

NIH Pragmatic Trials Collaboratory

Enabling pragmatic clinical trials embedded in
healthcare systems



**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

The NIH Collaboratory Story



History: Initiated through the NIH Common Fund in 2012
Selected as the Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM) Resource Coordinating Center in 2019

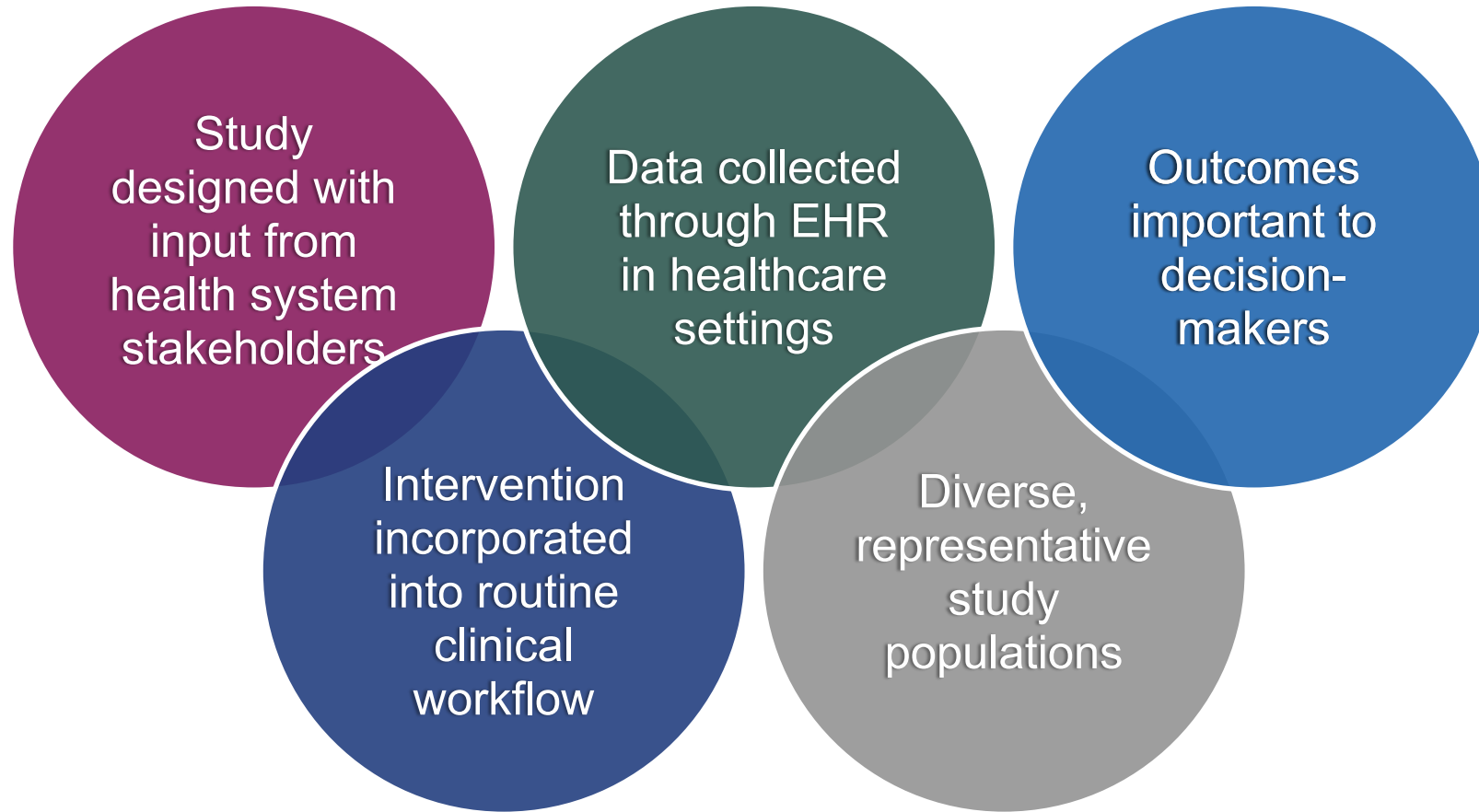


Goal: Strengthen the national capacity to implement cost-effective large-scale research studies that engage healthcare delivery organizations as research partners



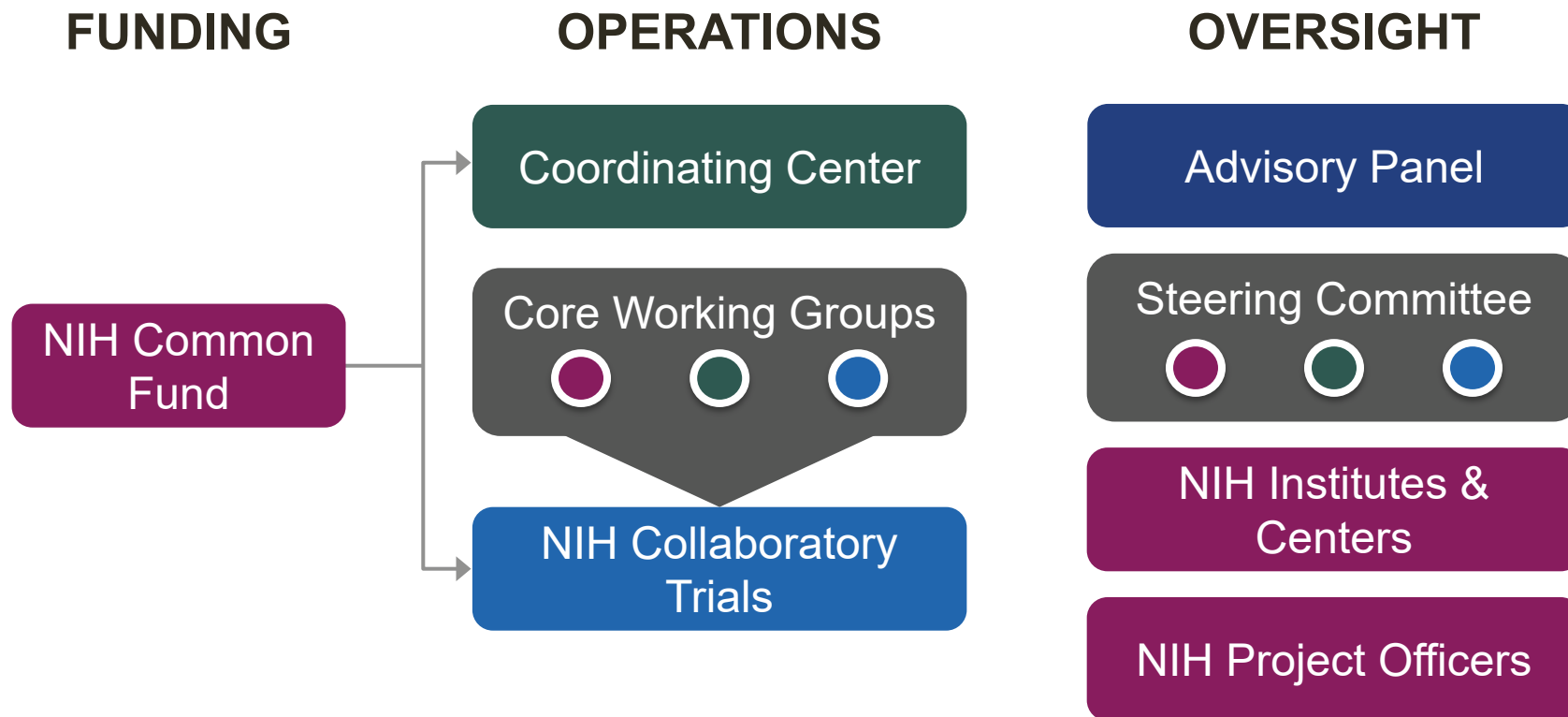
Vision: Support the design and execution of innovative pragmatic clinical trials to establish best practices and proof of concept

