Definitions, General Considerations, Historical Perspective and Best Practices on Patient Engagement in Clinical Pain Research

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pcori®
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Agenda

- About PCORI
- Patient Engagement
    - Definitions and Best Practices
    - What We Have Learned
    - Challenges
- Pain Studies
- Resources
- Takeaways

The Patient-Centered Outcomes Research Institute: Established to Meet Stakeholders’ Needs

“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

PCORI's Mission

PCORI helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from ***research guided by patients, caregivers, and the broader healthcare community***.

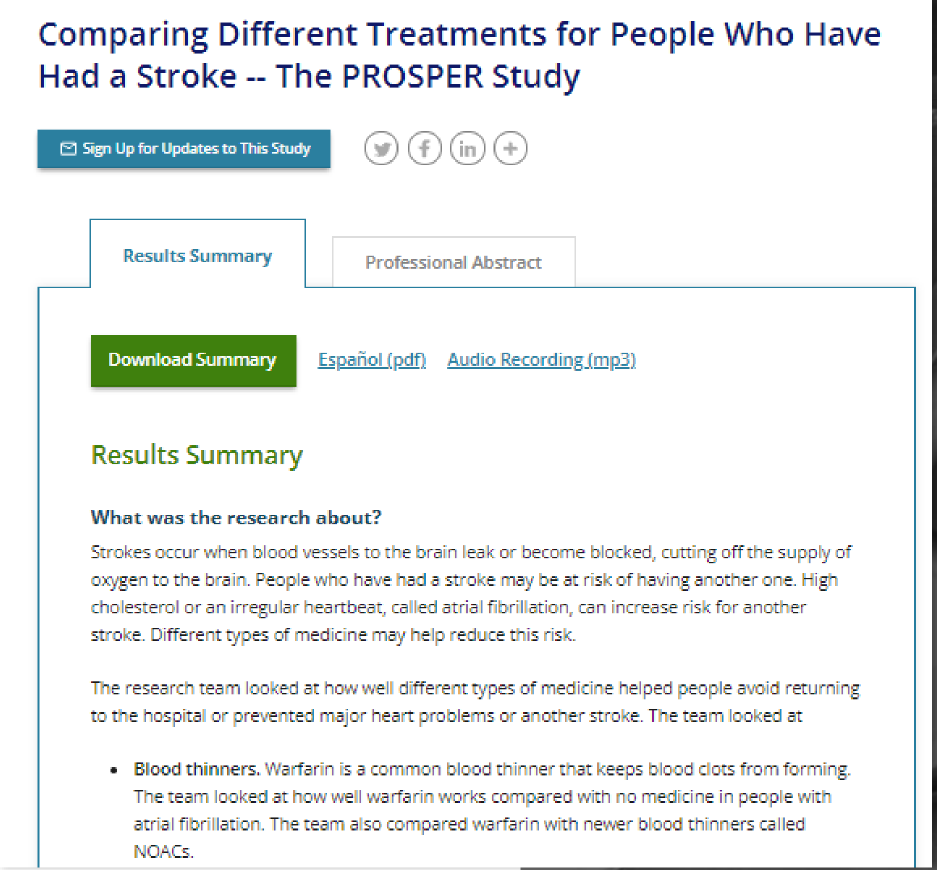
Comparative Clinical Effectiveness Research (CER)

- 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

PROSPER Stroke Study



Comparing Different Treatments for People Who Have Had a Stroke -- The PROSPER Study

