

NIH Pragmatic Trials Collaboratory

Enabling research embedded in
healthcare delivery since 2012

Updated January 29, 2026



**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®



History: Initiated in 2012 via the NIH Common Fund, now transitioned to sustained funding from multiple NIH Institutes and Centers plus NIH HEAL Initiative



Goal: Strengthen the national capacity to implement cost-effective, large-scale research studies that engage healthcare delivery organizations as partners



Vision: Support the design and conduct of innovative embedded pragmatic clinical trials (ePCTs) to establish best practices and disseminate knowledge

Why Do an ePCT? The 5 Rs



Relevant Question

The question is pressing, and healthcare system leaders, patients, and front-line clinicians care about the answer.



Real-World Setting

Desire to test in diverse healthcare delivery settings with the hope of implementing findings widely.



Representative Population

Ability to enroll participants reflective of the real-world population with the disease or condition.



Routinely Collected Data

Can use data collected as part of healthcare delivery to answer the question, supplemented by data from other sources.



Rigorous Methods

Randomized research is needed to answer the question and inform changes in care, policy, or reimbursement.

	Clinical Trials Networks	NIH Pragmatic Trials Collaboratory	Quality Improvement
<i>Purpose</i>	Provides infrastructure for clinical trial conduct	Provides expertise and support for pragmatic trials (Resource Coordinating Center)	Provides data for immediate improvements in a particular healthcare delivery setting
<i>Setting</i>	Establishes partnerships with clinical sites, primarily academic medical centers	Researchers bring their own partnerships with diverse healthcare delivery sites	Individual health system
<i>Population</i>	Patients with condition recruited by trial (homogenous)	Patients with condition receiving healthcare (heterogeneous)	Patients at facility
<i>Data</i>	Creates new data systems for research	Leverages existing infrastructure (EHR, etc.)	Leverages existing infrastructure (EHR, etc.)
<i>Research</i>	Rigorous, randomized (individual) clinical trials	Rigorous, randomized (individual or cluster) pragmatic trials	Systematic and data-guided activities
<i>Intervention</i>	Delivered by trial staff	Delivered by health system staff	Delivered by health system staff
<i>Outcomes</i>	Efficacy, safety	Effectiveness, implementation	Effectiveness, implementation
<i>Conditions</i>	Highly controlled	Real-world	Real-world
<i>Comparator</i>	Placebo or control	Usual care or active comparison	Pre-post comparison



NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

- **Support center** for catalyzing pragmatic research
- Researchers establish their own partnerships—possibilities unlimited
- Offers expertise and technical assistance
- Different model for scaling learning health
- No centralized data requirements
- Gathers and shares lessons widely to advance methods

COMPLEMENTARY INITIATIVES



pcornet®

The National Patient-Centered Clinical Research Network



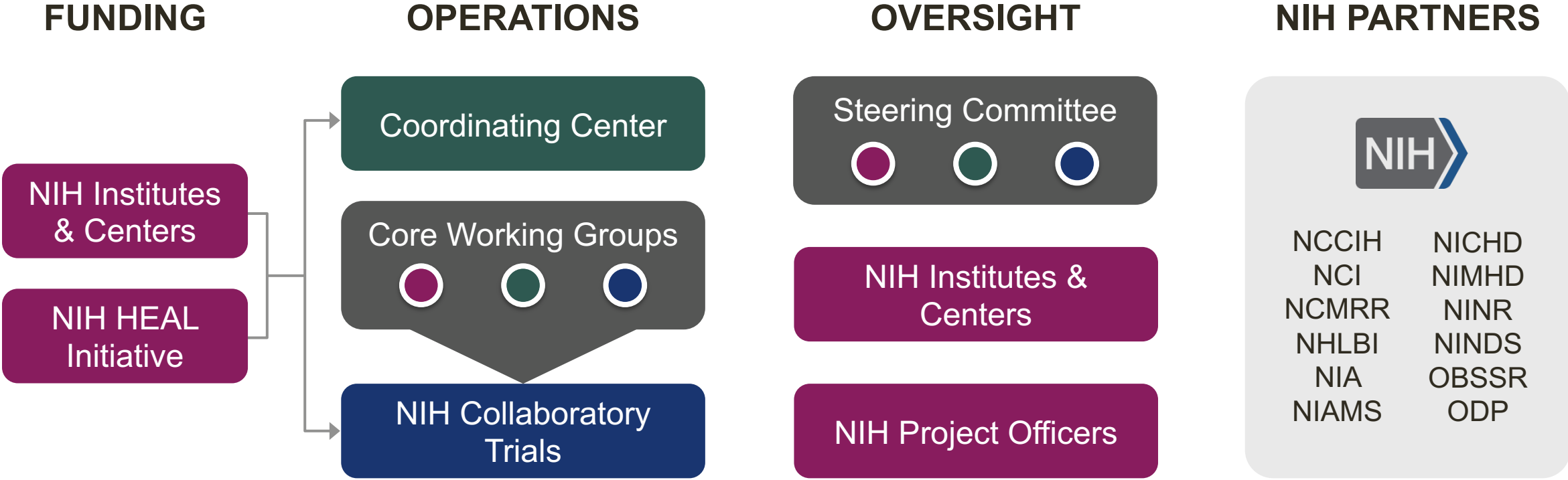
pcori

- **Reusable infrastructure**
- Nationwide network of diverse clinical research networks
- Research-ready, standardized clinical data
- Researchers can securely query data
- Community partnerships
- Supports efficient pragmatic research, population health research, and more

Program Success and Evolution

- Initial funding from Common Fund gave support for new ways to think about clinical research and allowed these ideas to take hold by demonstrating feasibility and rigor
- Successful transition from Common Fund to IC support showed appreciation of the program's value and uptake among broad group of ICs
- Integration with NIH HEAL Initiative[®] extended the program's reach into a major NIH-wide program to address the overdose and pain crisis
- Informed other NIH initiatives using ePCTs to address major health challenges
 - Pain Management Collaboratory (PMC) in military and Veterans healthcare systems
 - People living with dementia and their care partners (IMPACT Collaboratory)
 - CARE for Health[™] program embedding clinical research in primary care settings

Program Structure

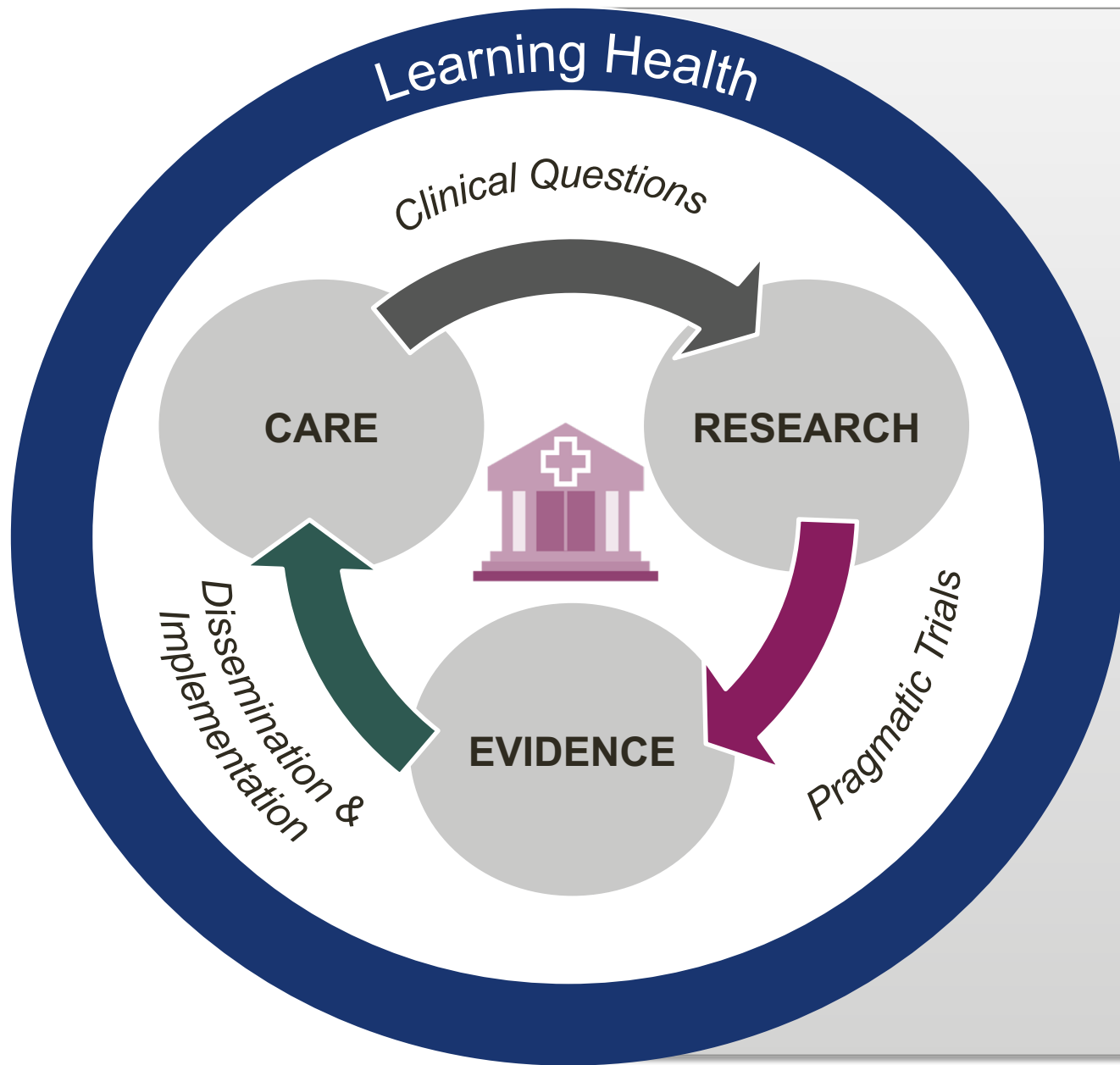


Coordinating Center

Functions

- Provide national leadership and technical expertise
- Produce, document, and disseminate standards
- Support synergy within program
- Coordinate communication and dissemination





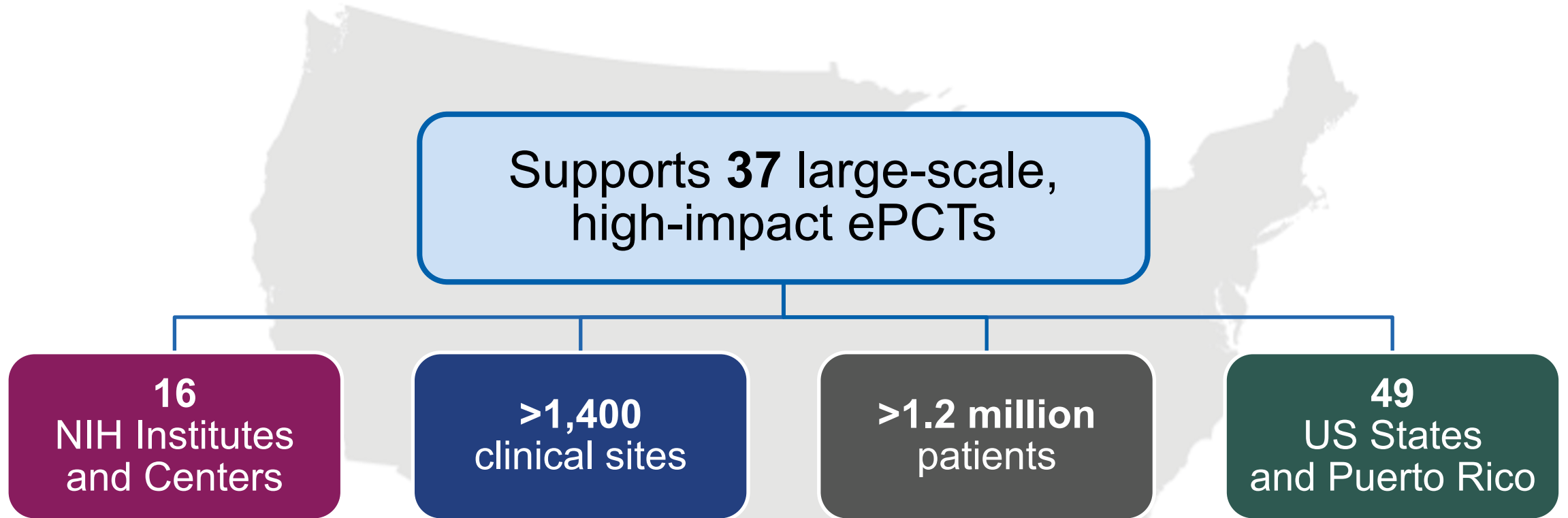
NIH PRAGMATIC TRIALS COLLABORATORY

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SUPPORT SERVICES

- Consult and provide guidance on:
 - Study design and analysis
 - Regulatory issues and consent practices
 - Use of EHR and real-world data sources
 - Translating results into practice
- Offer strategies to:
 - Contribute to healthier communities
 - Engage healthcare system partners
- Assist with:
 - Defining study endpoints
 - Measuring patient-centered outcomes
 - Assessing feasibility of clinical workflows
 - Addressing challenges that arise