Embedded PCTs Bridge Research Into Clinical Care



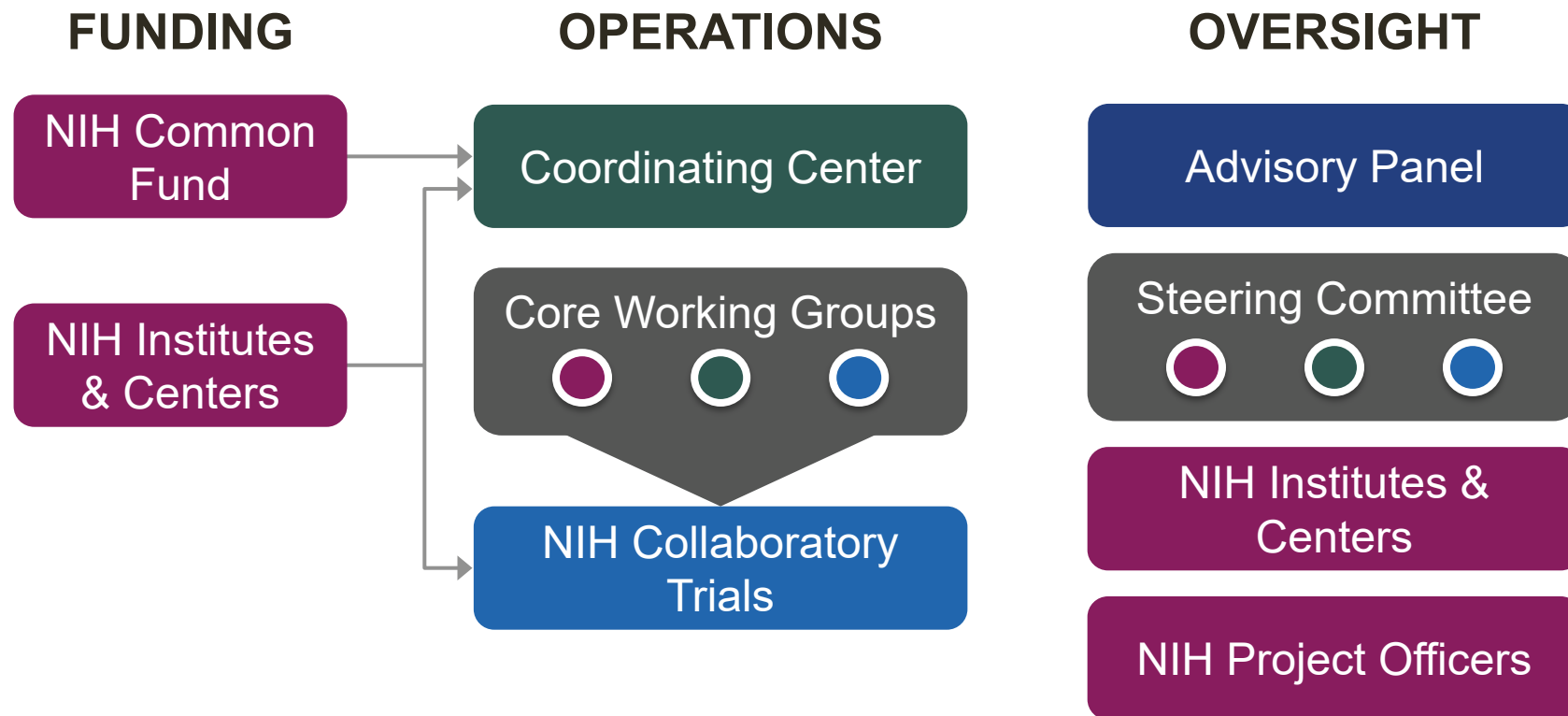
NIH Collaboratory Structure: 2012-2017

- The NIH Collaboratory began as an NIH Common Fund-initiated program. It includes centralized operational support for its pragmatic trials from a Coordinating Center and its Core Working Groups