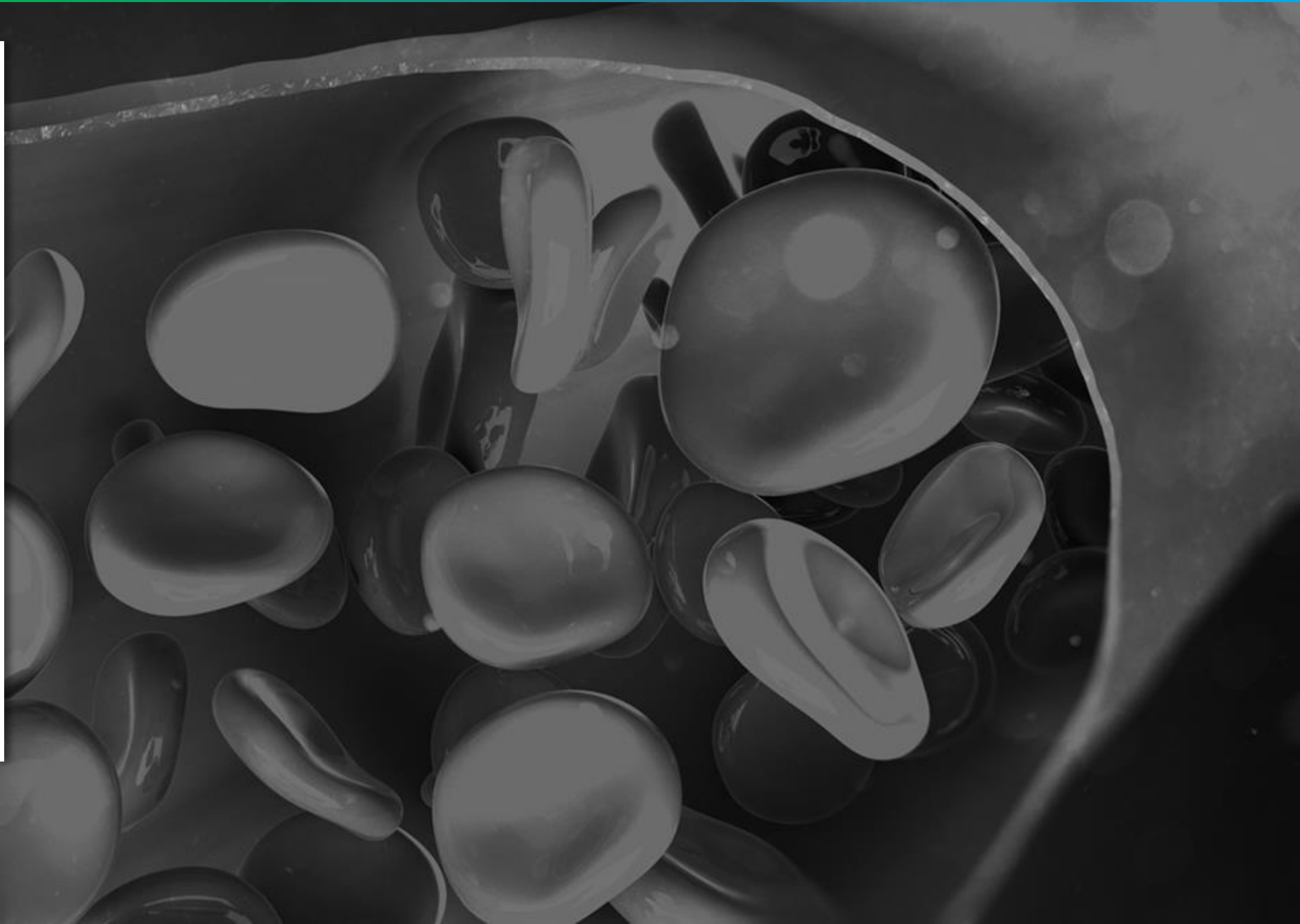
Results Summary

What was the research about?

Strokes occur when blood vessels to the brain leak or become blocked, cutting off the supply of oxygen to the brain. People who have had a stroke may be at risk of having another one. High cholesterol or an irregular heartbeat, called atrial fibrillation, can increase risk for another stroke. Different types of medicine may help reduce this risk.

The research team looked at how well different types of medicine helped people avoid returning to the hospital or prevented major heart problems or another stroke. The team looked at

- **Blood thinners.** Warfarin is a common blood thinner that keeps blood clots from forming. The team looked at how well warfarin works compared with no medicine in people with atrial fibrillation. The team also compared warfarin with newer blood thinners called NOACs.



What We Mean By…

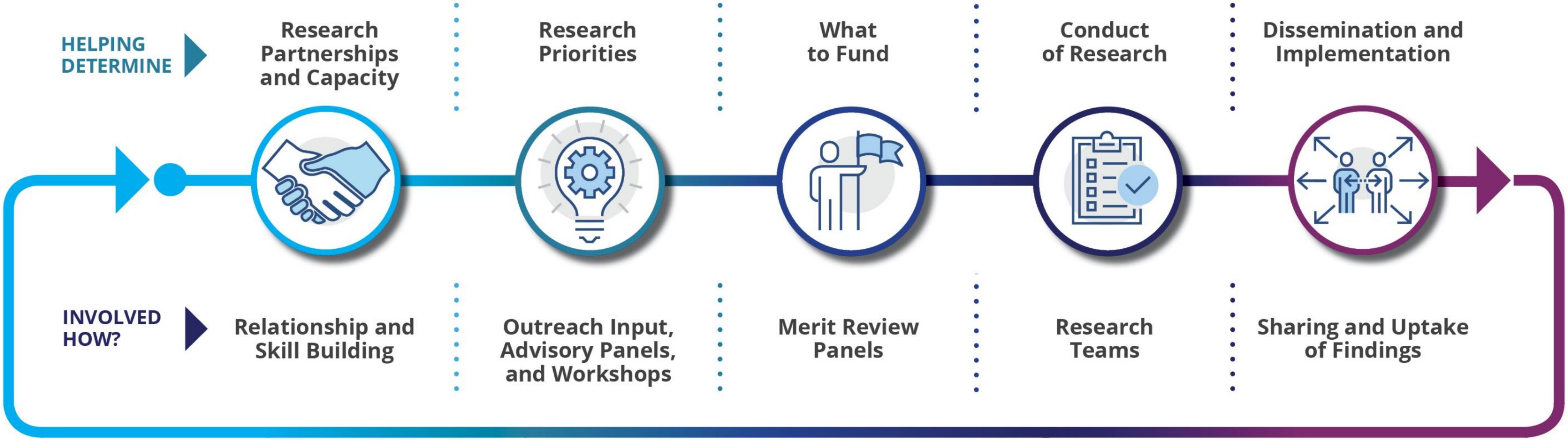
“Patient-centeredness”

