

Implementation Experiences from NIH Pragmatic Trials Collaboratory

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Objectives

- Provide a brief overview of the NIH Pragmatic Trials Collaboratory including PRISM
- Highlight examples of successful implementation of Demonstration Projects
- Describe PRISM projects and their use of implementation research methods
- Discuss potential opportunities for synergy across Collaboratories



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NIH Collaboratory Story



The Collaboratory Story



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



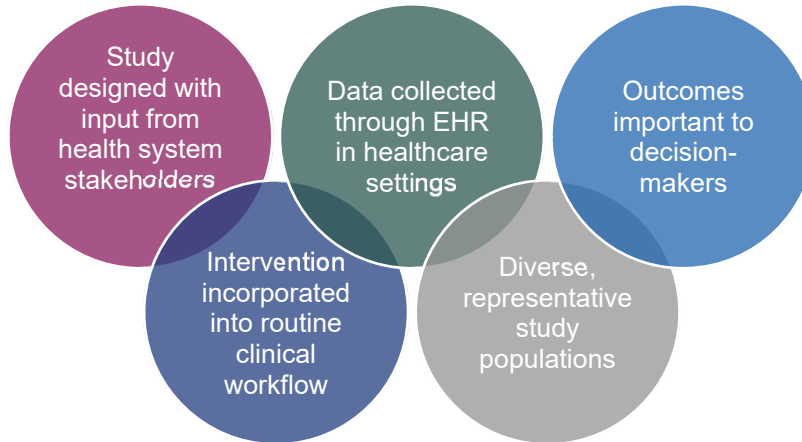
Goal: Strengthen the national capacity to implement cost-effective large-scale research studies that engage health care delivery organizations as research partners



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

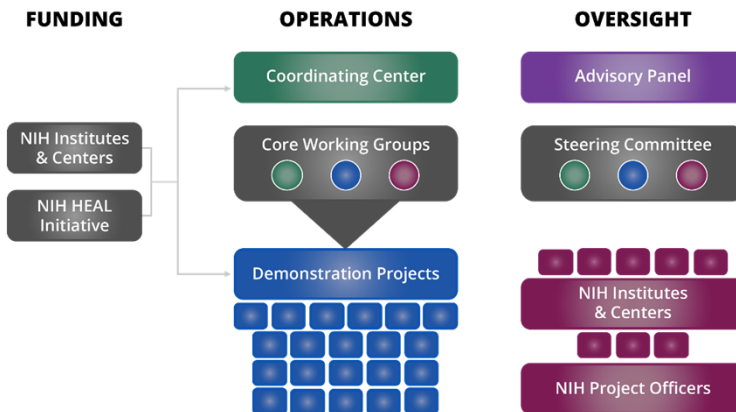


Embedded PCTs Bridge Research Into Clinical Care

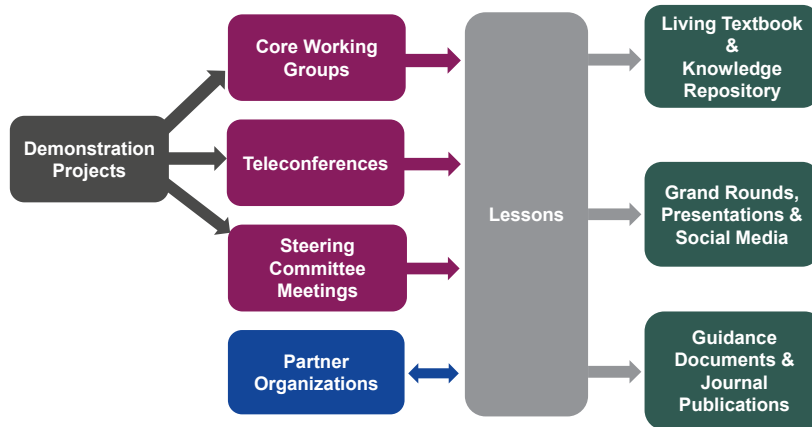


Collaboratory Structure

- The program is currently funded by the NIH HEAL Initiative, along with individual NIH Institutes and Centers



Flow of Information



Core Working Groups

- Guide and support Demonstration Projects
- Disseminate knowledge
- Chair from Coordinating Center and representatives from NIH and Demonstration Projects