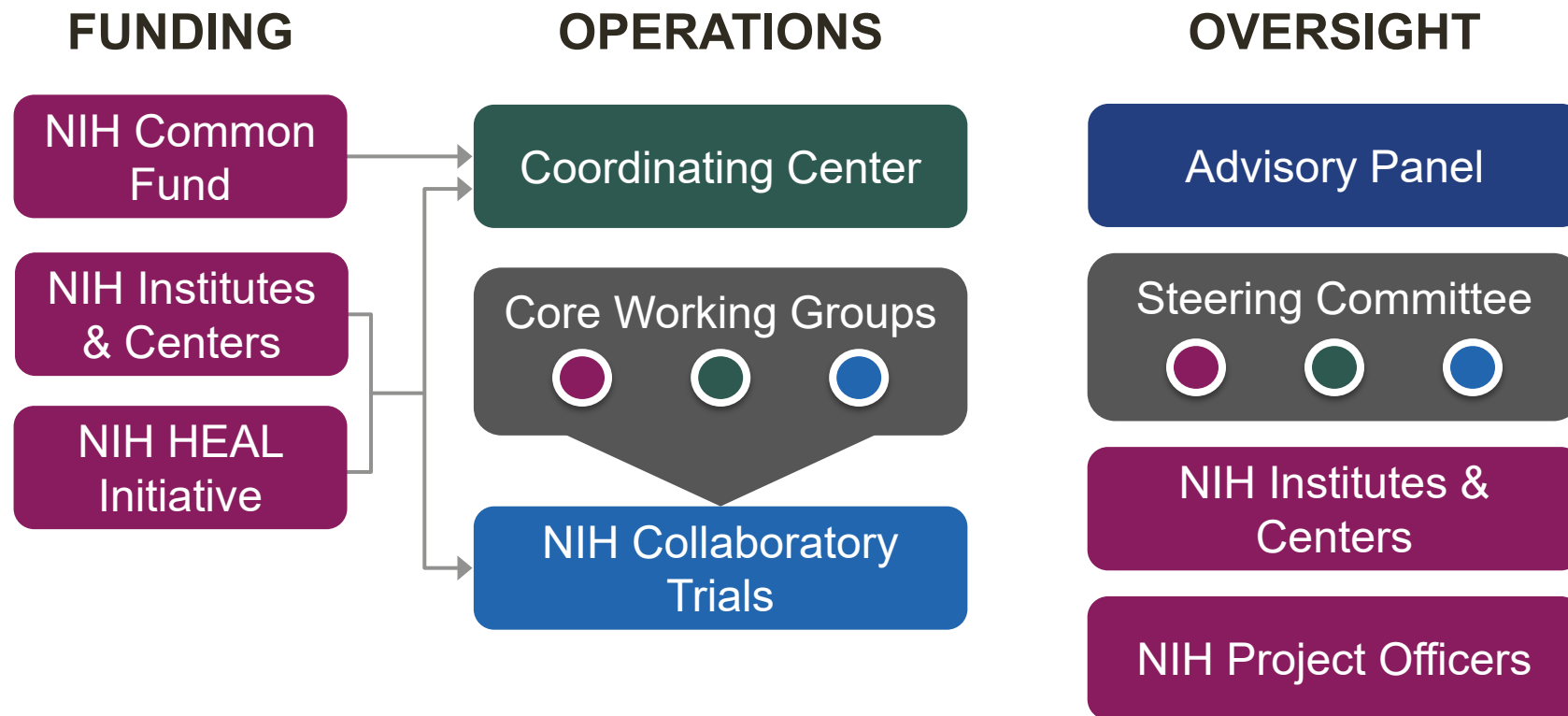
NIH Collaboratory Structure: 2017-2019

- Starting in 2017, individual NIH Institutes and Centers began providing funding for NIH Collaboratory Trials and the Coordinating Center, along with the Common Fund



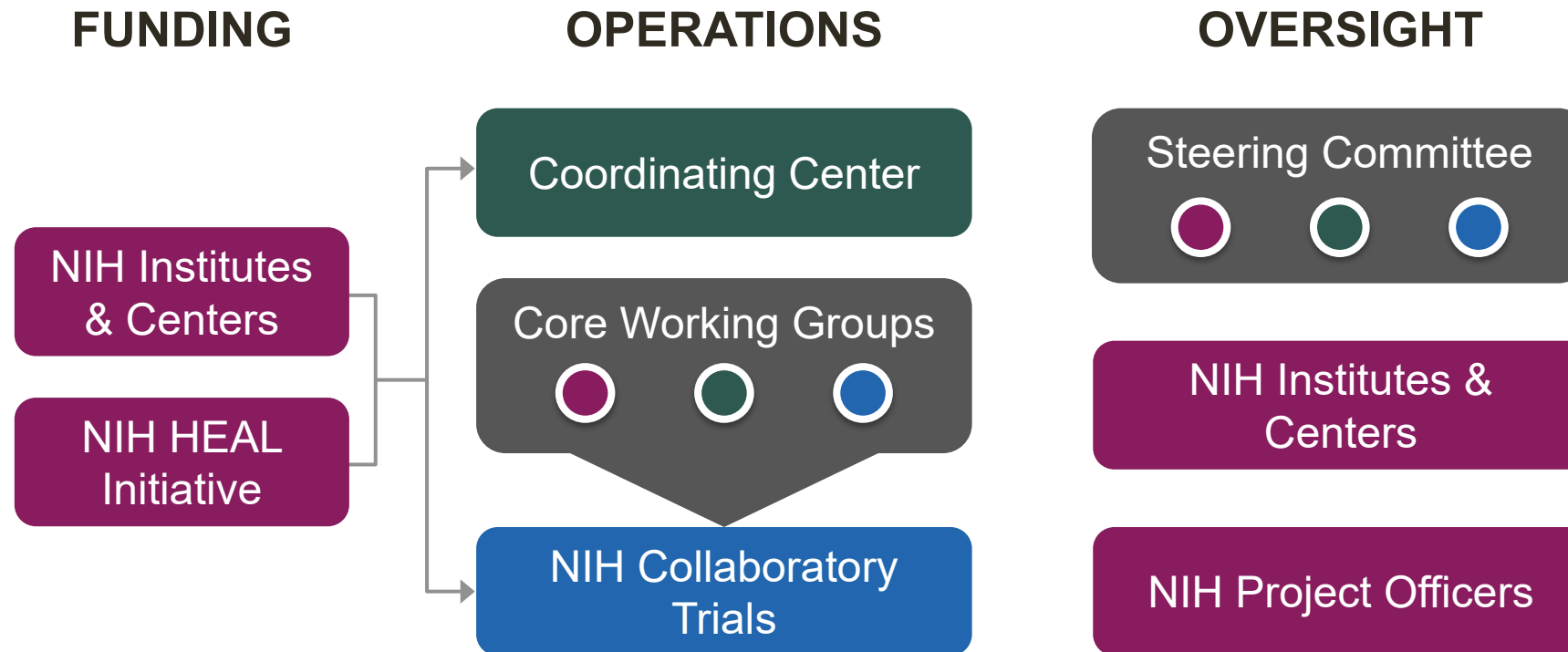
NIH Collaboratory Structure: 2019-2021

- Starting in 2019, the NIH HEAL Initiative began providing some Coordinating Center and NIH Collaboratory Trial funding, in addition to existing funding mechanisms



Collaboratory Structure: 2022-Present

- Starting in 2022, the program is entirely funded by the NIH HEAL Initiative, along with individual NIH Institutes and Centers



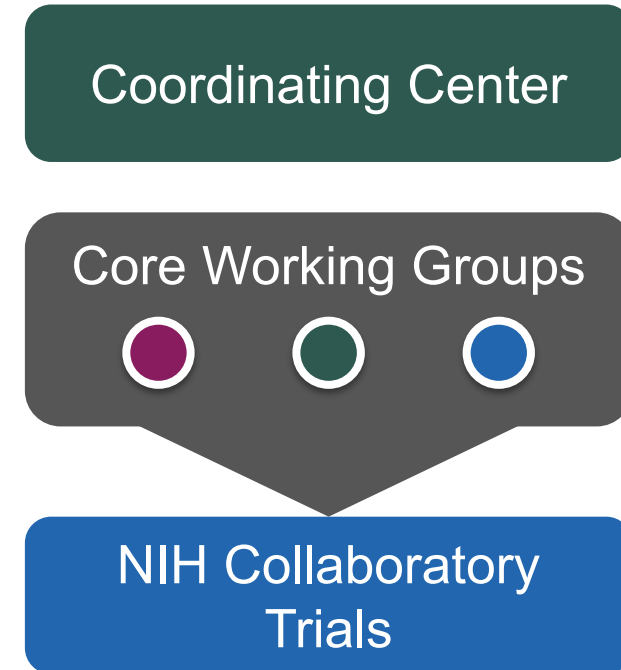
NIH Collaboratory Trials

- Pragmatic trials embedded in healthcare systems to address questions of major public health importance
- Trials span multiple NIH Institutes, Centers, and Offices
- Most have a 1-year planning phase (UG3) followed by implementation phase (UH3)



Core Working Groups

- Component of Coordinating Center focusing on key areas
- Each led by Chair(s) from Coordinating Center
- Include representatives from
 - NIH Collaboratory Trials
 - NIH



Core Working Groups: Purpose

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

Biostatistics and Study Design

Electronic Health Records

Ethics and Regulatory

Health Care Systems
Interactions

Health Equity

Implementation Science

Patient-Centered Outcomes

Biostatistics and Study Design Core

Co-Chairs



Patrick Heagerty,
PhD



Elizabeth L. Turner,
PhD

Mission

- Provide expertise in study design and biostatistics to the NIH Collaboratory Trials, particularly in novel designs and methods for embedded PCTs
- Document new statistical and methodological issues that arise, and share knowledge through case studies
- Identify areas in need of methods development, and work to address these challenges