Program Reach



No sites in Arkansas

NIH Collaboratory Trials

- ePCTs addressing questions of major public health importance
 - Wide variety of therapeutic areas
 - Many have phased funding
 - Planning/startup phase
- ↓
- Implementation phase



HEAL-Funded NIH Collaboratory Trials

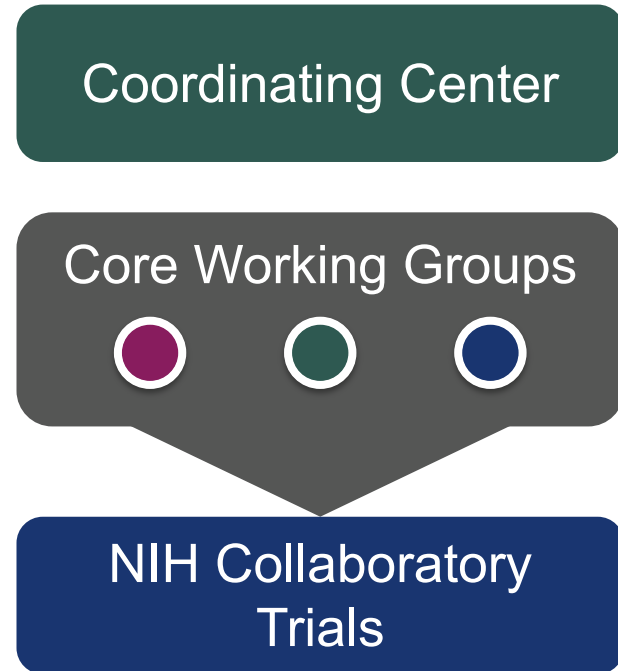
- NIH HEAL Initiative[®] funding since 2019
- Supports ePCTs of non-opioid interventions for:
 - Treating pain
 - Improving pain management
 - Reducing reliance on opioids

Aim: Improve availability of, effectiveness of, and adherence to evidence-based, nonpharmacologic pain management



Core Working Groups

- Component of Coordinating Center focusing on key areas of ePCTs
- Led by chairs from Coordinating Center
- Include representatives from
 - NIH Collaboratory Trials
 - NIH



Core Working Groups: Purpose

COORDINATING CENTER

Biostatistics
and Study
Design

Community
Health
Improvement

Electronic
Health
Records

Ethics and
Regulatory

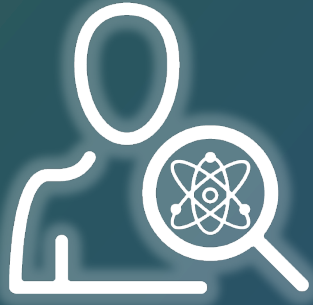
Health Care
Systems
Interactions

Implementation
Science

Patient-
Centered
Outcomes



- Guide and support NIH Collaboratory Trials
- Disseminate knowledge
 - Guidance
 - Lessons learned



Biostatistics and Study Design Core

Co-Chairs:

- Patrick Heagerty, PhD
- Elizabeth L. Turner, PhD



Mission

- Provide expertise in novel designs and methods for ePCTs
- Document new statistical issues and share knowledge
- Develop methods to address challenges



Co-Chairs:

- Rosa Gonzalez-Guarda, PhD, MPH
- Cherise Harrington, PhD, MPH



Community Health Improvement Core

Mission

- Examine strategies to
 - Help trials be widely conducted across the US, including in rural areas
 - Implement evidence-based interventions across settings to improve the health of all populations
 - Ensure research is relevant to the most people affected



Chair:

- Keith A. Marsolo, PhD



Electronic Health Records Core

Mission

- Help trials acquire, assess, use, and share real-world data
- Create tools to leverage EHRs for research across multiple health systems
- Share lessons broadly



Co-Chairs:

- Jeremy Sugarman, MD
- Pearl O'Rourke, MD
- Stephanie Morain, PhD, MPH



Ethics and Regulatory Core

Mission

- Identify areas of regulatory and ethical uncertainty for ePCTs
- Help trials navigate regulatory and ethical complexities
- Advance understanding of the ethical issues in ePCTs



Chair:

- Greg Simon, MD, MPH



Health Care Systems Interactions Core

Mission

- Engage those involved in healthcare delivery systems to:
 - Identify priority research questions
 - Efficiently embed research in health care delivery
 - Effectively engage patients and front-line clinicians
 - Understand and communicate trial results



Co-Chairs:

- Devon Check, PhD
- Hayden Bosworth, PhD



Implementation Science Core

Mission

- Support trials in achieving their implementation-related research aims
- Promote the uptake and sustainability of effective interventions
- Produce guidance for conducting implementation research in ePCTs
- Promote sustainment and scale-up of interventions



Co-Chairs:

- Christy Zigler, PhD, MEd
- Emily C. O'Brien, PhD



Patient-Centered Outcomes Core

Mission

- Define best practices for:
 - Selecting, compiling, and curating appropriate PRO measures
 - Developing new instruments when needed
 - Creating efficient, quality data collection systems compatible with EHRs

Impact of Cores



>250 trial consultations



>200

publications & products



>1100 Core meetings



PI Testimonials

“Take the Biostats Core Working Group advice seriously—get it early and act on it early.”

“The CC helped greatly with the selection of our secondary outcome measures.”

“Have as many key members of your team work closely with Collaboratory Cores.”

“Having adjusted our strategy prior to IRB submission based on input from the Core was likely a major reason the IRB review went so smoothly.”

Examples: NIH Collaboratory Trials Informing Clinical Care



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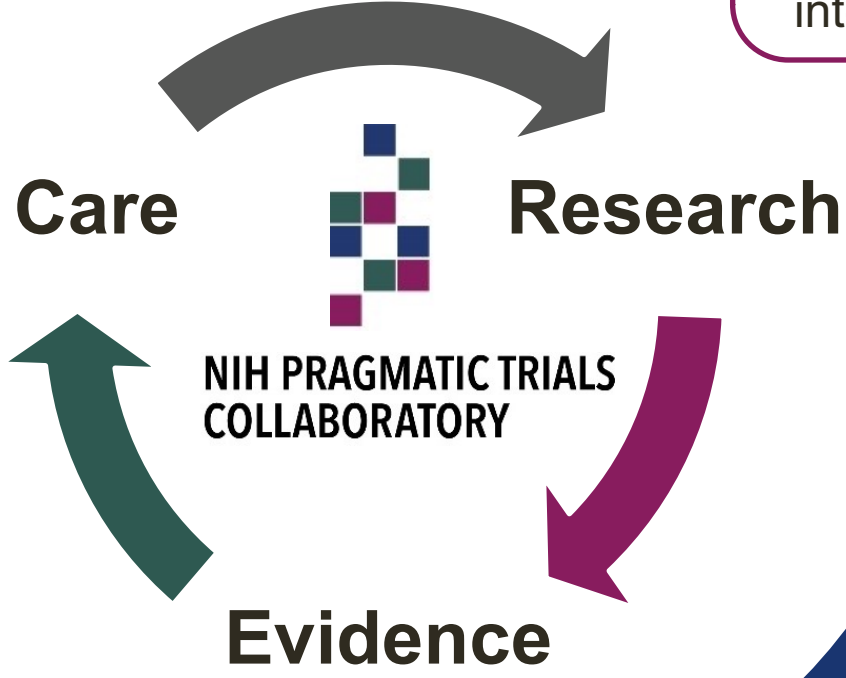
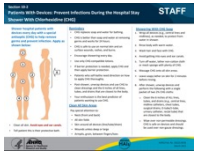
ABATE

Question:
Does daily antiseptic bathing reduce drug-resistant infections in hospitalized (non-ICU) patients?

Pragmatic Trial:
53 hospitals randomized to routine care or intervention



Clinical Impact:
Adopted intervention in all health system hospitals for patients with medical devices
Implementation toolkit published for hospitals



NIH Collaboratory Support:

- *Regulatory:* Consulted regarding FDA oversight
- *Data:* Advised on data standardization, cleaning, and sharing
- *Engagement:* Underscored partnerships between health systems and researchers

Results:
Negative primary outcome but reduced infections in patients with medical devices

Study Population:
>500,000 patients with 20 million data records

STOP CRC

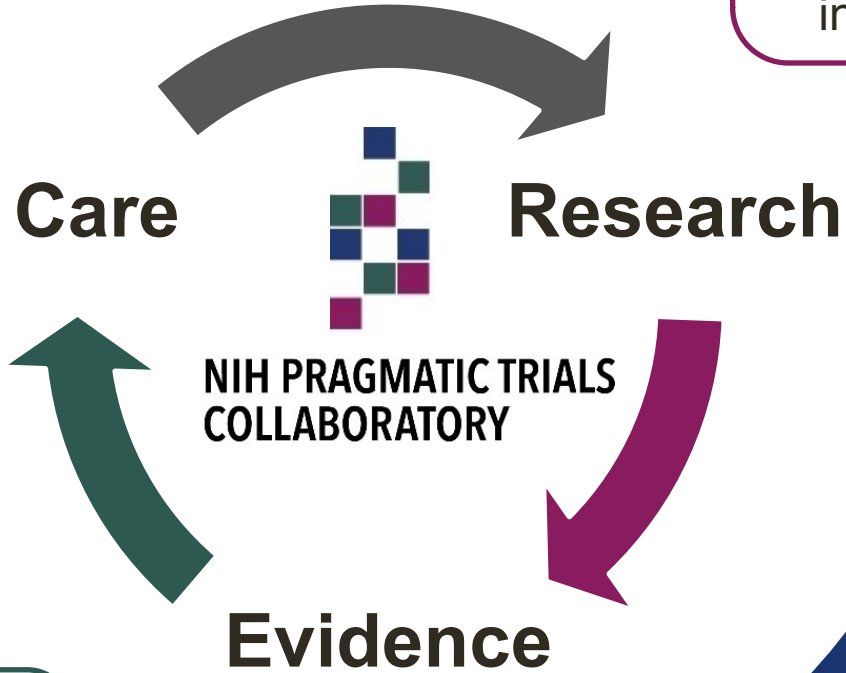
Question:
Does an EHR-based outreach program with mailed stool-tests improve rates of colorectal cancer screening?

Pragmatic Trial:
26 FQHC clinics randomized to routine care or intervention



Clinical Impact:
Adopted intervention in at least 150 clinics
Implementation materials published to support uptake

The flyer includes statistics: '1 in 20 people in the United States will be diagnosed with colorectal cancer', '50,000 people in the United States die from colorectal cancer', and 'Take control of your health. Get tested today!'.



