help of the PCORI Translation Center.

CME/CE Activities

PCORI’s continuing medical education/continuing education (CME/CE) activities are designed to provide accredited professional education for clinicians in areas pertinent to patient-centered outcomes research and clinical knowledge. Any member of the healthcare community may access the activities at no cost. Find out more about the activities on our Blog or in our Newsroom.

The CME/CE activities are offered by different providers. Please review each provider’s requirements for earning a credit certificate or a certificate of participation.

- Contemporary Treatment Options for Prostate Cancer (Available soon)
- Applying Evidence from the PCORI PROSPER Studies in Stroke Prevention & Care
- Engaging Patients and Other Stakeholders: Guidance from the PCORI Engagement Hub

Contemporary Treatment Options for Prostate Cancer

This CME module will be available soon. Please check back here in the coming weeks.

Applying Evidence from the PCORI PROSPER Studies in Stroke Prevention & Care

This video activity is designed to support healthcare professionals, patients and caregivers, and other stakeholders in applying key findings from the PCORI-funded PROSPER studies to improve outcomes for patients with atrial fibrillation and stroke risk. An expert panel addresses key issues in care coordination for ischemic stroke prevention and recovery. Five short comparison videos feature focused discussions on specific applications of the insights into anticoagulant medication use and patient-centered perspectives revealed through the PROSPER studies.

This program is accredited for...
DECISIONAL DILEMMA

• Should we use a catheter for intravenous antibiotics through a PICC line, or should we use oral antibiotics?
  o Children who have been hospitalized for a severe infection (osteomyelitis or complicated pneumonia) require **weeks of antibiotic therapy** after discharge from the hospital
  o Antibiotics can be administered at home either orally or intravenously through a peripherally inserted central catheter (PICC)
  o Catheters carry a risk for serious complications in children, but limited evidence exists on the effectiveness of oral therapy
Treatment of Osteomyelitis in Children

MAIN PCORI STUDY FINDING

“Given the magnitude and seriousness of PICC complications, clinicians should reconsider the practice of treating otherwise healthy children with acute osteomyelitis, [and] complicated pneumonia...with prolonged intravenous antibiotics after hospital discharge when an equally effective oral alternative exists.”

Community Health Workers

- **56 studies** in PCORI’s portfolio involve Community Health Workers (CHW)
  - CHWs are the primary focus of the research in **46** of the studies
Research on opioid use and pain management is an ongoing priority for PCORI.

Applications due Wednesday on delivery of Medication Assisted Treatment (MAT) for pregnant women with substance use disorders.
Opioid Studies Across the Care Continuum

Prevention
3 studies look at preventing inappropriate opioid use from the start, including testing how various tools, strategies, and policies can improve prescribing practices.

Early-Stage and Chronic Use
6 studies, including one large study of veterans, examine ways to decrease inappropriate opioid use and taper long-term use.

Dependence
2 studies evaluate ways to reduce harm among dependent patients. Interventions test medication assisted therapy and non-medication treatments.
Self-Monitoring of Blood Glucose

Effect of Glucose Monitoring on Patient and Provider Outcomes in Non-Insulin Treated Diabetes
This study compared 3 approaches of SMBG in patients with non-insulin-dependent Type 2 diabetes for effects on hemoglobin A1c levels and health-related quality of life at 1 year of follow-up. They found that self-monitoring achieves no significant differences in disease control, hospitalization rates, need to start using insulin, or quality of life—results that augment findings of previous research.

Results of PCORI-Funded Research:
For many with Type 2 diabetes, daily finger stick offers little value.


Our study results have the potential to transform current clinical practice for patients and their providers by placing a spotlight on the perennial question, ‘to test or not to test?’

—Dr. Katrina Donahue, Study Investigator
Med.unc.edu Article
Antipsychotic Use in Foster Children

• For children diagnosed with DICD and/or ADHD, SGAs probably improve symptoms for which they are usually prescribed, such as aggression and disruptive behavior, but global clinical impressions of the severity of the disorders may not improve. SGAs may also cause adverse effects including weight gain, high triglyceride levels, extrapyramidal symptoms, sedation, and somnolence.

(We need a better, clearer way to say this.)

• PCORI will engage multiple stakeholder audiences—including representatives of the state policy community—to help us
  o Use natural language to communicate the evidence;
  o Develop evidence updates to disseminate the findings; and,
  o Disseminate the evidence updates to right people.

• STAY TUNED!
Thank You

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