Electronic Health Records Core

Co-Chairs



Rachel Richesson,
PhD, MPH



Keith A. Marsolo, PhD

Mission

- Help the NIH Collaboratory Trials acquire, assess, and use real-world data for pragmatic research
- Act as the key repository for the tools and infrastructure we create to leverage EHRs to support clinical research across multiple health systems
- Identify ideas and lessons that might be generalizable and share them broadly

Health Care Systems Interactions Core

Chair



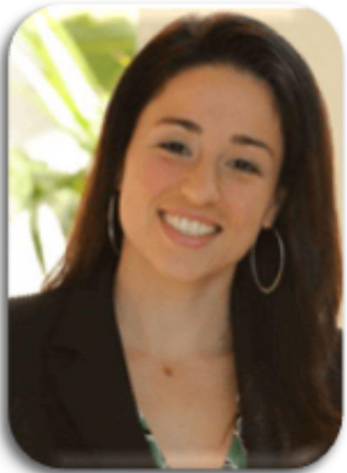
Greg Simon, MD, MPH

Mission

- Engage those involved in healthcare delivery systems to:
 - Participate in research
 - Facilitate the design and conduct of research protocols attractive to practitioners
 - Lower administrative barriers
 - Communicate results to all parties
- Facilitate collaborative learning across the NIH Collaboratory Trials, synthesize lessons learned, and create real-world generalizable knowledge about PCTs

Health Equity Core

Co-Chairs



Rosa Gonzalez-Guarda, PhD, MPH,
RN, CPH, FAAN



Cherise Harrington,
PhD, MPH

Mission

- Develop guidance for PCTs on how to integrate a health equity lens, including:
 - Considerations for enrollment
 - Strategies for selecting outcomes
 - Tailored research methods that better suit the study population
- Document barriers to the integration of a health equity lens in pragmatic research
- Develop strategies and tools to facilitate a health equity lens in PCTs

Patient-Centered Outcomes Core

Co-Chairs



Christy Zigler,
PhD, MEd



Emily C. O'Brien,
PhD

Mission

- Creates guidelines and defines best practices with respect to:
 - Selecting, compiling, and curating the most appropriate PRO measures
 - Stimulating the development of new instruments when needed
 - Creating efficient, high-quality PRO data collection systems compatible with EHRs and registries
- Identify ideas and lessons that might be generalizable and share them broadly

Ethics and Regulatory Core

Co-Chairs



Jeremy
Sugarman, MD



Pearl
O'Rourke, MD



Stephanie
Morain, PhD,
MPH

Mission

- Identify areas of regulatory and ethical uncertainty
- Help NIH Collaboratory Trials navigate regulatory and ethical complexities affecting PCTs
- Develop policies and practices to provide a framework for the ethical conduct of health systems research in compliance with relevant regulations

Implementation Science Core

Co-Chairs



Devon Check,
PhD



Hayden Bosworth,
PhD

Mission

- Support NIH Collaboratory Trials in achieving their implementation-related research aims
- Promote the uptake and sustainability of NIH Collaboratory Trial interventions that have proven effective in routine practice
- Provide guidance on de-implementation of interventions when necessary
- Produce guidance and best practices for conducting implementation research as part of ePCTs

Reach of NIH Collaboratory Trials

>1,100 clinical sites and >940,000 participants



No sites in Arkansas

Completed NIH Collaboratory Trials

Trial	Population	Intervention	Outcome
ABATE	Non-ICU patients	Decolonization strategies	MRSA and VRE clinical cultures
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
ICD-Pieces	Comorbid diabetes, chronic kidney disease, hypertension	Collaborative primary care program	All-cause hospitalizations for 3 conditions
LIRE	Low back pain	Insertion of epidemiologic benchmarks in lumbar spine imaging reports	Relative value unit for spine-related interventions
PPACT	Nonmalignant chronic pain	Multidisciplinary behavioral care management	Brief Pain Inventory
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 & skills training)	Suicide attempts

Completed NIH Collaboratory Trials (cont)

Trial	Population	Intervention	Outcome
STOP CRC	Adults aged 50-75 years	Direct mail colorectal cancer (CRC) screening program (FIT kit)	CRC 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

UG3 NIH Collaboratory Trials (Planning)

Trial	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 (CV) risk factors	Multilevel intervention leveraging cellphone-based text messages	Global CV health and control of CV risk factors (e.g., hypertension, diabetes)
I CAN DO Surgical ACP	Older adults undergoing major elective surgery	Patient-facing advance care planning (ACP) tool	ACP completion rates and patient engagement with ACP
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

R01 NIH Collaboratory Trials

Trial	Population	Intervention	Outcome
iPATH	Patients with type 2 diabetes from health disparity populations	Multi-level, multi-component, technology-enabled practice transformation strategy	Reduction in patients with poorly controlled diabetes (A1c>9%) at 12 and 24 months
MOMs Chat & Care	Black 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

UH3 NIH Collaboratory Trials

Trial	Population	Intervention	Outcome
ACP PEACE	Patients with advanced cancer	Clinician communication skills training and patient video decision aids for advanced care planning	Advance care plans completion; medical orders for resuscitation preferences; palliative care consultations; hospice use
GGC4H	Parents of early adolescents	Anticipatory guidance curriculum	Behavioral health problems; health service utilization
HiLo	Patients undergoing hemodialysis	Liberalizing serum phosphate target	Rate of hospitalization
IMPACT-LBP	Adults with low back pain	Primary Spine Practitioner (PSP) 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
INSPIRE	Non–critically ill hospitalized patients with abdominal infections or skin and soft tissue infections	Predictive algorithm integrated into the computerized provider order entry system, plus audit and feedback	Reduction in prescribing of unnecessary extended-spectrum antibiotics while maintaining good clinical outcomes as measured by length of stay and transfer to an intensive care unit

UH3 NIH Collaboratory Trials (cont)

Trial	Population	Intervention	Outcome
Nudge	Patients with chronic CV conditions	Text messages and chat bot	Adherence to CV medications
PRIM-ER	Older adults (>65 years)	Palliative care education; simulation-based workshops; clinical decision support; provider audit and feedback	Healthcare utilization and survival

PRISM Trials

- Embedded PCTs of non-opioid interventions for treating pain, improving pain management, and reducing reliance on opioids
- Aim: Improve availability of, effectiveness of, and adherence to evidence-based, nonpharmacologic pain management
- Funded by NIH HEAL Initiative®
 - Supports a wide range of programs to develop new or improved prevention and treatment strategies for opioid addiction



UG3 PRISM Trials (Planning)

Trial	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
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
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

UH3 PRISM Trials

Trial	Population	Intervention	Outcome
BackInAction	Older adults with low back pain	Standard and enhanced 12-week courses of acupuncture	Back-related function at 26 weeks; cost-effectiveness
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
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

NIH Collaboratory Trial Resources



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](https://clinicaltrials.gov/ct2/show/study/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