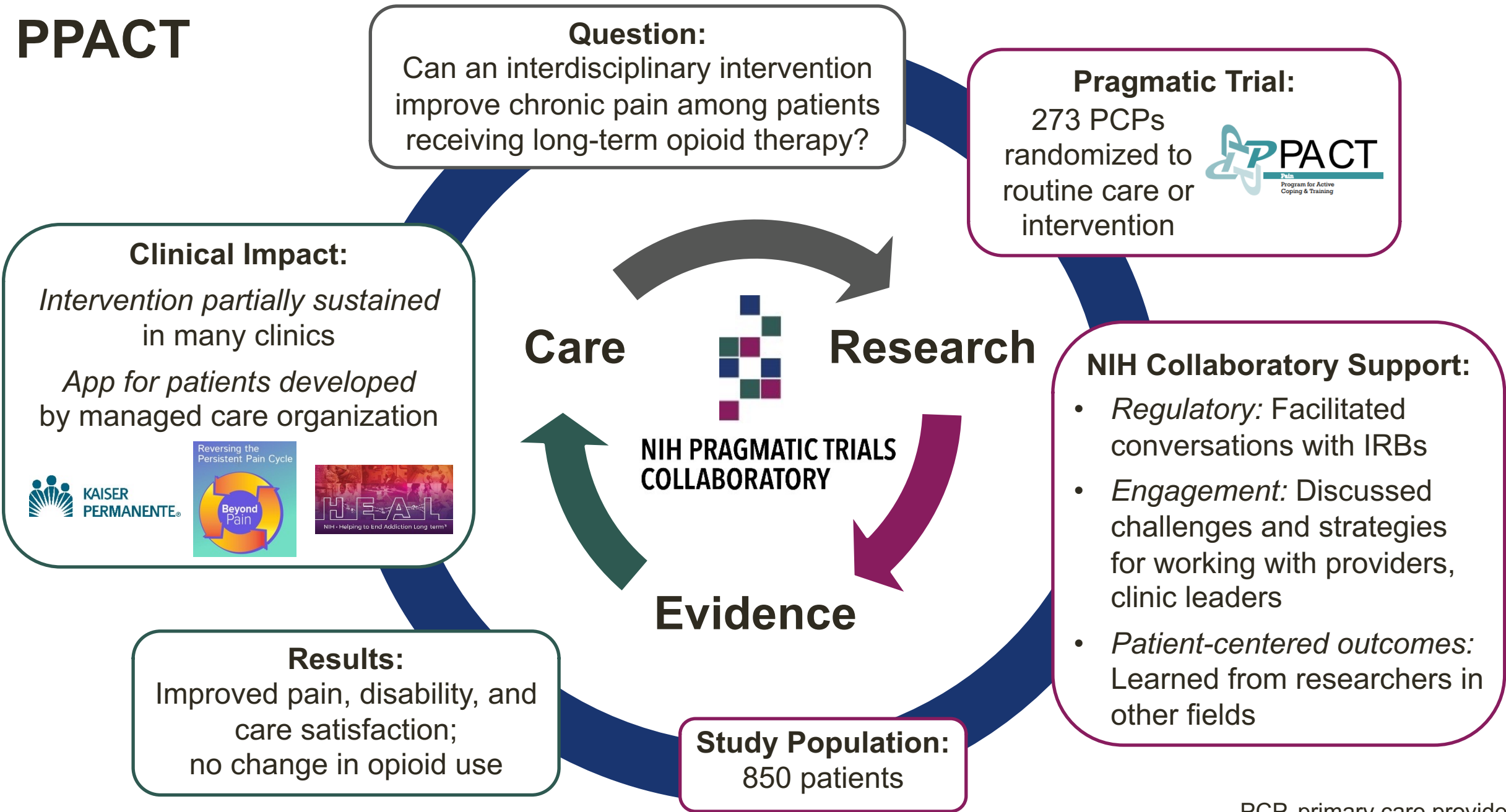
NIH Collaboratory Support:

- *Biostatistics:* Extensive support to modify analysis, develop secondary analysis
- *Data:* Helped team learn and implement standards and methods for validating EHR code
- *Overall:* Knowledge sharing, troubleshooting

Results:
Significantly improved screening rates

Study Population:
>40,000 patients and ~6,300 mailed stool-tests

PPACT



PCP, primary care provider

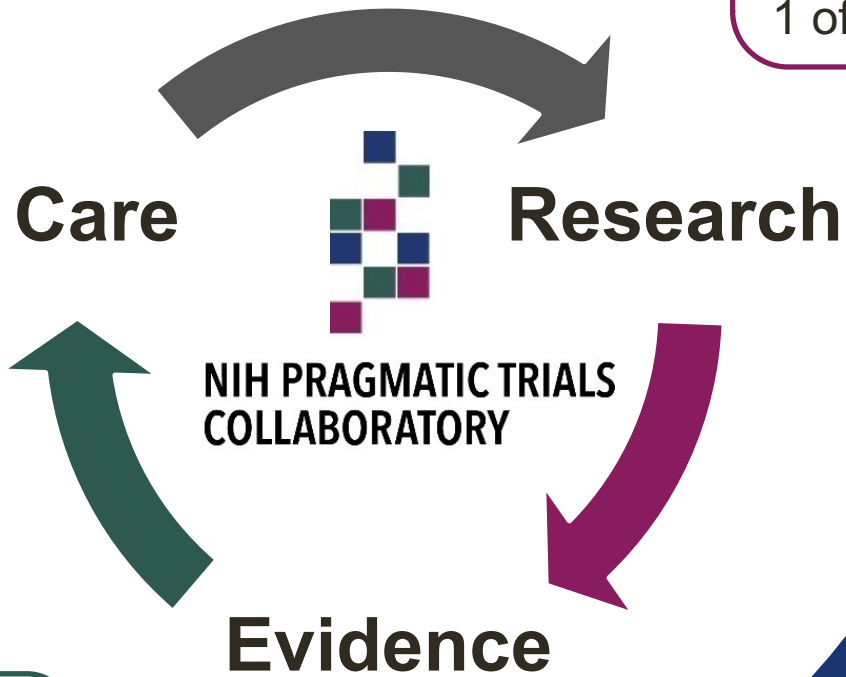

SPOT

Question:
Does offering low-intensity care management or skills training to adults experiencing frequent suicidal ideation reduce their risk of self-harm?

Pragmatic Trial:
Patients at 4 health systems randomized to usual care or 1 of 2 interventions

SUICIDE PREVENTION OUTREACH TRIAL

Clinical Impact:
Findings *did not support* implementation of the approaches
Future resources not spent on ineffective (or harmful) practices
Suggests exploring other methods



NIH Collaboratory Support:

- *Regulatory:* Helped navigate consent, IRB, and data monitoring issues
- *Biostatistics:* Guidance on analytic considerations
- *Electronic health records:* Advice on handling major change in diagnostic coding mid-study

Results:
Increased risk of self-harm with brief skills training and no difference with care management, vs usual care

Study Population:
18,882 patients

Disseminating Knowledge and Best Practices



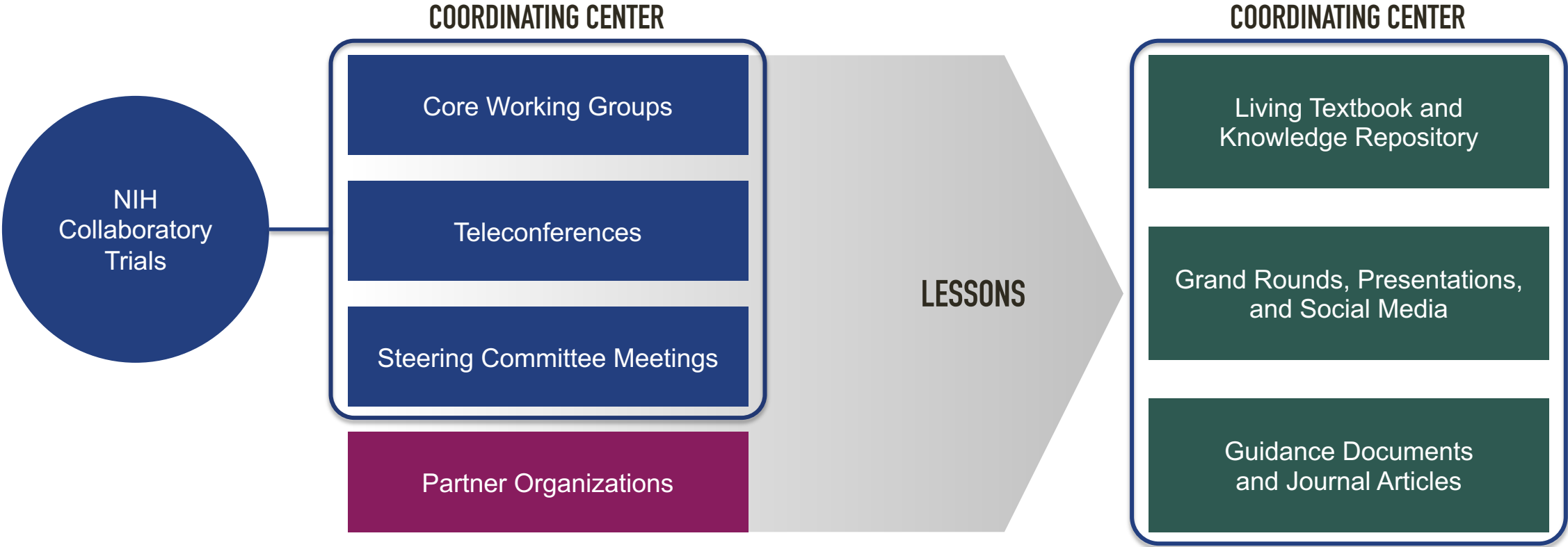
**NIH PRAGMATIC TRIALS
COLLABORATORY**

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We've learned a lot about how to integrate research with practice...

- Using EHRs for research is complex
- Unexpected changes occur, but there are ways to mitigate their effects
- Strong partnerships with healthcare systems are essential
- Some ethical and regulatory uncertainties remain
- Many factors involved in whether an intervention will be sustained
- **Sharing challenges and lessons promotes success, advances methods**

Flow of Information



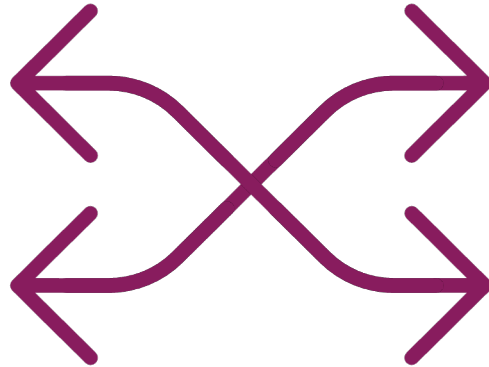
Partnerships

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

- Grand Rounds
- Workshops
- Publications
- Living Textbook
- Podcast
- Tools
- Resources
- Knowledge

COLLABORATION



SHARING

NIH → **NCCIH NCI NCMRR NHLBI NIA NIAID**
NIAMS NICHD NIDA NIDDK NIMH
NIMHD NINR NINDS OBSSR ODP

Bold denotes current NIH partner

Publications*

TOTAL PUBLISHED

>385

CITATIONS

>13,000

JOURNALS

>140



*As of December 31, 2025

Living Textbook of Pragmatic Clinical Trials

Website & Online Textbook



rethinkingclinicaltrials.org

- Program information
- Comprehensive ePCT resource
- Continuously updated and expanded
- Internal and external contributors
- Reliable and citable

Living Textbook Content and Reach

TOPICS INCLUDE:

30+ chapters



>100,000
visitors/year

>120

contributors



Design

- Developing a Grant
- Experimental Designs
- Building Partnerships
- Patient Engagement
- What Is a Pragmatic Trial
- Endpoints & Outcomes
- Using EHR Data
- Intervention Complexity

Dissemination & Implementation

- Data Sharing
- Dissemination
- Implementation
- End-of-Trial Decision-Making

Data, Tools & Conduct

- Assessing Feasibility
- Acquiring & Assessing Real-World Data
- Study Startup
- Participant Recruitment
- Monitoring Fidelity
- Clinical Decision Support
- Patient-Reported Outcomes
- Mobile Health

Ethics & Regulatory

- Privacy
- Consent, Disclosure & Nondisclosure
- Collateral Findings
- Data & Safety Monitoring
- IRB Responsibilities and Procedures

Tools and Guidance Documents

CHEAT SHEETS

- Intraclass Correlation Coefficient
- Assessing Fitness-for-Use of Clinical Data for ePCTs
- End-of-Trial Decision-Making

TOOLS & TOOLKITS


- Intervention Complexity Calculator
- Patient-Centered Outcomes Toolkit
- Data Sharing Information
- Quick Start Guides

TEMPLATES & CHECKLISTS

- Data Monitoring Committee Charter
- Reporting ePCTs Template
- Trial Documentation Checklist
- Data Sharing Checklist

GUIDANCE DOCUMENTS

- Engagement in ePCTs
- Assessing Data Quality
- Cluster Randomized Trial Design
- Data Sharing



NIH PRAGMATIC TRIALS COLLABORATORY
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Engagement in Research for Pragmatic Clinical Trials

Determining which individuals are most engaged in research (those engaged according to those engaged according to service provider) and document provides consent as institutional review board Protections (OHRP), the subjects, issued guidance directed at PCTs in part guidance from OHRP work

PURPOSE

This document provides an important for the design and by individual participant, the or primary-care practice, although

DEFINITION

The **intracluster correlation coefficient** cluster are likely to be similar from other clusters. The ICC, the sample size needed to detect cluster-randomized trials is determined

Key Questions

- Which individual
- Are these individual providers?
- Why does it matter

Addressing these questions relationship to the research providers.