- The project aims to answer questions or examine outcomes that matter to patients within the context of patient preferences
- Research questions and outcomes should reflect what is important to patients and caregivers

“Patient and stakeholder engagement”

- Patients are partners in research, not just “subjects”
- Active and meaningful engagement between scientists, patients, and other stakeholders
- Community, patient, and caregiver involvement already in existence or a well-thought-out plan

Engagement in Research



PATIENTS AND OTHER STAKEHOLDERS ARE INVOLVED IN…

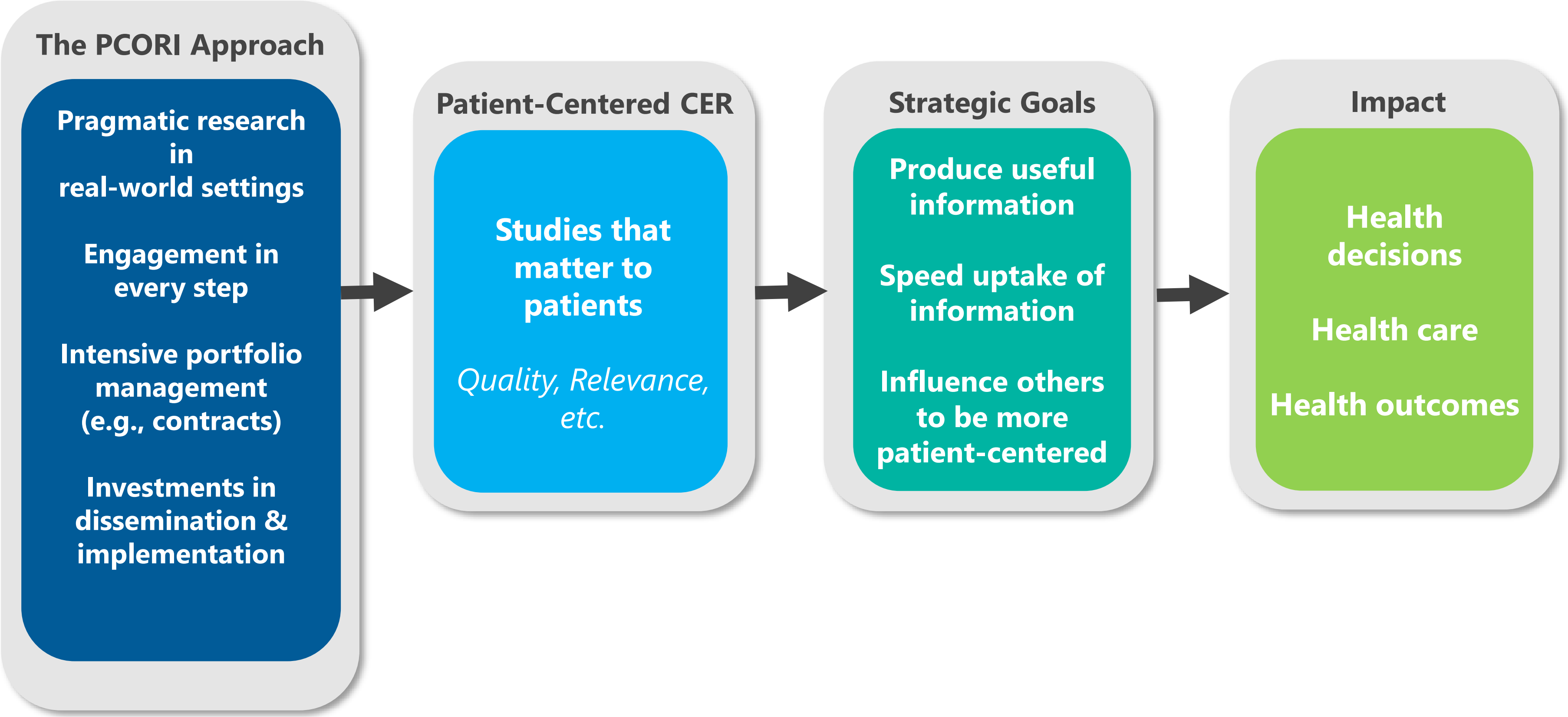
HELPING DETERMINE	Research Partnerships and Capacity	Research Priorities	What to Fund	Conduct of Research	Dissemination and Implementation
INVOLVED HOW?	Relationship and Skill Building	Outreach Input, Advisory Panels, and Workshops	Merit Review Panels	Research Teams	Sharing and Uptake of Findings

Why Engage?