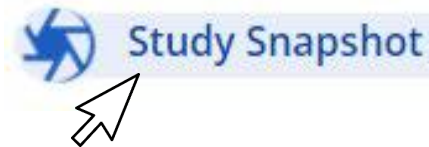
Assessment of 1,413,693 ED visits for study eligibility identified 5047 patients with opioid use disorder (2787 in the intervention arm, 2260 in the usual care arm) under the care of 599 attending physicians (340 in the intervention arm, 259 in the usual care arm) for analysis. Buprenorphine was initiated 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 151 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

Publications, Presentations &
Study Snapshots
available on the
NIH Collaboratory Trial
pages of the
Living Textbook



Data and Resource Sharing

- Completed trials expected to share data and resources publicly
 - Study tools
 - Datasets and documentation
- Materials added to NIH Collaboratory website at trial closeout

[rethinkingclinicaltrials.org/
data-and-resource-sharing/](https://rethinkingclinicaltrials.org/data-and-resource-sharing/)

Study Tools

[Protocols](#)



[Ethics and Regulatory Documentation](#)



[Computable Phenotypes and Analytic Code](#)



Datasets and Documentation

[Datasets and Dictionaries](#)



[Data Sharing Checklists](#)



Publications

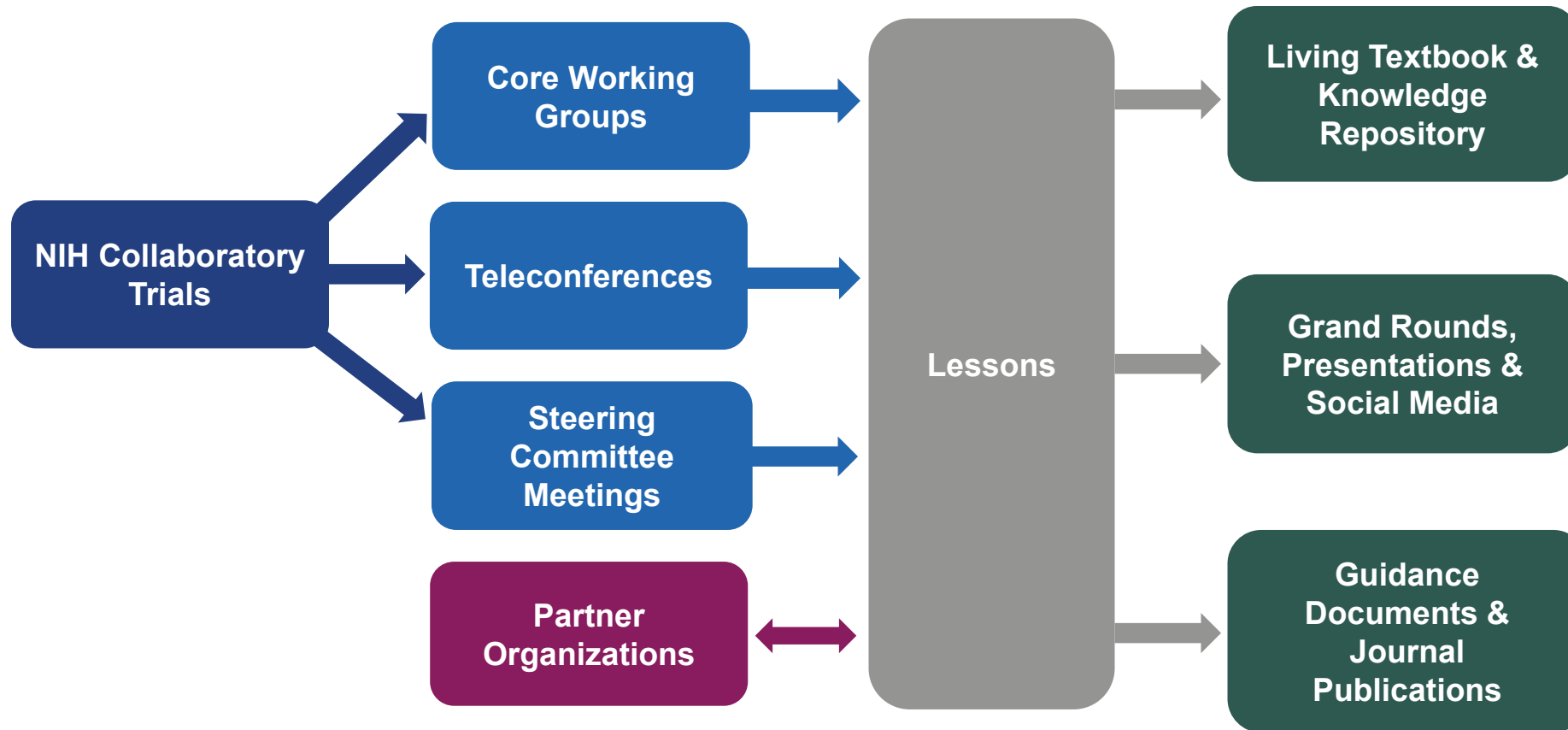
[Study Design Paper](#)



[Main Outcome Paper](#)