Research Subjects

It is generally easy to identify and Human Services (DHHS) subject:

"a living individual information or bi individual, and us obtains, uses, stores identifiable biospecimens"

Intracluster Correlation Coefficient Cheat Sheet

IDEAS AND OPINIONS

Annals of Internal Medicine

Moving From Idealism to Realism With Data Sharing

Keith A. Marsolo, PhD; Kevin P. Weinfurt, PhD; Karen L. Staman, MS; and Bradley G. Hammill, DrPH

Significant efforts have been made in the past decade to promote open science and data sharing in clinical research. The moral and scientific arguments are clear: If data are shared, it could promote transparency and understanding of the results, honor the participation of individuals, and enable new discoveries (1).

The White House Office of Science and Technology Policy recently updated guidance requiring that results of federally funded research be made immediately available, and federal agencies have drafted a series of policies that outline expectations of their awardees. For example, the National Institutes of Health (NIH) has released a new Policy for Data Management and Sharing that will take effect in January 2023 (2).

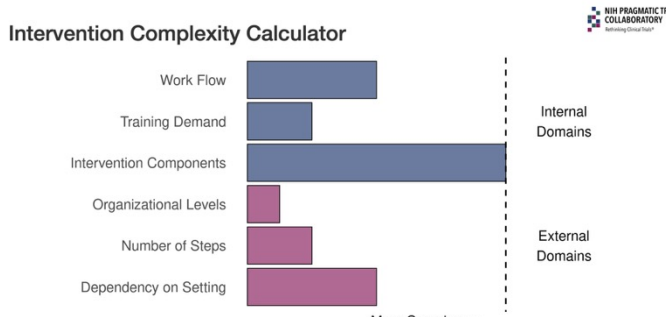
The NIH's background rationale for data sharing is that it enables researchers "to rigorously test the validity of research findings, describe what works, and build on existing knowledge."

generative science also becomes less feasible. Most NIH guidance on deidentification is concerned with patient privacy (4), and rightly so, but there is an opportunity to also describe best practices and methods that can better support specific goals of reuse.

Second, what do we mean by reproducibility? Reproducibility can be interpreted in different ways, and the types of data and metadata differ depending on the interpretation. As shown in the Figure, repeating an analysis starting with the raw data requires more metadata than simply rerunning an analysis on the analytic data set.

Third, what metadata should be shared? Data definitions are always needed so people can understand the shared data. For reproducibility, metadata like the study protocol and statistical analysis plan are needed to know what the study team has done. In some cases, the underlying code may be required as well. This expanded list of

Intervention Complexity Calculator



Category	Complexity Level (Relative)	Domain
Work Flow	High	Internal
Training Demand	Medium-High	Internal
Intervention Components	Very High	Internal
Organizational Levels	Low	External
Dependency on Setting	Medium	External

Learn About Our ePCTs

TRIAL WEBPAGES

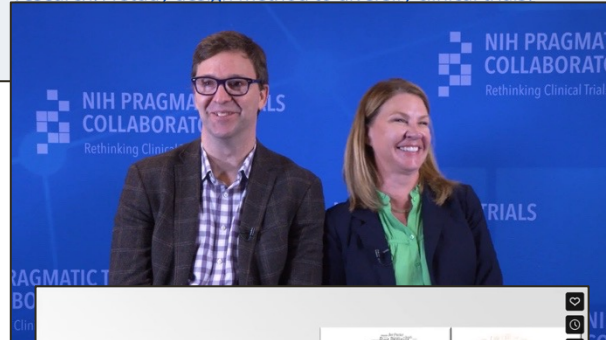
- Trial details
- Study snapshots
- News & interviews
- Publications
- Presentations
- Shared resources

Publications

[Patient engagement with prescription refill text reminders across time and major societal events](#)

[Description of patient questions received by clinical pharmacists in the Nudge Study](#)

[Secondary analysis of electronic opt-out consent in pragmatic research: A study design method to diversify clinical trials?](#)



ICD-Pieces: Lessons Learned in an Ongoing Trial

MIGUEL A. VAZQUEZ, MD AND GEORGE H. OLIVER, MD
FOR THE ICD-PIECES STUDY TEAM AND NIH COLLABORATORY



Data and Resource Sharing

[TSOS Data Dictionary](#)

[TSOS Protocol](#)

[TSOS Data Quality and Phenotyping Manual](#)

[TSOS Consent Form](#)



Study Snapshot



Pragmatic Trial of User-Centered Clinical Decision Support to Implement Emergency Department-Initiated Buprenorphine for Opioid Use Disorder (EMBED)

Principal Investigators
Edward Melnick, MD, MHS;
Gail D'Onofrio, MD, MS
ClinicalTrials.gov Identifier
[NCT03658642](#)

Sponsoring Institution
Yale University

Collaborators
• University of North Carolina at Chapel Hill
• University of Alabama at Birmingham
• University of Colorado Denver
• UMass Chan Medical School-Baystate

NIH Institutes Providing Oversight
• National Institute on Drug Abuse (NIDA)

DATA AND RESOURCE SHARING

• [Data sharing checklist](#)
• Melnick ER, Nath B, Dziura JD, et al. User centered clinical decision support to implement initiation of buprenorphine for opioid use disorder in the emergency department: EMBED pragmatic cluster randomized controlled trial. *BMJ*. 2022 Jun 27;377:e069271. doi: 10.1136/bmj-2021-069271. PMID: 35760423.

STUDY AT A GLANCE

STUDY QUESTION AND SIGNIFICANCE

Patients with untreated opioid use disorder often seek medical care in emergency departments (EDs). ED-initiated buprenorphine doubles the rate of engagement in addiction treatment by these patients. However, the practice of initiating buprenorphine in the ED has not been implemented into ED care. One major challenge for implementing evidence-based medicine has been the poor usability of health information technology. User-centered design of health information technology interventions can improve the user experience and the uptake of evidence-based medical care.

DESIGN AND SETTING

Pragmatic cluster randomized controlled trial with 599 attending emergency physicians caring for 5047 adult patients who presented with opioid use disorder in 18 ED clusters across 5 healthcare systems in 5 states between November 2019 and May 2021.

INTERVENTION AND METHODS

The study seamlessly integrated a user-centered, physician-facing clinical decision support system into user workflows in the electronic health record (EHR) to support initiation of buprenorphine in the ED. The system was designed to help clinicians diagnose opioid use disorder, assess withdrawal severity, motivate patients to accept treatment, and complete EHR tasks by automating clinical and after-visit documentation, order entry, prescribing, and referral. The primary study outcome was the rate of buprenorphine administration or prescription in the ED among patients with opioid use disorder. Secondary implementation outcomes were measured using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework.

FINDINGS

Assessment of 1,413,693 ED visits for study eligibility identified 5047 patients with opioid use disorder (2787 in the intervention arm, 2260 in the usual care arm) under the care of 599 attending physicians (340 in the intervention arm, 259 in the usual care arm) for analysis. Buprenorphine was initiated in 347 patients (12.5%) in the intervention arm and 271 patients (12.0%) in the usual care arm (odds ratio [OR] from adjusted generalized estimating equations, 1.22; 95% CI, 0.61-2.43; $P = .58$). Buprenorphine was initiated at least once by 153 physicians (44.4%) in the intervention arm and 88 physicians (34.0%) in the usual care arm (OR, 1.83; 95% CI, 1.16-2.89; $P = .01$).

CONCLUSIONS AND RELEVANCE

Although user-centered clinical decision support did not increase patient-level rates of buprenorphine initiation in the ED, when used, EMBED was associated with high rates of initiation of buprenorphine. EMBED also increased the number of unique physicians who provided initiation of buprenorphine in the ED and prescribed naloxone. Clinical decision support that streamlines and automates electronic workflows can increase physician adoption of complex, unfamiliar evidence-based practices. More interventions are needed to examine other barriers to the treatment of addiction at the patient level in the ED for patients with opioid use disorder.

rethinkingclinicaltrials.org

Sharing Trial Resources & Data

rethinkingclinicaltrials.org/data-and-resource-sharing/



Completed trials share data and resources publicly

STUDY TOOLS

- Protocols
- Consent forms
- Implementation tools
- Site materials
- Questionnaires
- Toolkits
- Ethics and regulatory documentation

DATASETS AND DOCUMENTATION

- Data dictionaries
- Public use datasets
- Analytic code
- Computable phenotypes
- Data quality manuals
- Data request forms
- Data sharing checklists

PUBLICATIONS

- Study design papers
- Main outcomes papers
- Qualitative research
- Other publications

Rethinking Clinical Trials® Grand Rounds



Weekly webinars

- **Fridays, 1:00-2:00 pm ET**
- Open to public
- >600 held to date
- >150 attendees/session
- Timely, high-interest topics
- Feature NIH Collaboratory work and beyond

The collage features six distinct webinar promotional slides:

- Slide 1 (Top Left):** NIH Pragmatic Trials Collaboratory Grand Rounds, January 24, 2025. Topic: The HEALing Communities Study – 10 Million People, 67 Communities. A Community-based Cluster Randomized Trial to Reduce Opioid Overdose Deaths. Speaker: Jeffrey H. Samet MD, MA, MPH.
- Slide 2 (Top Right):** The All of Us Research Program: Improving Health Through Diverse Technology, Huge Cohorts, and Precision Medicine. Date: May 5, 2023. Speaker: Joshua Denny, MD, MS, Chief Executive Officer.
- Slide 3 (Middle Left):** CLINICAL TRIALS TRANSFORMATION INITIATIVE, September 30, 2022. Topic: CTTI's Digital Health Trials Hub. Recommendations and Resources to Run Your Digital Health Trial. Speaker: Marianne Chase, MGH, CTTI Team Lead.
- Slide 4 (Middle Right):** State of Clinical Trials: An Analysis of Clinical.Trials.Gov. Speaker: Adrian F. Hernandez, MD, MHS, Executive Director, Duke Clinical Research Institute.
- Slide 5 (Bottom Left):** NIH Pragmatic Trials Collaboratory Grand Rounds, 24 June 2022. Topic: FDA Draft Guidance on Real-World Evidence. Speaker: John Concato, MD, MS, MPH, Associate Director for Real-World Evidence Analytics, Office of Medical Policy, Center for Drug Evaluation and Research.
- Slide 6 (Bottom Right):** From Observational Studies to Pragmatic Clinical Trials: (Almost) A Decade of Research in PCORnet®. Speakers: Erin Holve, PhD, MPH, MPP; Russell Rothman, MD, MPP; Neha Pagidipati, MD, MPH; W. Schuyler Jones, MD.