- To make research reflect the needs and values of patients, caregivers, clinicians, and other stakeholders
- To improve the feasibility of doing studies in real-world settings
- To improve relevance, and encourage uptake and use, of research results
- ***Because PCORI researchers and partners have found it to be valuable and worthwhile***

> "At first we viewed it as burdensome. But over time we started to see the value in the way it was impacting the decisions we were making and how we were carrying out the study so that it would be more relevant to patients and providers on the front lines."
>
> —*Principal Investigator*

The Path to Impact: PCORI‘s Conceptual Model



The PCORI Approach

Pragmatic research in real-world settings

Engagement in every step

Intensive portfolio management (e.g., contracts)

Investments in dissemination & implementation

Patient-Centered CER

Studies that matter to patients

Quality, Relevance, etc.

Strategic Goals

Produce useful information

Speed uptake of information

Influence others to be more patient-centered

Impact

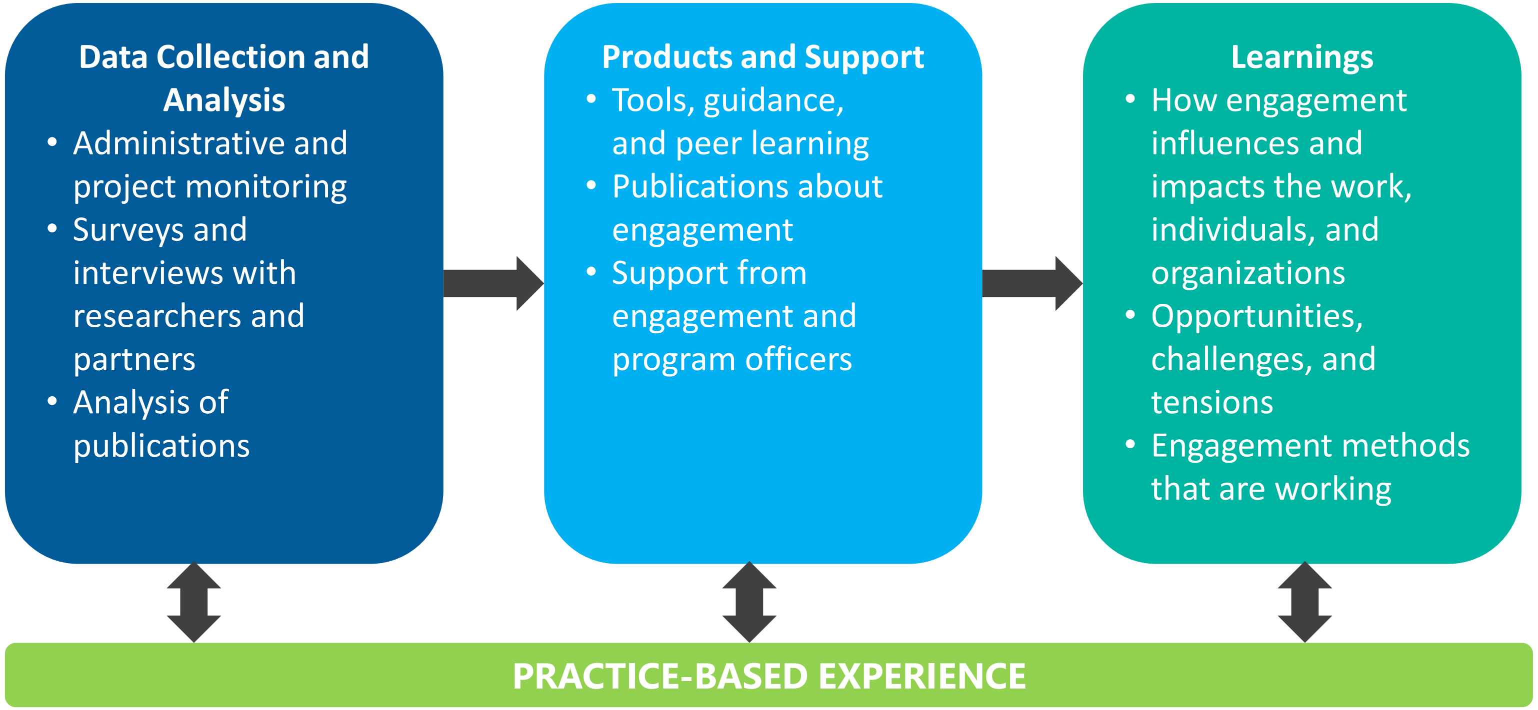
Health decisions

Health care

Health outcomes

PCORI Has Created a Body of Evidence about Engagement

Findings synthesized across efforts to build evidence and inform practice



Data Collection and Analysis

- Administrative and project monitoring
- Surveys and interviews with researchers and partners
- Analysis of publications

Products and Support

- Tools, guidance, and peer learning
- Publications about engagement
- Support from engagement and program officers