Flow of Information



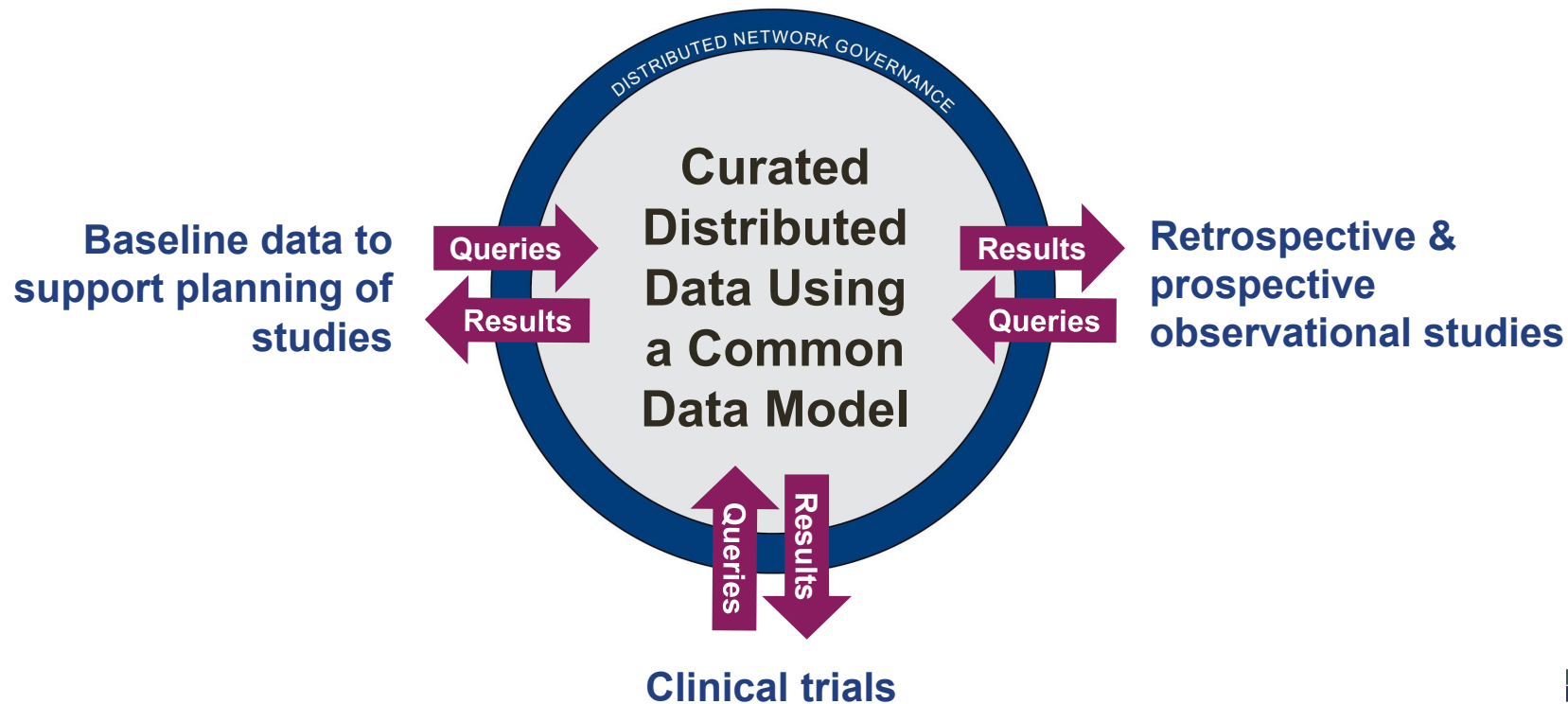
Partner Organizations

- Grand Rounds
 - Shared NIH Collaboratory– PCORnet forum
 - Frequent presentations by partner organizations
- Collaboration on
 - Workshops
 - Publications
 - Living Textbook
- Share knowledge, tools, and resources



Distributed Research Network

- Enables investigators to collaborate in the use of electronic health data while safeguarding protected health information



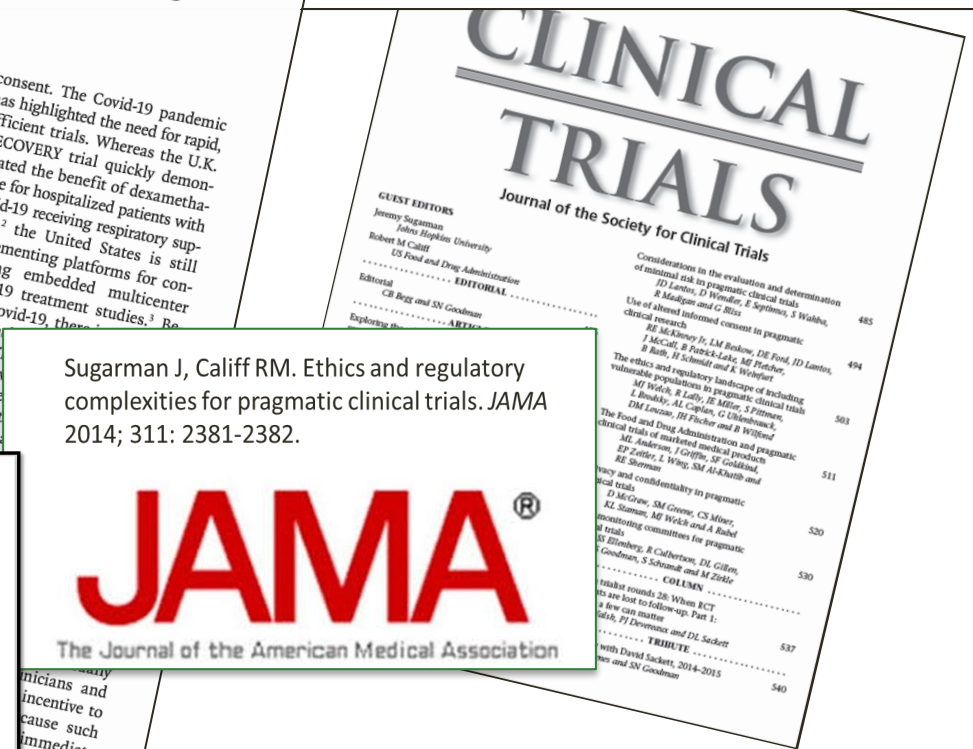
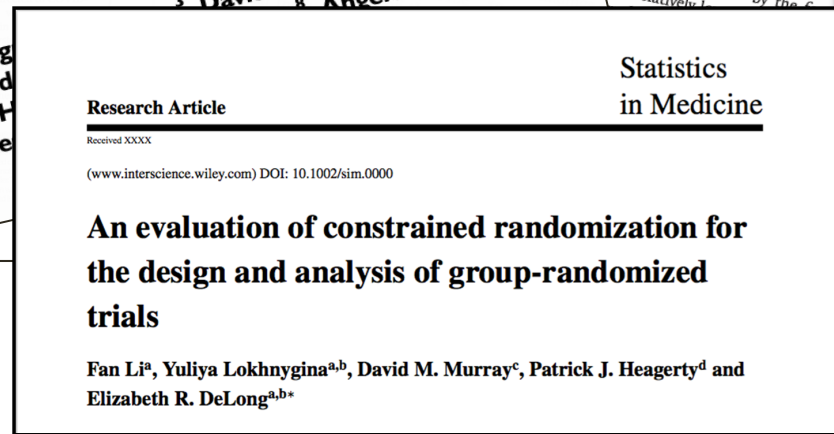
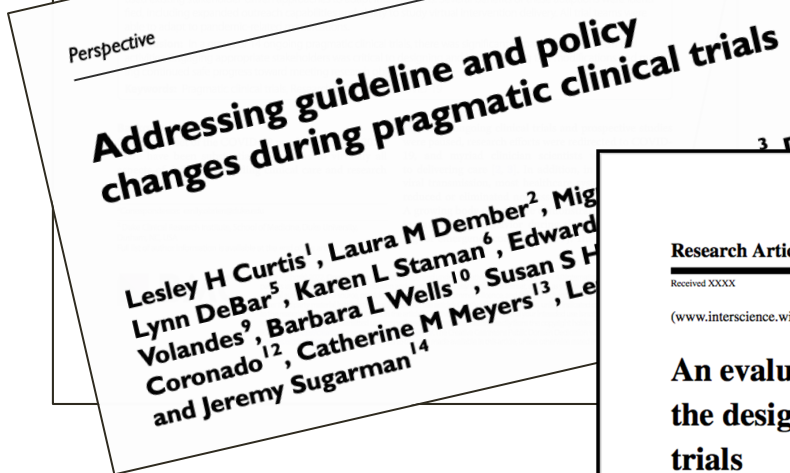
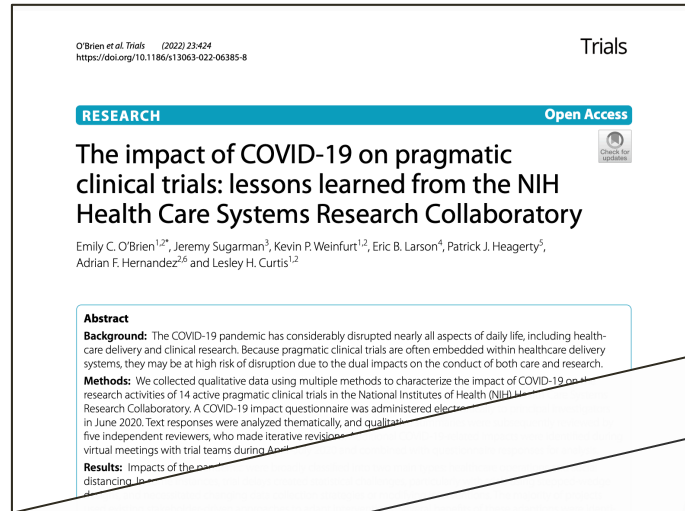
Living Textbook of Pragmatic Clinical Trials