Rethinking Clinical Trials® Podcast



Podcast episodes

- >50 episodes available
- >24,000 plays
- Timely, high-interest topics
- Feature NIH Collaboratory work and beyond

VIEWPOINT **INTEGRATING CLINICAL TRIALS AND PRACTICE**
Making Pragmatic Clinical Trials More Pragmatic

Richard Platt, MD, MSc
Department of Population Medicine, Harvard Pilgrim Health Care Institute and Harvard Medical School

Pragmatic clinical trials are having a moment—actually, a decade. More than 80% of National Library of Medicine citations identified by searching “pragmatic clinical trials” were published in the past 10 years. The Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) has been cited almost 700 times since its publication in

health care system. Although it was expected that widespread dissemination and implementation might require both replication and time, in a surprising number of instances, the collaborating health care systems in which the trials were conducted did not make decisions strictly consistent with the trial findings for the pro-

10 years ago, the National Academy of Medicine called for a “Learning Health System”—in which clinical trials would be integrated with health care delivery in a continuous

or adopting the findings of these studies. In some instances, health care system leaders did not adopt a practice that had been shown to be effective by the trial’s cri-

RETHINKING CLINICAL TRIALS PODCAST

Public-Private Partnerships in the Trustworthy Health AI Ecosystem

Michael Pencina, PhD, and Brian Anderson, MD
Coalition for Health AI

RETHINKING CLINICAL TRIALS PODCAST

NIH PRAGMATIC TRIALS

Informing and Consenting: What Are the Goals?

P. Pearl O’Rourke, PhD, and Stephanie R. Morain, PhD
NIH Pragmatic Trials Collaboratory

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Rethinking Clinical Trials®

Integrating the BeatPain Study With PRaCTiCe, A New Network Research Hub of the CARE for Health Initiative

Julie M Fritz, PhD, PT
University of Utah

Sebastian Tong, MD, MPH
University of Washington

RETHINKING CLINICAL TRIALS PODCAST

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Training Activities

14 workshops



>750 attendees

>50 presenters



>90 hours
of presenter-led training



AUDIENCES REACHED

- Academic researchers
- Funding agencies
- Investigators
- Health system leaders
- Healthcare practitioners
- Other ePCT partners



AcademyHealth



health care systems
research network



National Institutes
of Health

Duke
UNIVERSITY


ePCT Training Resources

rethinkingclinicaltrials.org/training-resource/


- Learning pathway
- Learning modules
- Video library
- Tools (handouts, checklists, guides, etc)
- Workshop materials (slides, recordings, etc)
- Upcoming opportunities

Training Resources


Pathways to Learning




The NIH Pragmatic Trials Collaboratory Learning Path offers an innovative way to learn about designing a pragmatic clinical trial. The interactive, self-paced modules are led by an expert in study design and include videos, reference materials, and knowledge checkpoints. Learners can earn a certificate by completing this free, 1-hour course. To get started, click the Learn More button below.

[Learn More](#) 


Learning Modules



The NIH Pragmatic Trials Collaboratory Learning Modules offer a series of self-paced, guided learning for researchers interested in pragmatic clinical trials. These modules are organized by topic and can be watched sequentially or individually. Learn from our experts as they answer common questions about pragmatic clinical trials.


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Learn about upcoming NIH Pragmatic Trials Collaboratory workshops and view materials from past workshops, such as agendas, recordings, slides, participant guides, and more.

Upcoming Learning Opportunities

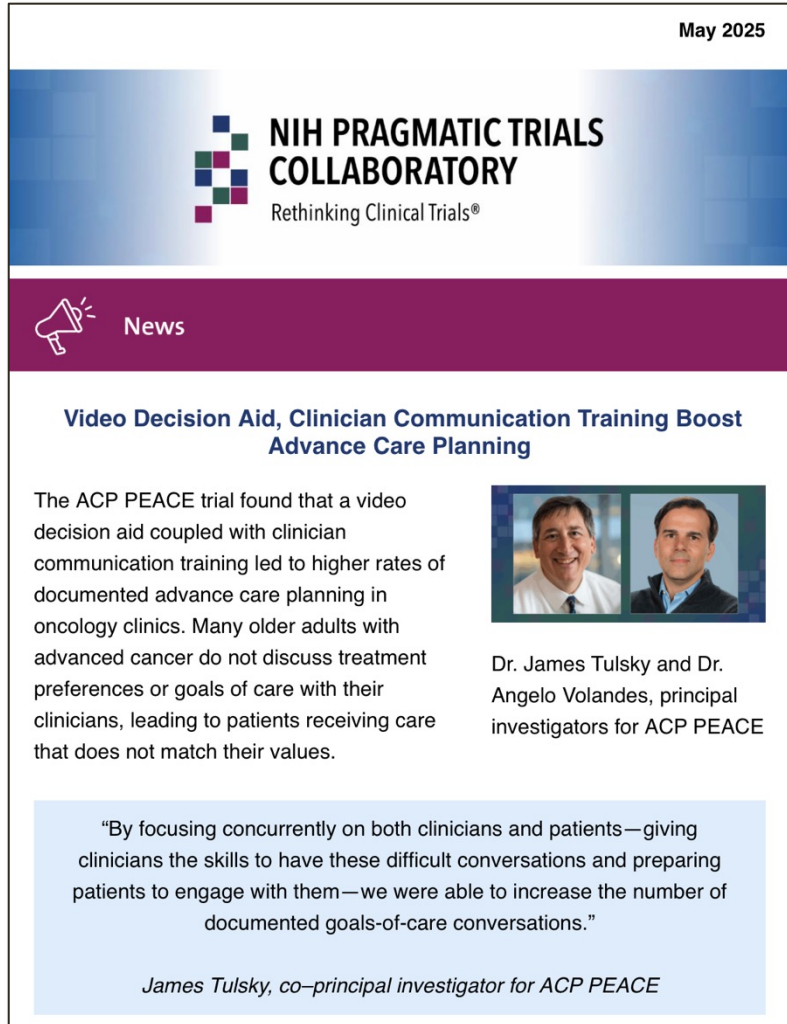
August 1 @ 1:00 pm - 2:00 pm
[Grand Rounds August 1, 2025: Clinical Trial Notifications Triggered by Artificial Intelligence-Detected Cancer Progression \(Kenneth L. Kehl, MD, MPH\)](#)

August 8 @ 1:00 pm - 2:00 pm
[Grand Rounds August 8, 2025: Varenicline for Youth Nicotine Vaping Cessation: A Randomized Clinical Trial \(A. Eden Evins, MD, MPH\)](#)

August 15 @ 1:00 pm - 2:00 pm
[Grand Rounds August 15, 2025: Dexmedetomidine or Clonidine-Based Sedation Compared with Propofol in Critically Ill Patients: The A2B Randomized Clinical Trial \(Tim Walsh, MD, FFICM; Chris Weir, PhD; Richard Parker, MSc\)](#)

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NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Appendix: NIH Collaboratory Trials



**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

NIH Collaboratory Trials: Completed

Project	Population	Intervention	Outcome
ABATE	Non-ICU patients	Decolonization strategies	MRSA and VRE clinical cultures
ACP PEACE	Older patients with advanced cancer	Video decision aid patients and communication skills training for clinicians	Documentation of advance care planning in the electronic health record
BackInAction	Older adults with low back pain	Standard and enhanced 12-week courses of acupuncture	Back-related function at 26 weeks; cost-effectiveness
EMBED	Patients with opioid use disorder	User-centered computerized clinical decision support	Rate of emergency department–initiated buprenorphine/naloxone; referral for ongoing medication-assisted treatment
HiLo	Patients undergoing hemodialysis	Liberalizing serum phosphate target	Rate of hospitalization
ICD-Pieces	Concurrent diabetes, chronic kidney disease, hypertension	Collaborative primary care program	All-cause hospitalizations for 3 conditions
INSPIRE	Non–critically ill hospitalized patients with abdominal or skin and soft tissue infections	Predictive algorithm and automated prompt in the computerized provider order entry system to improve judicious antibiotic prescribing	Reduction in unnecessary prescribing of extended-spectrum antibiotics
LIRE	Low back pain	Insertion of epidemiologic benchmarks in lumbar spine imaging reports	Relative value unit for spine-related interventions

NIH Collaboratory Trials: Completed (cont)

Project	Population	Intervention	Outcome
Nudge	Patients with chronic cardiovascular conditions	Text messages and chat bot	Adherence to cardiovascular medications
PPACT	Nonmalignant chronic pain	Multidisciplinary behavioral care management	Brief Pain Inventory
PRIM-ER	Older adults (>65 years)	Palliative care education; simulation-based workshops; clinical decision support; provider audit and feedback	Healthcare utilization and survival
PROVEN	Nursing home residents	Advance care planning video (behavioral program)	Hospitalizations; presence of advance directives
SPOT	Suicidal ideation or depression	Collaborative care behavioral program (care management and skills training)	Suicide attempts
STOP CRC	Adults aged 50-75 years	Direct mail colorectal cancer screening program (FIT kit)	Colorectal screening rates
TiME	Patients initiating dialysis	Dialysis session of at least 4.25 hours	All-cause mortality, hospitalization
TSOS	Traumatic injury	Collaborative care management program	PTSD checklist; PHQ-9 scale; alcohol use disorders; SF-12/36

ABATE

Active Bathing to Eliminate Infection

- Cluster trial comparing 2 **quality improvement strategies to reduce multidrug-resistant organisms and healthcare-related infections** in non-ICU population
- 53 hospitals
- 331,584 patients



THE LANCET

Chlorhexidine versus routine bathing to prevent multidrug-resistant organisms and all-cause bloodstream infections in general medical and surgical units (ABATE Infection trial): a cluster-randomised trial

Susan S Huang, Edward Septimus, Ken Kleinman, Julia Moody, Jason Hickok, Lauren Heim, Adrijana Gombosev, Taliser R Avery, Katherine Haffnerreffer, Lauren Shimelman, Mary K Hayden, Robert A Weinstein, Caren Spencer-Smith, Rebecca E Kaganov, Michael V Murphy, Tyler Forehand, Julie Lankiewicz, Micaela H Coady, Lena Portillo, Jalpa Sarup-Patel, John A Jernigan, Jonathan B Perlin, Richard Platt, for the ABATE Infection trial team

ACP PEACE

Advance Care Planning: Promoting Effective and Aligned Communication in the Elderly

- Stepped-wedge, cluster randomized trial testing whether testing the delivery of a video decision aid to patients and goals-of-care communication skills training to oncology clinicians will increase **advance care planning** in older patients with advanced cancer
- 29 oncology clinics in 3 healthcare systems
- 13,800 patients



BackInAction

Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults

- Evaluating the **safety and effectiveness of acupuncture** in older adults with chronic low back pain
- 4 performance sites
- 828 expected patients



EMBED

Pragmatic Trial of User-Centered Clinical Decision Support to Implement Emergency Department-Initiated Buprenorphine for Opioid Use Disorder

- Cluster trial testing the effect of user-centered computerized clinical decision support on rates of **emergency department–initiated buprenorphine/naloxone and referral for ongoing medication-assisted treatment** in patients with opioid use disorder
- 3 health systems
- 5,047 patients



thebmj

RESEARCH

OPEN ACCESS

Check for updates

User centered clinical decision support to implement initiation of buprenorphine for opioid use disorder in the emergency department: EMBED pragmatic cluster randomized controlled trial

Edward R Melnick,^{1,2} Bidisha Nath,¹ James D Dziura,^{1,2} Martin F Casey,³ Molly M Jeffery,⁴ Hyung Paek,² William E Soares III,⁵ Jason A Hoppe,⁶ Haseena Rajeevan,² Fangyong Li,² Rachel M Skains,⁷ Lauren A Walter,⁷ Mehul D Patel,³ Srihari V Chari,³ Timothy F Platts-Mills,⁸ Erik P Hess,⁹ Gail D'Onofrio^{1,2}