Learnings

- How engagement influences and impacts the work, individuals, and organizations
- Opportunities, challenges, and tensions
- Engagement methods that are working

PRACTICE-BASED EXPERIENCE

There Is A Continuum Of Engagement Practices

Levels of partners' decision-making authority for study design and implementation

Input

EXAMPLE

Focus Groups, Town Halls, Crowdsourcing

Consultation

EXAMPLE

Advisory Committee

Collaboration

EXAMPLE

Patient Co-I or Multi-Disciplinary Executive Team

Shared Leadership

EXAMPLE

Patient Co-PI, Patient-led tasks

Adapted from:
Hanley et al. (2004). Involving the public in NHS, public health and social care research.
Carman et al. (2013). Patient and family engagement: A framework for understanding the elements and developing interventions and policies. *Health Affairs, 32*(2), 223–231.
Arnstein, S. R. (1969). A ladder of citizen participation. *Journal of the American Planning Association, 35*, 216–24

Partners Influence Study Activities in Different Ways

➦	**Co-producing**	Partners and researchers work together or collaborate
⤵	**Redirecting**	Partners shift the direction
↔	**Refining**	Partners edit or modify
⇶	**Confirming**	Partners validate existing plans
✖	**Limited or no influence**	Partner input could not be implemented

Ways that Engagement Impacts PCORI-Funded Research Projects

	User-Orientation & Acceptability: studies in which patients and clinicians will be willing to participate based on burden, usability, and alignment with preferences, values, and needs
	Feasibility: interventions, enrollment, and data collection that are more doable in real-world settings
	Study Quality: study rigor, comprehensiveness, and quality of materials and products
	Relevance: results applicable and important for decision-making
	Engagement Scope & Quality: engagement processes are effective, and stakeholders are well equipped

Case Example: User Orientation and Acceptability
Intervention and Study Participation

Situation

- The study team was planning to evaluate interventions to improve quality of life for Latina breast cancer survivors and their caregivers.

Process

- Patient, caregiver, clinician, and community group partners helped plan study eligibility, strategies for increasing participation, and components of the intervention.

Effect

- The team expanded eligibility criteria to any survivor, regardless of time since diagnosis.
- The team reduced number of intervention sessions to improve participation and retention.
- Interventions included workshops on topics important to patients and caregivers, like stress and sexual intimacy.

Case Example: Quality
Data Collection

Situation

- PI and patient partner worked together on an interview guide.

Process

- The partner taught the researcher that information can be missing from claims data because many patients pay out of pocket for psychiatric care.

Effect

- The research team added questions to the interview guide that generated concepts not captured in other studies.
- The PI had a new, more well-rounded perspective on the data.
- The patient perspective has been incorporated into abstracts and papers.

Engagement Benefits All Those Involved

Patients & Stakeholders

- More knowledge and enthusiasm for research
- Developed skills and professional opportunities
- Improved personal health and healthcare
- New or better relationships
- Feeling of making a difference

Communities

- Built trust
- Increased research capacity
- Strengthened relationships among stakeholders
- Increased awareness of different stakeholder perspectives

Researchers

- Deeper understanding of real-world experiences and concerns of their study populations
- More knowledge about engagement
- Commitment to engagement in the future

Hemphill, RC, Forsythe, LP, Heckert, A, et al. (2019) Understanding what motivates patients and caregivers to engage in research and how engagement affects their lives: Qualitative findings from a survey of PCORI research partners.

Engagement Can Be Challenging

Infrastructure and Resources

- Knowledge
- Skills & Experience
- Money
- Time

People and Teams

- Access
- Ensuring Diversity & Inclusivity
- Relationships & Communication

Organizations

- Competing Priorities
- Contracting Policies
- IRBs

Balancing Views and Priorities

- Differing Perspectives
- Value Conflicts
- Internal vs. External Validity

Heckert, A, et al. Researchers, patients, and other stakeholders' perspectives on challenges to and strategies for engagement. (under review)

Community: The Vital Ingredient

> *"It is absolutely fundamental to have people from the community who are the interface for the participants in the project, and that really becomes evident when you don't do it."*
>
> — Debra Moser

Managing Pain and Reducing Opiod Use: The VOICE Study

Comparing Ways to Help Veterans Manage Pain and Reduce Use of Prescription Opioid Medicines -- The VOICE Study

Project Summary

PCORI has identified opioid use for chronic pain as an important research topic. Pati
others want to learn: How can patients lower their use of opioid medications while m
or eliminate use of these drugs altogether? To help answer this question, PCORI laur
initiative in 2016 on Clinical Strategies for Managing and Reducing Long Term Opioid
This research project is one of the studies PCORI awarded as part of this program.

This research project is in progress. PCORI will post the research findings on this page wit
results are final.

What is the research about?