- Comprehensive resource for PCTs
- Content organized around Design, Conduct, Dissemination, and Ethics and Regulatory collections
- Authors from NIH Collaboratory Trials, Cores, and partners
- Continuously updated

rethinkingclinicaltrials.org



Guidance Documents



Rethinking Clinical Trials® Grand Rounds

Join Us on Fridays 1-2 pm ET

- Weekly webinars on a wide range of research topics
 - Open to the public
 - >500 presentations to date
 - Average 250 attendees/session
 - Timely, high-interest topics
 - Feature NIH Collaboratory work and beyond
- Podcasts of featured expert interviews

Grand Rounds

Join our weekly Rethinking Clinical Trials webinars on Fridays from 1-2 pm ET. Open to the public; no registration required.

[Join our mailing list](#)

Upcoming Grand Rounds

[Grand Round December 10: Decentralized Trials: Naughty or Nice?](#)

[View Calendar of All Events](#)

Recent Grand Rounds

[Grand Rounds November 19: Exploring Approaches in Using Digital and Mobile Health in Patient-oriented Research: Pearls and Pitfalls \(Anish K. Agarwal MD, MPH MS\)](#)

[Grand Rounds November 12: Using Financial Incentives to Increase COVID-19 Vaccine Uptake \(Charlene Wong, MD MSHP; Noel T. Brewer, PhD\)](#)

Recent Podcasts

[Podcast August 5, 2021: Survivor Corps: Long-Term COVID-19 Patient Engagement \(Diana Berrent, JD; Natalie Lambert, PhD; Nick Guthe\)](#) August 16, 2021

[Podcast August 2, 2021: Diversity Workshop Series: Increasing Diversity in Pragmatic Clinical Trials \(Dr. Boineau, Dr. Chambers, Dr. Curtis, Dr. O'Brien, Dr. Weber, Dr. Zimmerman\)](#) August 9, 2021

[Podcast June 2, 2021: Online Recruitment in the Era of COVID-19: Pitfalls and Progress \(Megan L. Ranney, MD, MPH\)](#) June 2, 2021

[View All](#)

Training Resources

rethinkingclinicaltrials.org/training-resource/

- Learning modules
- Educational video library
- Resources (handouts, checklists, guides, etc.)
- Workshop materials (slides, recordings, etc.)
- Upcoming opportunities

Training Resources

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.

[Learn More](#)



Videos

View our training videos, which feature NIH Pragmatic Trials Collaboratory experts and guest speakers presenting on topics that cover every phase of a pragmatic clinical trial.



Resources

Access downloadable resources developed by the NIH Pragmatic Trials Collaboratory, including educational handouts, guidance documents, and worksheets that provide information about pragmatic clinical trials.



Workshops

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

November 17 @ 1:00 pm - 2:00 pm

[Grand Rounds November 17, 2023: Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications: Results from the Nudge Study \(Michael Ho, MD, PhD; Sheana Bull, PhD\)](#)

November 24 @ 1:00 pm - 2:00 pm

[Grand Rounds November 24, 2023: No Presentation \(Holiday\)](#)

November 28 @ 1:00 pm - 3:00 pm

[Exploratory and Inferential Spatial Statistical Methods: Tools To Understand the Geography of Health Across the U.S.](#)

December 1 @ 1:00 pm - 2:00 pm

[Grand Rounds Biostatistics Series December 1, 2023: Guidelines for Design and Analysis of Stepped-Wedge Trials \(Jim Hughes, PhD; Moderator: Patrick Heagerty, PhD\)](#)

[View Calendar of All Events](#)

Newsletter & Social Media



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@Collaboratory1



Appendix: NIH Collaboratory Trials



**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

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

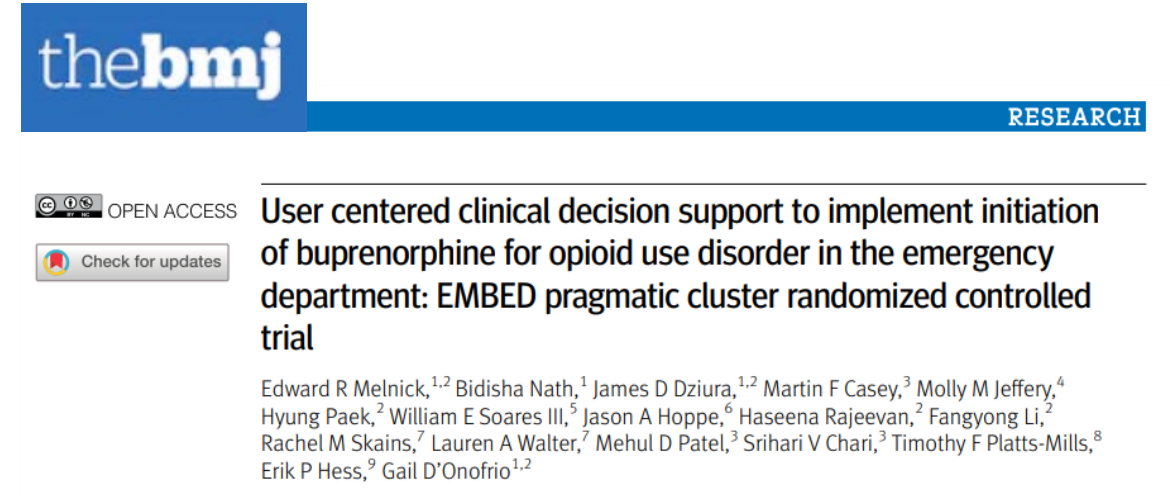
Chlorhexidine versus routine bathing to prevent multidrug-resistant organisms and all-cause bloodstream infections in general medical and surgical units (ABATE Infection trial): a cluster-randomised trial

Susan S Huang, Edward Septimus, Ken Kleinman, Julia Moody, Jason Hickok, Lauren Heim, Adrijana Gombosev, Taliser R Avery, Katherine Haffner, 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

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



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



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. Cherkin, 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

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



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; Roee 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 Winkelmayer,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; Riddhi 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

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



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



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



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 birthing people and reduce risk for severe maternal morbidity
- Largest healthcare provider in New York
- 674 expected patients