HiLo

Pragmatic Trial of Higher vs. Lower Serum Phosphate Targets in Patients Undergoing Hemodialysis

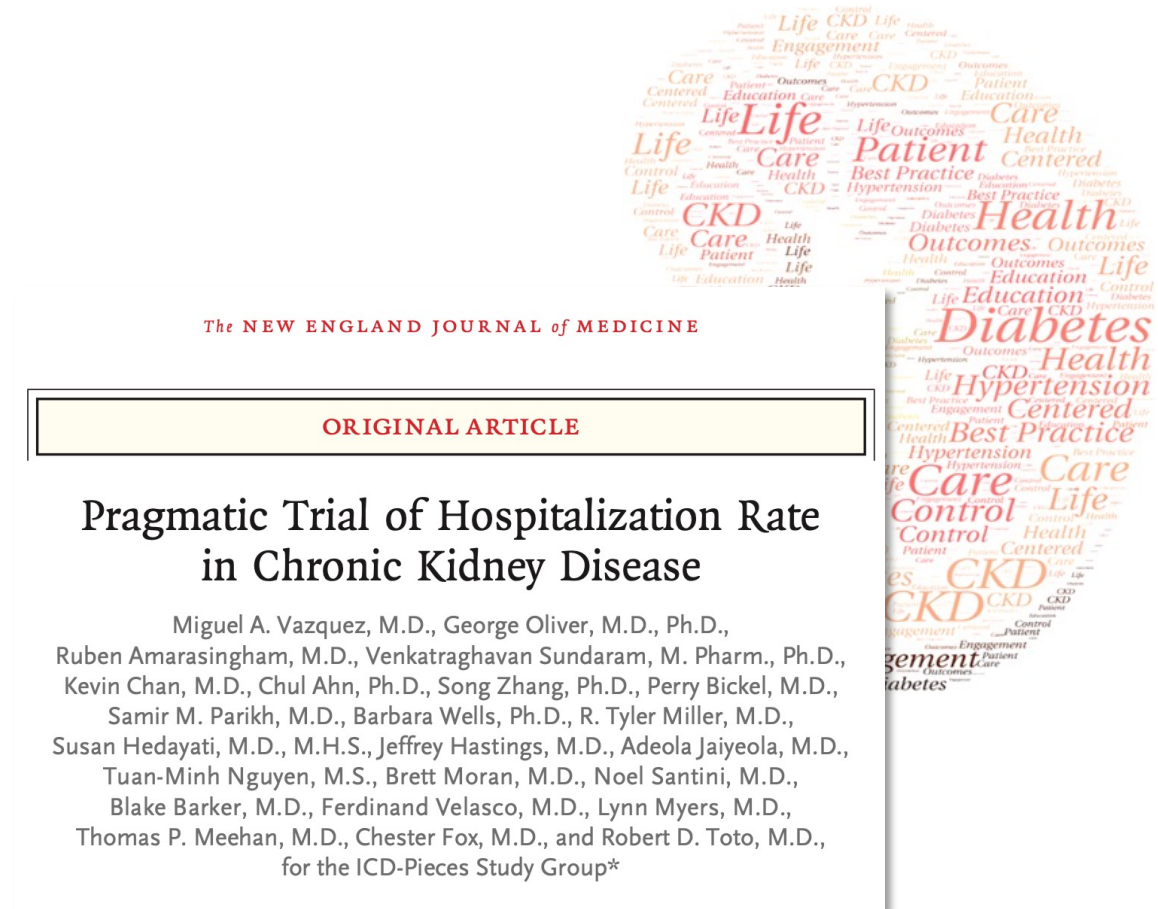
- Cluster trial testing whether less stringent control of serum phosphate levels will yield **noninferior rates of all-cause hospitalization** in patients with end-stage renal disease undergoing hemodialysis
- >100 dialysis facilities
- 4,400 expected patients



A Pragmatic Trial Sponsored by the
National Institutes of Health

ICD-Pieces *Improving Chronic Disease Management with Pieces™*

- Novel platform to test effective ways to reduce heart problems, hospitalizations & deaths in patients with multiple chronic conditions
- 94 clinical sites
- 11,000 patients



INSPIRE

INtelligent Stewardship Prompts to Improve Real-time Empiric Antibiotic Selection for Patients

- 2 cluster randomized trials that used personalized clinical decision support to improve judicious antibiotic prescribing for non–critically ill hospitalized with **abdominal infections or skin and soft tissue infections**
- 60,725 patients with skin or soft tissue infections, and 105,004 patients with abdominal infections



JAMA Surgery | **Original Investigation**

Improving Empiric Antibiotic Selection for Patients Hospitalized With Abdominal Infection
The INSPIRE 4 Cluster Randomized Clinical Trial

Shruti
Taliser
Laura
Julia
Mary
Jonat

JAMA Internal Medicine | **Original Investigation** | **LESS IS MORE**

Improving Empiric Antibiotic Selection for Patients Hospitalized With Skin and Soft Tissue Infection
The INSPIRE 3 Skin and Soft Tissue Randomized Clinical Trial

Shruti K. Gohil, MD, MPH; Edward Septimus, MD; Ken Kleinman, ScD; Neha Varma, MPH; Kenneth E. Sands, MD, MPH; Taliser R. Avery, MS; Amarah Mauricio, MPH; Selsebil Sijivo, MPH; Risa Rahm, PharmD; Kaleb Roemer, PharmD; William S. Cooper, PharmD; Laura E. McLean, MEd; Naoise G. Nickolay, RPh; Russell E. Poland, PhD; Robert A. Weinstein, MD; Samir M. Fakhry, MD; Jeffrey Guy, MD, MSc; Julia Moody, MS; Micaela H. Coady, MS; Kim N. Smith, MBA; Brittany Meador, BS; Allison Froman, MPH; Katyuska Eibensteiner, BA; Mary K. Hayden, MD; David W. Kubiak, PharmD; Chenette Burks, PharmD; L. Hayley Burgess, PharmD; Michael S. Calderwood, MD, MPH; Jonathan B. Perlin, MD, PhD; Richard Platt, MD, MSc; Susan S. Huang, MD, MPH

LIRE

Lumbar Imaging with Reporting of Epidemiology

- Cluster trial evaluating whether **inserting epidemiologic benchmarks** into lumbar spine imaging reports reduces subsequent tests and treatments
- 98 clinical sites
- 246,289 patients



JAMA
Network | **Open**



Original Investigation | Imaging

The Effect of Including Benchmark Prevalence Data of Common Imaging Findings in Spine Image Reports on Health Care Utilization Among Adults Undergoing Spine Imaging: A Stepped-Wedge Randomized Clinical Trial

Jeffrey G. Jarvik, MD, MPH; Eric N. Meier, MS; Kathryn T. James, MPH; Laura S. Gold, PhD; Katherine W. Tan, PhD; Larry G. Kessler, ScD; Pradeep Suri, MD; David F. Kallmes, MD; Daniel C. Cherkov, PhD; Richard A. Deyo, MD, MPH; Karen J. Sherman, PhD; Safwan S. Halabi, MD; Bryan A. Comstock, MS; Patrick H. Luetmer, MD; Andrew L. Avins, MD, MPH; Sean D. Rundell, DPT, PhD; Brent Griffith, MD; Janna L. Friedly, MD; Danielle C. Lavalley, PhD; Kari A. Stephens, PhD; Judith A. Turner, PhD; Brian W. Bresnahan, PhD; Patrick J. Heagerty, PhD

Nudge

Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications

- Patient-level randomized pragmatic trial comparing the effects of digital interventions (text messages and chat bot) on **medication adherence** in patients with chronic cardiovascular conditions
- 3 health systems



JAMA | **Original Investigation**

Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications A Randomized Pragmatic Trial

P. Michael Ho, MD, PhD; Thomas J. Glorioso, MS; Larry A. Allen, MD, MHS; Richard Blankenhorn, MSDA, BSF; Russell E. Glasgow, PhD; Gary K. Grunwald, PhD; Amber Khanna, MD; David J. Magid, MD, MPH; Joel Marrs, PharmD, MPH; Sylvie Novins-Montague, BA; Steven Orlando, PharmD; Pamela Peterson, MD, MSPH; Mary E. Plomondon, PhD; Lisa M. Sandy, MA; Joseph J. Saseen, PharmD; Katy E. Trinkley, PharmD, PhD; Shawni Vaughn, MAS; Joy Waughtal, MPH; Sheana Bull, PhD

PPACT

Collaborative Care for Chronic Pain in Primary Care

- Mixed-methods cluster trial evaluating **integration of multidisciplinary services within the primary care environment** to improve chronic pain management
- 3 regional health systems
- 2,000 patients



Automating Collection of Pain-Related Patient-Reported Outcomes to Enhance Clinical Care and Research

Ashli Owen-Smith, PhD, SM^{1,2}, Meghan Mayhew, MPH³, Michael C. Leo, PhD³, Alexandra Varga, MPH³, Lindsay Benes, PhD, RN, CNS^{3,4}, Allison Bonifay, MA, LPC³, and Lynn DeBar, PhD, MPH⁵

PRIM-ER *Primary Palliative Care for Emergency Medicine*

- Cluster trial testing the effects of implementing primary palliative care in emergency medicine on **healthcare utilization and survival**
- 35 emergency departments across 18 health systems

JAMA | **Original Investigation**

Palliative Care Initiated in the Emergency Department A Cluster Randomized Clinical Trial

Corita R. Grudzen, MD, MSHS; Nina Siman, MA, MEd; Allison M. Cuthel, MPH; Oluwaseun Adeyemi, MBBS, PhD; Rebecca Liddicoat Yamarik, MD; Keith S. Goldfeld, DrPH, MS, MPA; and the PRIM-ER Investigators



PROVEN

Pragmatic Trial of Video Education in Nursing Homes

- Evaluating the **effectiveness of advance care planning video** shown in nursing homes of 2 large healthcare systems
- 359 nursing homes
- 211,469 patients



Research

JAMA Internal Medicine | [Original Investigation](#)

Advance Care Planning Video Intervention
Among Long-Stay Nursing Home Residents
A Pragmatic Cluster Randomized Clinical Trial

Susan L. Mitchell, MD, MPH; Angelo E. Volandes, MD, MPH; Roe Gutman, PhD; Pedro L. Gozalo, MSc, PhD; Jessica A. Ogarek, MS; Lacey Loomer, MSPH; Ellen M. McCreedy, PhD; Ruoshui Zhai, MS; Vincent Mor, PhD

SPOT *Suicide Prevention Outreach Trial*

- Collaborative care model to test treatments intended to reach large groups of **adult patients who have serious thoughts of suicide**
- 4 clinical sites
- 18,644 patients

SUICIDE PREVENTION OUTREACH TRIAL

Research

JAMA | [Original Investigation](#)

Effect of Offering Care Management or Online Dialectical Behavior Therapy Skills Training vs Usual Care on Self-harm Among Adult Outpatients With Suicidal Ideation
A Randomized Clinical Trial

Gregory E. Simon, MD, MPH; Susan M. Shortreed, PhD; Rebecca C. Rossom, MD, MS; Arne Beck, PhD; Gregory N. Clarke, PhD; Ursula Whiteside, PhD; Julie E. Richards, MPH, PhD; Robert B. Penfold, PhD; Jennifer M. Boggs, PhD, MSW; Julia Smith, MS

STOP CRC

Strategies and Opportunities to Stop Colorectal Cancer

- Cluster trial testing a culturally tailored, healthcare system–based program to **improve CRC screening rates** in community-based collaborative network
- 30 clinical sites
- 62,155 patients



JAMA Internal Medicine | [Original Investigation](#)

Effectiveness of a Mailed Colorectal Cancer Screening Outreach Program in Community Health Clinics The STOP CRC Cluster Randomized Clinical Trial