Chronic pain is pain that occurs on at least half the days for six months or more. Chr
hard to do everyday activities such as sleeping, walking, working, and spending time
family. Many doctors prescribe opioid medicines to manage chronic pain. But these
as well as other treatments. They also can have serious side effects, and can even cause addiction and death. Patients with chronic pain need treatments that manage their pain, don't interfere with everyday activities, and don't have the risks that come with taking opioid pain medicine.

VA HEALTH SERVICES RESEARCH & DEVELOPMENT SERVICE

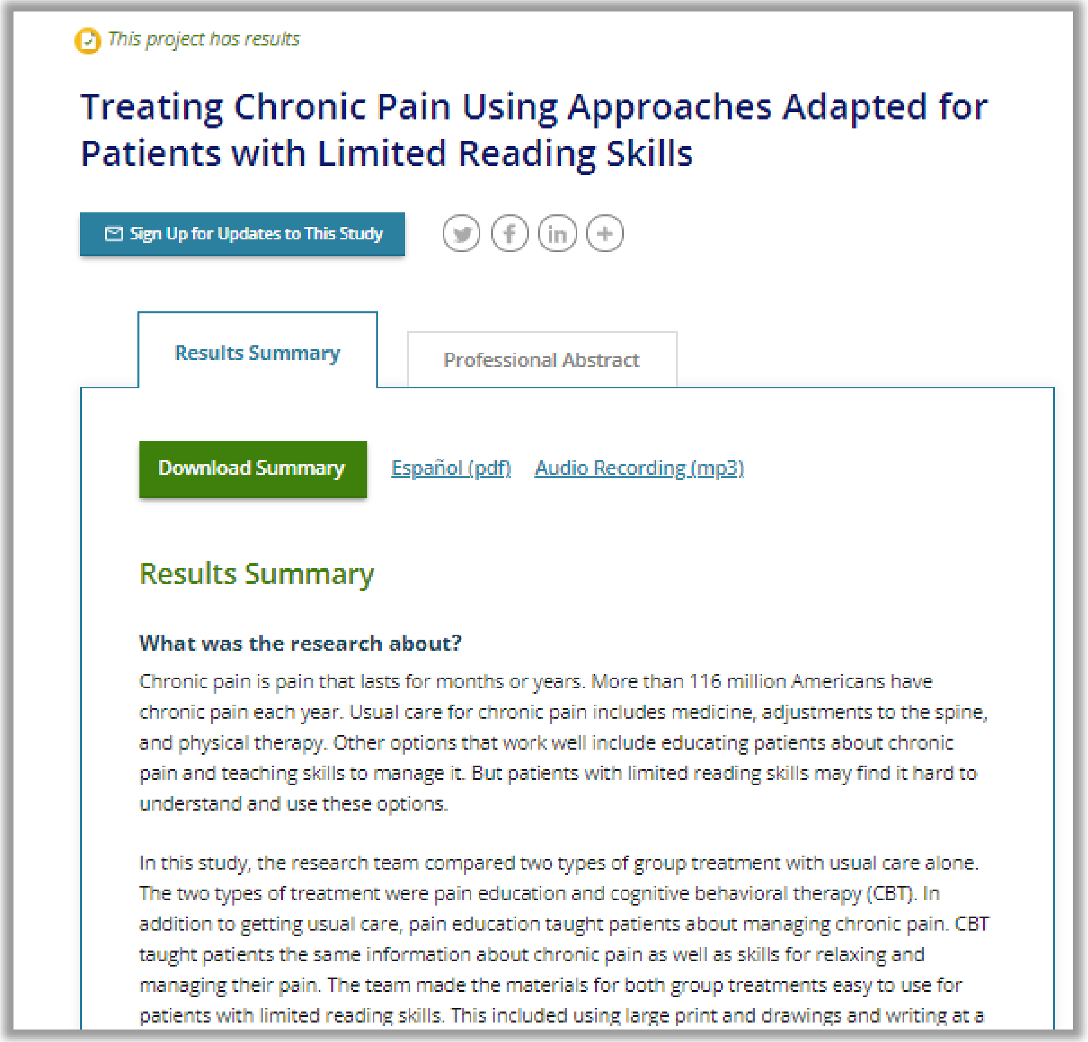
Veterans' PERSPECTIVES

VOICE Study Partners with Veteran Engagement Panel to Improve Pain Care, Reduce Harms of Opioid Therapy

HSR&D's monthly publication *Veterans' Perspectives* highlights research conducted by HSR&D and/or QUERI investigators, showcasing the importance of research for Veterans – and the importance of Veterans for research.

Literacy-Adapted Chronic Pain Study

- Usual care compared to group pain education or cognitive behavioral therapy
- Materials were adapted for low literacy levels
- Patients and clinicians helped design the study



Treating Chronic Pain Using Approaches Adapted for Patients with Limited Reading Skills

Results Summary

What was the research about?

Chronic pain is pain that lasts for months or years. More than 116 million Americans have chronic pain each year. Usual care for chronic pain includes medicine, adjustments to the spine, and physical therapy. Other options that work well include educating patients about chronic pain and teaching skills to manage it. But patients with limited reading skills may find it hard to understand and use these options.