ACP PEACE

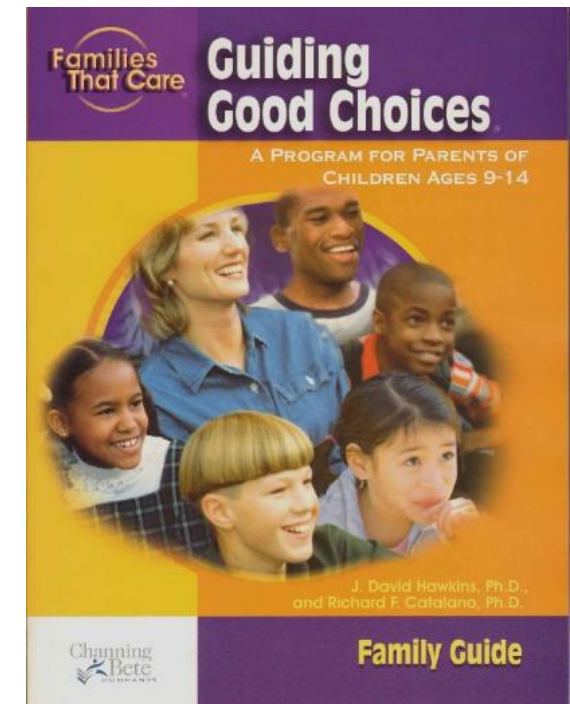
Advance Care Planning: Promoting Effective and Aligned Communication in the Elderly

- Cluster trial testing whether clinician communication skills training and patient video decision aids will increase **advance care plan completion** in patients >65 with advanced cancer
- 36 oncology clinics across 3 health systems
- 4,500 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



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

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



INSPIRE

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

- 2 cluster randomized trials using personalized clinical decision support to improve judicious antibiotic prescribing for non–critically ill patients hospitalized with **abdominal infections or skin and soft tissue infections**
- 90,000 expected patients

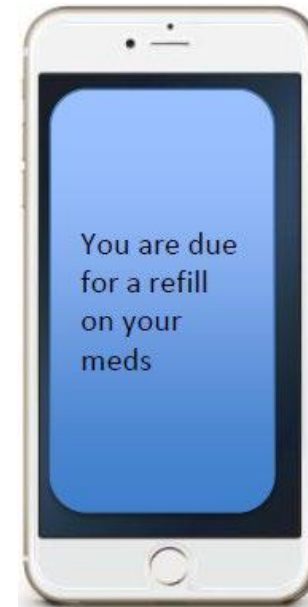


Nudge

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

Nudge



PRIM-ER *Primary Palliative Care for Emergency Medicine*

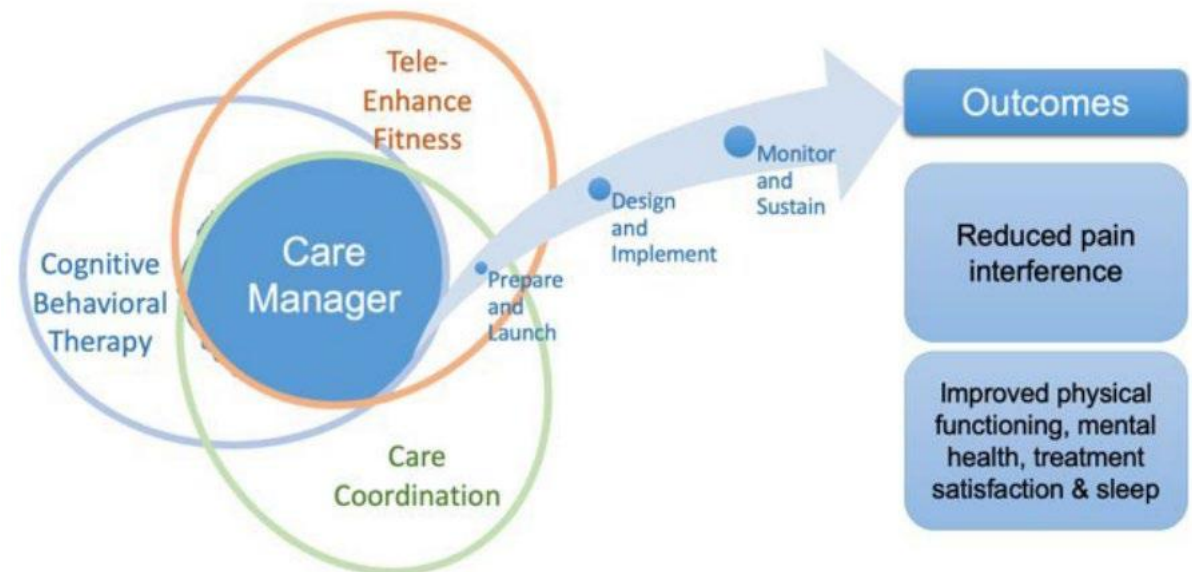
- Cluster trial testing the effects of implementing primary palliative care in emergency medicine on **healthcare utilization and survival**
- 35 emergency departments across 18 health systems



AIM-CP

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

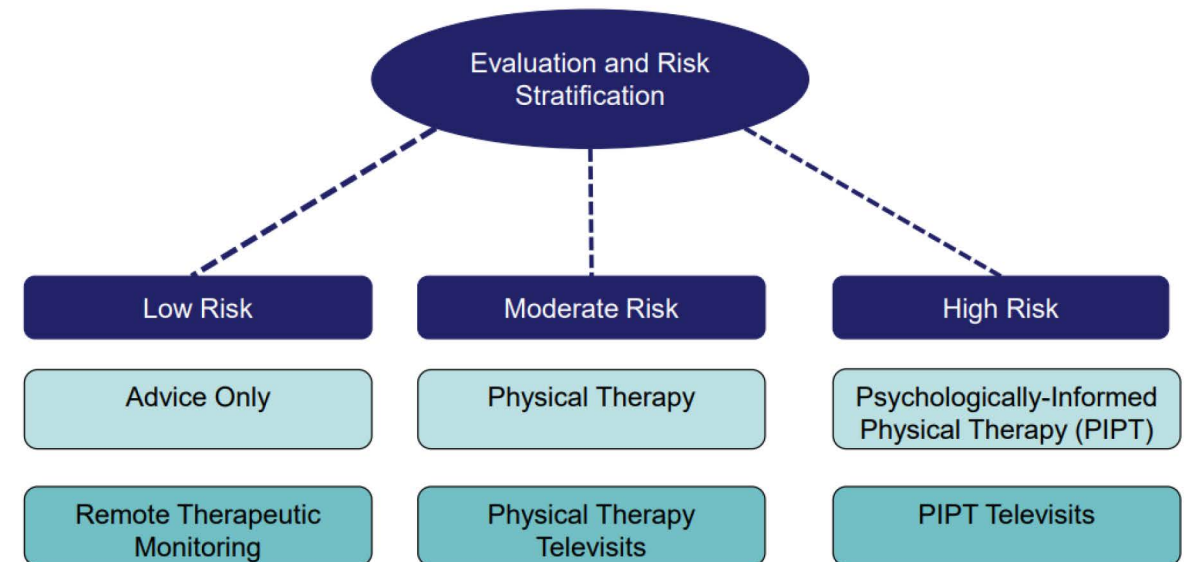
- Adapting and test a **nurse care management model** to provide comprehensive coordinated care for patients with chronic pain in rural communities
- 6 health systems
- 416 expected patients



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



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



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 non-pharmacologic 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

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