Gloria D. Coronado, PhD; Amanda F. Petrik, MS; William M. Vollmer, PhD; Stephen H. Taplin, MD, MPH;
Erin M. Keast, MPH; Scott Fields, MD; Beverly B. Green, MD, MPH

TiME

Time to Reduce Mortality in End-Stage Renal Disease

- Cluster trial testing whether a **longer hemodialysis session can improve survival & quality of life** for patients with kidney failure who require chronic treatment with dialysis
- 256 clinical sites
- 7,053 patients



JOURNAL OF THE AMERICAN SOCIETY OF NEPHROLOGY

The TiME Trial: A Fully Embedded, Cluster-Randomized, Pragmatic Trial of Hemodialysis Session Duration

Laura M. Dember,^{1,2} Eduardo Lacson, Jr.,³ Steven M. Brunelli,⁴ Jesse Y. Hsu,⁵ Alfred K. Cheung,⁶ John T. Daugirdas,⁷ Tom Greene,⁸ Csaba P. Kovesdy,⁹ Dana C. Miskulin,¹⁰ Ravi I. Thadhani,^{11,12} Wolfgang Winkelmayr,¹³ Susan S. Ellenberg,⁵ Denise Cifelli,¹⁴ Rosemary Madigan,¹⁴ Amy Young,⁴ Michael Angeletti,³ Rebecca L. Wingard,³ Christina Kahn,³ Allen R. Nissenson,^{15,16} Franklin W. Maddux,³ Kevin C. Abbott,¹⁷ and J. Richard Landis⁵

TSOS

Trauma Survivors Outcomes and Support

- Stepped-wedge cluster trial **testing innovative intervention for patients with PTSD and comorbidity**
- 25 level 1 trauma centers
- 960 patients



JAMA Surgery | **Original Investigation**

Stepped Collaborative Care Targeting Posttraumatic Stress Disorder Symptoms and Comorbidity for US Trauma Care Systems A Randomized Clinical Trial

Douglas Zatzick, MD; Gregory Jurkovich, MD; Patrick Heagerty, PhD; Joan Russo, PhD; Doyanne Darnell, PhD; Lea Parker, BA; Michelle K. Roberts, MPH; Rddhi Moodliar, BA; Allison Engstrom, MSW; Jin Wang, PhD; Eileen Bulger, MD; Lauren Whiteside, MD; Deepika Nehra, MD; Lawrence A. Palinkas, PhD; Kathleen Moloney, BA; Ronald Maier, MD

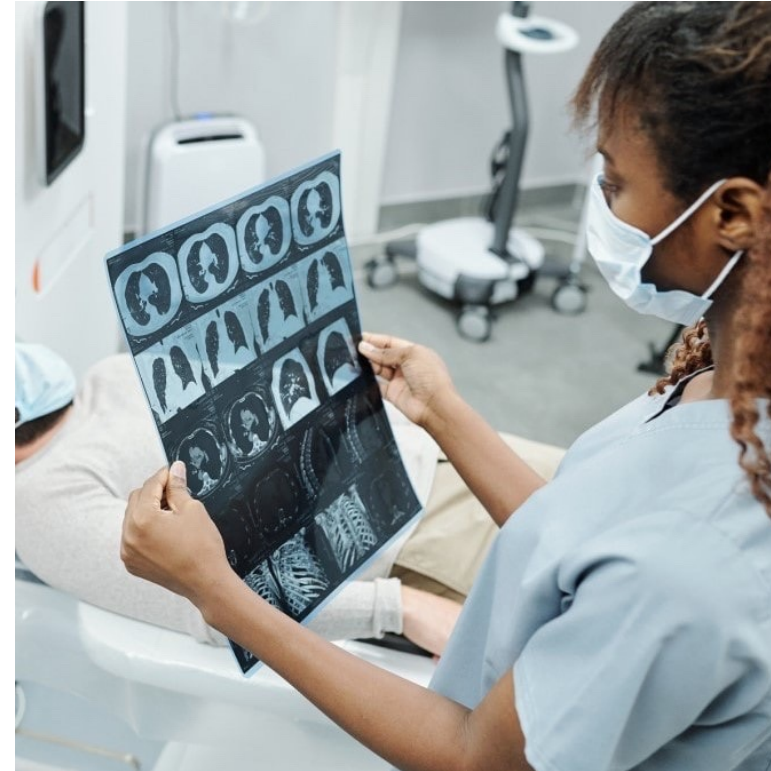
NIH Collaboratory Trials: Planning Phase

Project	Population	Intervention	Outcome
LungSmart	Current and former smokers, aged 50-80 years	Telehealth tools designed to engage people in lung cancer screening	Lung cancer screening completion
STEP-2	Women aged 30-65 years	HPV self-sampling	Screening proportion

LungSmart

Population Health Management Approaches to Increase Lung Cancer Screening in Community Health Centers

- Patient-level randomized trial
- Evaluating the effectiveness of digital and telehealth tools to **increase the reach of lung cancer screening** among people who get care at community health centers
- 14 federally qualified health centers in Utah operating ~50 primary care clinics



STEP-2

Self-Testing for Cervical Cancer in Priority Populations

- Cluster randomized trial
- Evaluating the effectiveness and implementation of **HPV self-sampling interventions**
- 42 federally qualified health center clinics



HEAL Trials: Planning Phase

Project	Population	Intervention	Outcome
CARNATION	Patients with chronic musculoskeletal pain	Implementation support package	Effectiveness of implementation support strategies
Equip PC	Patients with chronic pain	Behavioral health integration toolkit and digital therapeutic apps	Pain

CARNATION

*Coordinated cARe paiN mAnagement Technology
ImplementatiON*

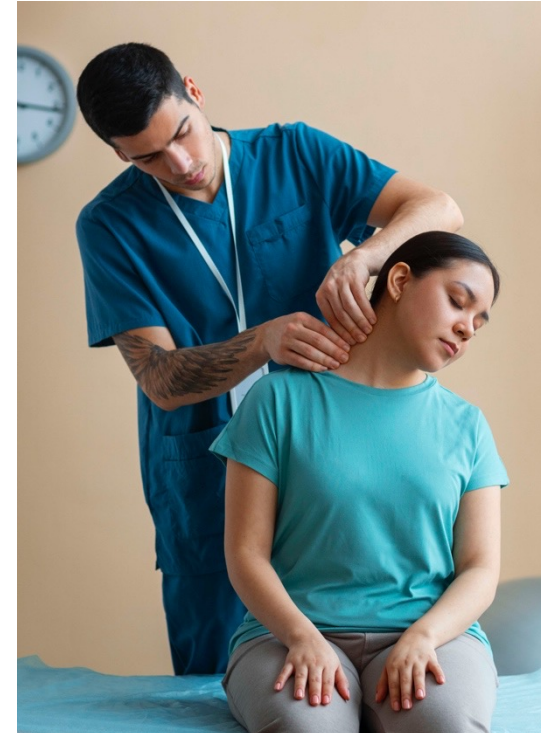
- Hybrid type 3 effectiveness-implementation randomized trial
- Test the impact of an **implementation support package** on clinics' use of the tailored technology **tools for the delivery of coordinated multidisciplinary pain care** among patients with chronic musculoskeletal pain
- 20 OCHIN community health centers



EquiP PC

Equitable Primary Care for Pain Care

- 3-arm, pragmatic, cluster randomized trial
- Test the effectiveness of an adapted **behavioral health integration toolkit to improve chronic pain care**
- 27 primary care practices



R01 NIH Collaboratory Trials

Project	Population	Intervention	Outcome
iPATH	Patients with type 2 diabetes from health disparity populations	Multilevel, multicomponent, technology-enabled practice transformation strategy	Reduction in patients with poorly controlled diabetes (A1c > 9%) at 12 and 24 months
MOMs Chat & Care Study	Black and Hispanic birthing people	Integrated care model approach at 2 different levels of intensity, high or low	Incidence of severe maternal morbidity at time of labor and delivery and related hospital admissions at 1 month and 1 year postpartum

iPATH

Implementing Scalable, PAtient-centered Team-based Care for Adults with Type 2 Diabetes and Health Disparities

- Hybrid type 2 effectiveness implementation study, including a stepped-wedge cluster randomized trial
- Evaluating whether an innovative multi-level, multi-component, technology-enabled **practice transformation strategy** can improve outcomes for patients with type 2 diabetes from health disparity populations
- 8 federally qualified health centers



MOMs Chat & Care

Maternal Outcomes Program: Testing Integrated Maternal Care Model Approaches to Reduce Disparities in Severe Maternal Morbidity

- Testing the effectiveness of an **integrated care model approach** at 2 different levels of intensity to facilitate timely, appropriate care for high-risk Black and Hispanic birthing people and reduce risk for severe maternal morbidity
- Largest healthcare provider in New York
- 674 expected patients



NIH Collaboratory Trials: Implementation Phase

Project	Population	Intervention	Outcome
BEST-ICU	Critically ill adults	Strategies to increase adoption of the ABCDEF bundle, a mechanical ventilation liberation and symptom management approach	Implementation (primary) and clinical (secondary) effectiveness outcomes
Chat 4 Heart Health	Patients from Federally Qualified Health Centers with sub-optimal control of their cardiovascular risk factors	Multilevel intervention leveraging cellphone-based text messages	Global cardiovascular health and control of cardiovascular risk factors (eg, hypertension, diabetes)
GGC4H	Parents of early adolescents	Anticipatory guidance curriculum	Behavioral health problems; health service utilization

NIH Collaboratory Trials: Implementation Phase (cont)

Project	Population	Intervention	Outcome
I CAN DO Surgical ACP	Older adults undergoing major elective survey	Patient-facing advance care planning tool	Advance care planning completion rates and patient engagement with advance care planning
IMPACT-LBP	Adults with low back pain	Primary spine practitioner model using doctors of chiropractic and physical therapists as first-line providers	Improve physical function, decrease pain, decrease opioid prescriptions, improve patient satisfaction, and decrease costs and utilization of healthcare services when compared with usual medical care
TAICHIKNEE	Patients with knee pain due to osteoarthritis	Remotely delivered web-based tai chi intervention	Physical health (including knee-related pain and function), mental health, and healthcare utilization

BEST-ICU

Behavioral Economic and Staffing Strategies to Increase Adoption of the ABCDEF Bundle in the ICU

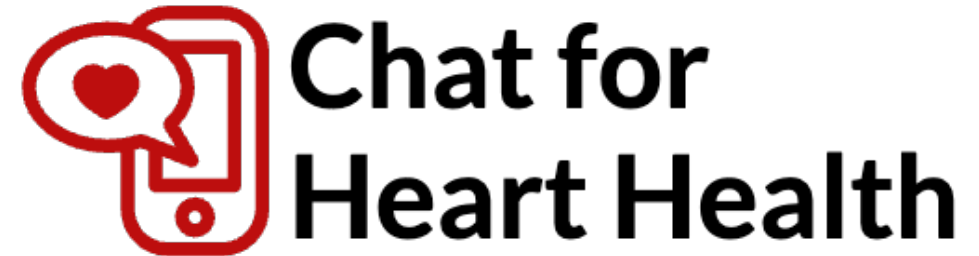
- 3-arm stepped-wedge, cluster-randomized trial to evaluate 2 strategies grounded in behavioral economic and implementation science theory to **increase adoption of the ABCDEF bundle**, a mechanical ventilation liberation and symptom management approach, in critically ill adults
- 12 ICUs from 3 safety net hospitals
- 8,100 expected patients