In this study, the research team compared two types of group treatment with usual care alone. The two types of treatment were pain education and cognitive behavioral therapy (CBT). In addition to getting usual care, pain education taught patients about managing chronic pain. CBT taught patients the same information about chronic pain as well as skills for relaxing and managing their pain. The team made the materials for both group treatments easy to use for patients with limited reading skills. This included using large print and drawings and writing at a

Chronic Pain: The EMPOWER Study

- Responding to patient despair over how to reduce opioid use while keeping pain and distress at bay
- Both the study design and the outcomes to be studied were informed by patient and clinician stakeholders
- Increased awareness of the crucial importance of the patient-clinician relationship

Comparing Cognitive Behavioral Therapy with Peer-Led Support Groups for Patients with Chronic Pain Who Want to Reduce Opioid Use -- The EMPOWER Study

Project Summary

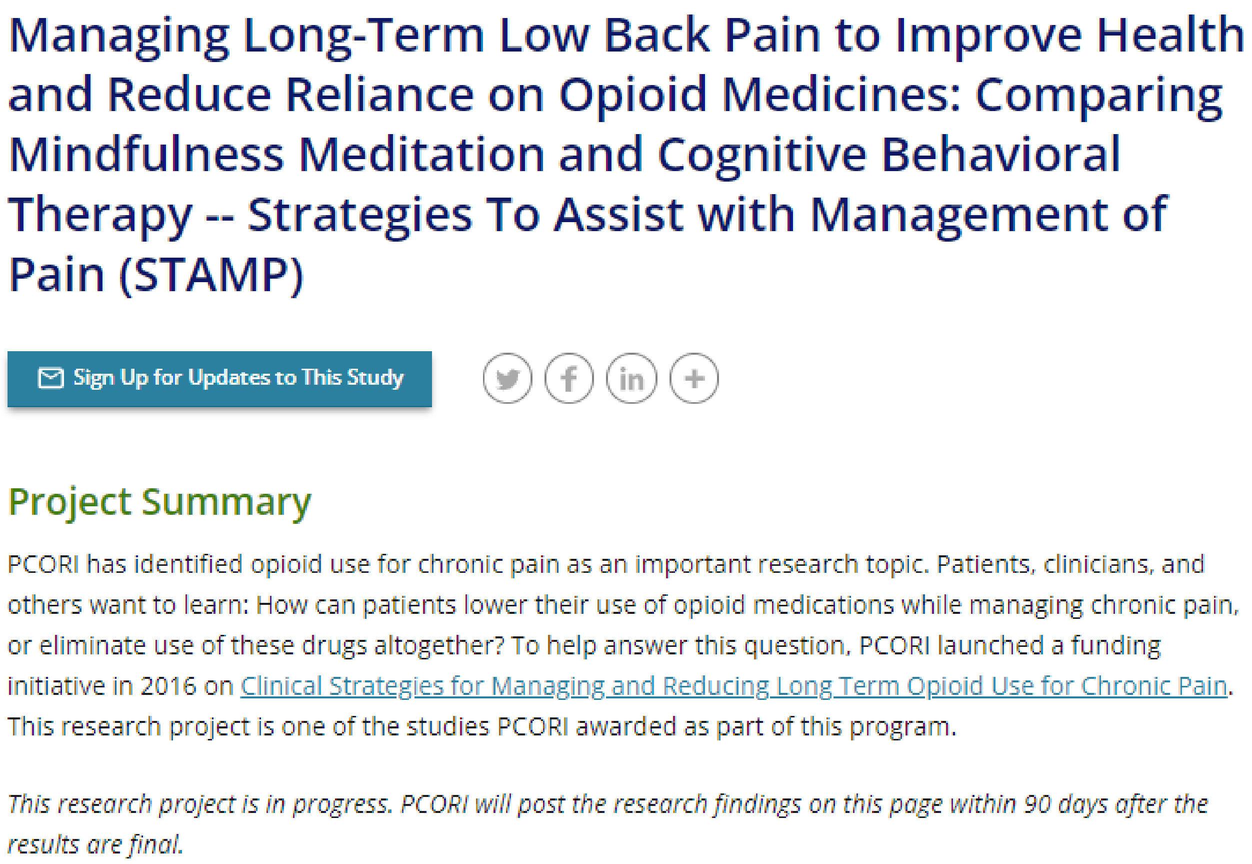
PCORI has identified opioid use for chronic pain as an important research topic. Patients, clinicians, and others want to learn: How can patients lower their use of opioid medications while managing chronic pain, or eliminate use of these drugs altogether? To help answer this question, PCORI launched an initiative in 2016 on Clinical Strategies for Managing and Reducing Long Term Opioid Use for Chronic Pain. The initiative funded this research project and others.

This research project is in progress. PCORI will post the research findings on this page within 90 days after the results are final.

What is this research about?

Chronic pain is pain that lasts for several months or longer. More than 116 million Americans live with some degree of chronic pain. Opioid medicines can help people control some short-term pain when taken as prescribed. But it is not clear if opioids are safe and effective for chronic pain. Cognitive behavioral therapy, or CBT, is one type of treatment for chronic pain, and may help people reduce opioid use. With CBT, patients learn to change their patterns of thinking and behaving.

The STAMP Study



Managing Long-Term Low Back Pain to Improve Health and Reduce Reliance on Opioid Medicines: Comparing Mindfulness Meditation and Cognitive Behavioral Therapy -- Strategies To Assist with Management of Pain (STAMP)

Project Summary

PCORI has identified opioid use for chronic pain as an important research topic. Patients, clinicians, and others want to learn: How can patients lower their use of opioid medications while managing chronic pain, or eliminate use of these drugs altogether? To help answer this question, PCORI launched a funding initiative in 2016 on Clinical Strategies for Managing and Reducing Long Term Opioid Use for Chronic Pain. This research project is one of the studies PCORI awarded as part of this program.

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The Science of Engagement Request for Information

- Describes Science of Engagement (SoE)
- Poses a specific set of questions on both the scientific research topic priorities and the process & resource elements
- Invites responses to questions and general comments
- Responses to the RFI are due by **November 19, 2021**
- Download the RFI at **www.pcori.org/soe**

Request for Information: Science of Engagement Funding Initiative

The submission deadline for this Request for Information (RFI) is Friday, November 19, 2021.

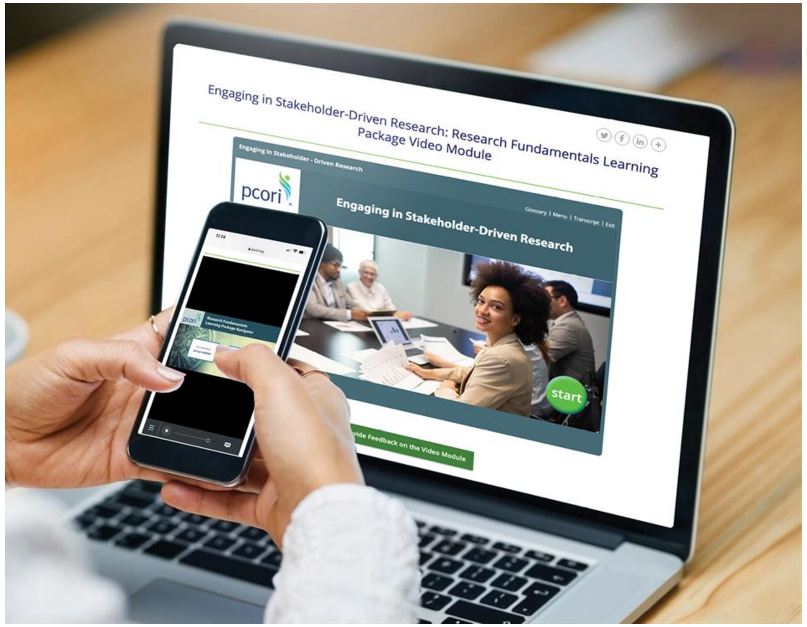
PCORI is seeking input to inform the potential development of a Science of Engagement funding initiative. Science of Engagement is the systematic study of methods for and outcomes of engagement to inform high quality, patient-centered research. Expanded funding for Science of Engagement could address high-priority knowledge gaps on approaches for effectively engaging diverse stakeholders throughout the research process.

The Science of Engagement Initiative could potentially involve two complementary, interrelated research program approaches: Stand-Alone Research Awards on engagement in research and Studies within a Study for ongoing PCORI CER awards. The intention of these complementary mechanisms would be to help create a strong evidence base of answers to critical research gaps that should be addressed to make engagement more effective and widespread.

Key Dates

- **Informational Webinar #1:**
  October 5, 2021 | Slides | Recording
- **Informational Webinar #2:**
  October 15, 2021 | Slides | Recording
- **Submit questions on this RFI by:**
  November 5, 2021
- **Responses to this RFI due by:**
  November 19, 2021

Free Resources to Support Multi-Stakeholder Research Teams



Research Fundamentals

- Provides **foundational knowledge in PCOR/CER** to **partners** on research and other projects.
- **Available at: *pcori.org/research-fundamentals***

Building Effective Multi-Stakeholder Research Teams

- For **new and experienced researchers and stakeholder partners**, offers **practical guidance and resources to support multi-stakeholder teams** in effectively working together.
- **Available at: *pcori.org/research-teams***

Conclusion and Takeaways

- Patients and other stakeholders must be involved from the beginning
- Engagement takes time, effort, and patience
- Trust is key
- Patient engagement is not without challenges
- It can improve the diversity of study participants and make results more relevant
- Patient engagement is in its infancy in pain studies
- More research needs to be done!

Thank you!

Questions?