Chat 4 Heart Health

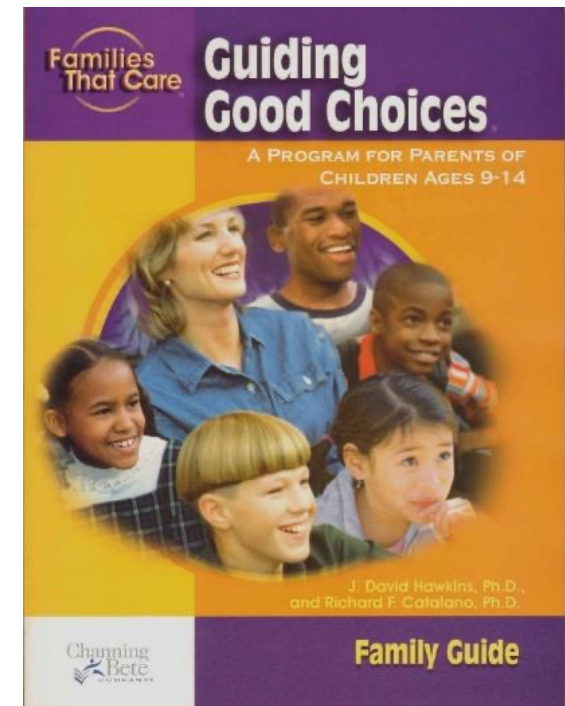
Using Artificially Intelligent Text Messaging Technology to Improve AHA's Life's Essential 8 Health Behaviors

- Patient-level randomized trial to evaluate the implementation and effectiveness of 3 different **automated patient communication approaches** for self-management support to improve control of cardiovascular disease risk factors
- Federally qualified health centers in 3 health systems
- 6,000 expected patients



GGC4H *Guiding Good Choices for Health*

- Cluster trial testing whether an anticipatory guidance curriculum for parents of early adolescents will reduce **behavioral health problems and health service utilization**
- 3 health systems
- 72 pediatricians and 4,500 families expected



I CAN DO Surgical ACP

Improving Completion, Accuracy, and Dissemination of Surgical Advanced Care Planning

- Patient-level randomized trial to evaluate a system-based approach to help older adults undergoing elective surgery **engage in advance care planning**
- 3 health systems



IMPACT-LBP

*Implementation of the American College of Physicians
Guideline for Low Back Pain*

- Refine and implement a **multidisciplinary collaborative care model for low back pain**
- Evaluate the effectiveness of this care model compared to usual medical care for low back pain
- 3 academic healthcare systems



TAI CHI KNEE

*Remote Tai Chi for Knee Osteoarthritis:
an Embedded Pragmatic Trial*

- Compare the effects of a remotely delivered **web-based tai chi intervention** versus routine care for patients with knee pain due to osteoarthritis
- 20-25 clinics across 4 health systems
- 600 expected patients



HEAL Trials: Implementation Phase

Project	Population	Intervention	Outcome
AIM-CP	Rural-dwelling patients with chronic pain	Nurse care management model incorporating care coordination, cognitive behavioral therapy, and a remotely delivered exercise program	Pain interference, physical functioning, mental health, treatment satisfaction, sleep, pharmacologic treatments, and healthcare utilization
APA-SM	Rural-dwelling patients with chronic musculoskeletal pain	4-week auricular point acupressure self-management program delivered via mobile app	Pain intensity, pain interference, and function; cost-effectiveness
ARBOR-Telehealth	Rural-dwelling patients with chronic low back pain	Risk-stratified telerehabilitation model	Change in low back pain-related disability and opioid use after 8 weeks
BeatPain Utah	Adults with back pain in federally qualified health centers in Utah	Brief pain teleconsult and phone-based physical therapy	Pain management; reduction of disparities; evaluation of implementation strategies

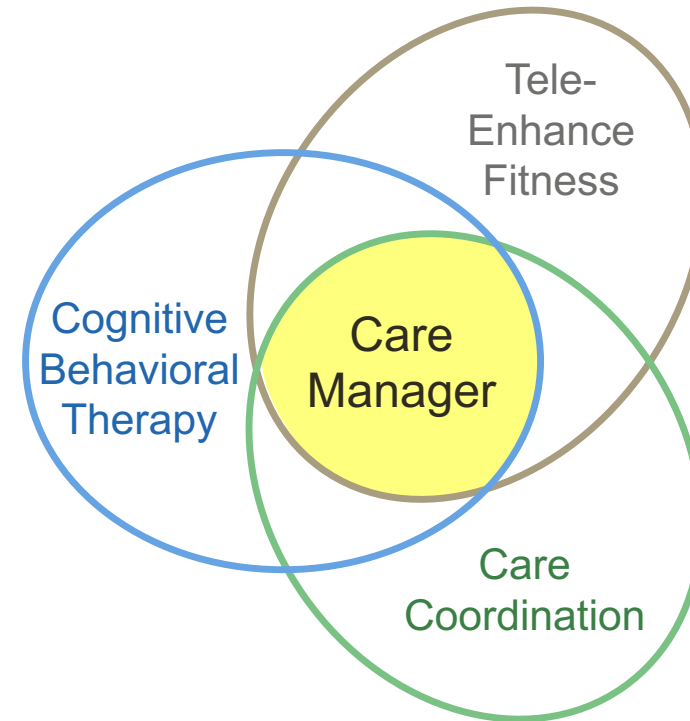
HEAL Trials: Implementation Phase

Project	Population	Intervention	Outcome
FM-TIPS	Fibromyalgia	Addition of transcutaneous electrical nerve stimulation (TENS) to physical therapy	Fibromyalgia symptoms; adherence to therapy; meeting therapeutic goals; medication use
GRACE	Patients with sickle cell disease	Acupuncture and guided relaxation	Pain control; effective treatment sequence; evaluation of implementation strategies
NOHARM	Postoperative pain	EHR-embedded tools to aid shared decision making about pain management	Postoperative opioid use, pain, function
OPTIMUM	Chronic low back pain	Group-based mindfulness in outpatient clinical settings	Pain, physical, and psychological function; opioid prescriptions for chronic low back pain
RAMP	Rural-dwelling veterans with chronic pain	Telehealth intervention with multiple evidence-based complementary and integrative health approaches for chronic pain	Pain interference at 13 and 26 weeks; opioid use

AIM-CP

Adapting and Implementing a Nurse Care Management Model to Care for Rural Patients with Chronic Pain

- Adapting and test a **nurse care management model** to provide comprehensive coordinated care for patients with chronic pain in rural communities
- 6 health systems
- 416 expected patients



APA-SM

Personalized Auricular Point Acupressure for Chronic Pain Self-Management in Rural Populations

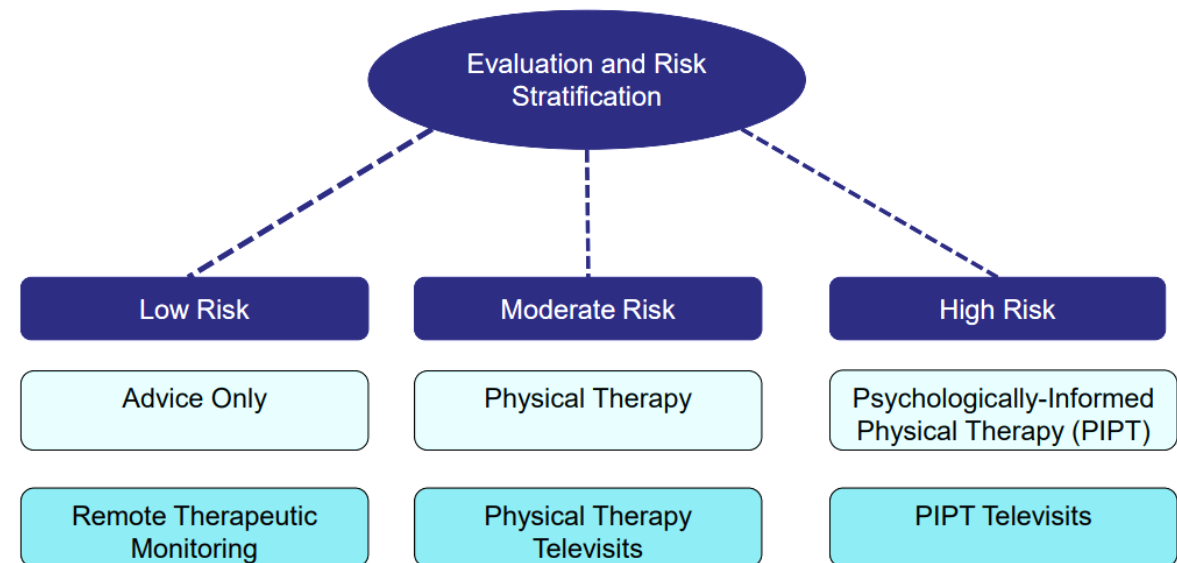
- Evaluating an **auricular point acupressure self-management** program for rural populations with chronic musculoskeletal pain
- Hybrid implementation-effectiveness trial



ARBOR-Telehealth

Advancing Rural Back Pain Outcomes through Rehabilitation Telehealth

- Comparing the effectiveness of a **risk-stratified telerehabilitation model** to improve outcomes in patients with chronic low back pain in rural communities
- Primary care clinics in Maryland
- 434 expected patients



BeatPain Utah

Nonpharmacologic Pain Management in Federally Qualified Health Centers Primary Care Clinics

- Testing the feasibility of a **telehealth strategy** that provides a brief **pain teleconsult** along with phone-based **physical therapy**
- Federally qualified health centers in Utah



FM-TIPS

Fibromyalgia TENS in Physical Therapy Study

- Testing the feasibility and effectiveness of **adding TENS** to treatment of patients with fibromyalgia **in a real-world physical therapy practice setting**
- 5 physical therapy health systems



FM-TIPS

*Fibromyalgia TENS In
Physical Therapy Study*

GRACE

Hybrid Effectiveness-Implementation Trial of Guided Relaxation and Acupuncture for Chronic Sickle Cell Disease Pain

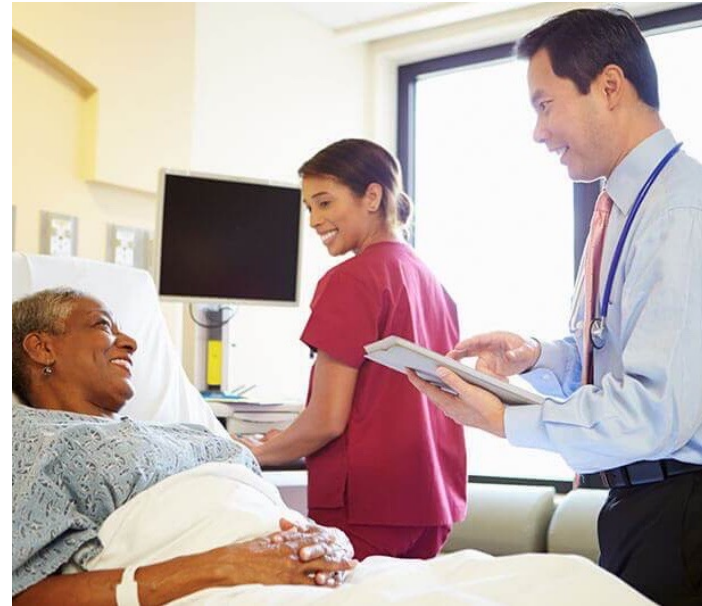
- Testing the effectiveness of **guided relaxation and acupuncture** to improve pain control and determine the most appropriate and effective treatment sequence for **patients with sickle cell disease pain**
- 3 health systems



NOHARM

Nonpharmacologic Options in Postoperative Hospital-based and Rehabilitation Pain Management

- Testing the feasibility of EHR-embedded **patient- and clinician-facing decision support for nonpharmacologic pain care** after surgery
- 4 health systems



OPTIMUM

Group-Based Mindfulness for Patients With Chronic Low Back Pain in the Primary Care Setting

- Evaluating effectiveness of a **group-based mindfulness intervention** for patients with chronic low back pain in a usual care setting
- 3 health systems
- 450 expected patients



RAMP

Reaching Rural Veterans: Applying Mind-Body Skills for Pain Using a Whole Health Telehealth Intervention

- Hybrid type 2 effectiveness-implementation trial evaluating a **telehealth intervention** with multiple evidence-based complementary and integrative health approaches for chronic pain
- VA health system
- 500 expected patients (rural-dwelling veterans)





NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®