Biostatistics and Study Design

Electronic Health Records

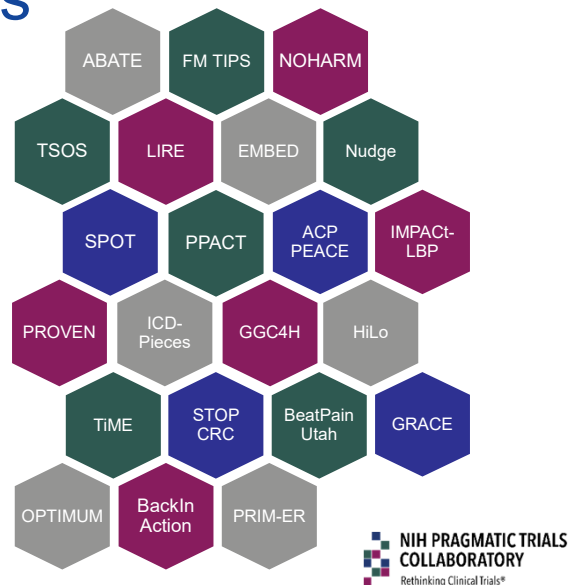
Health Care Systems Interactions

Patient-Centered Outcomes

Ethics and Regulatory

Demonstration Projects

- Pragmatic trials embedded in healthcare systems to address questions of major public health importance
- Projects span multiple NIH Institutes, Centers, and Offices
- One-year planning phase followed by implementation phase



PRISM Program

- A program of the NIH HEAL (Helping to End Addiction Long-termSM) Initiative
- The NIH Pragmatic Trials Collaboratory serves as the Resource Coordinating Center for PRISM
- PRISM trials
 - Focus on non-opioid interventions to manage pain and reduce reliance on opioids
 - Seek to identify effective strategies to implement evidence-based interventions



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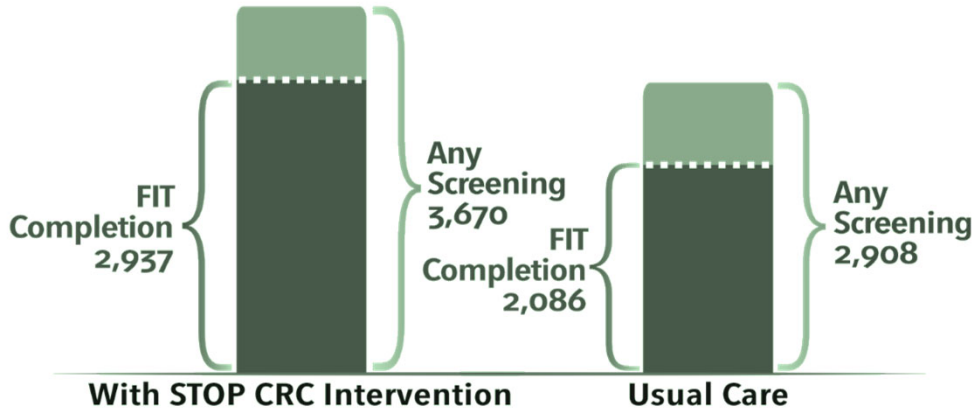
Implementation Examples from Demonstration Projects

STOP CRC

- Cluster-randomized trial of 26 FQHC clinics (in 8 health centers) in Oregon and California
- Tested effectiveness of a direct-mail program to increase colorectal cancer screening rates with fecal immunochemical test (FIT)

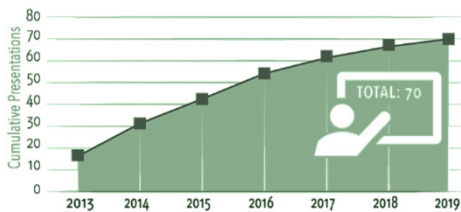


Project Results

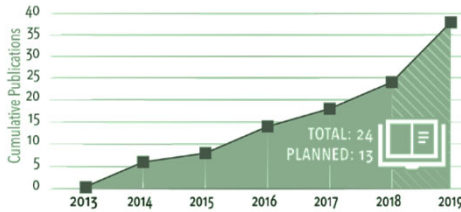


Presentations, Papers, Spinoff Projects

PRESENTATIONS (2013-2019)



PUBLICATIONS (2013-2019)



SPINOFF PROJECTS

- **BeneFIT (2015-2019)**
Mailed FIT program, Medicaid Health Plans, 2 states, funded by CDC
- **PROMPT (2016-2021)**
Patient-refined messaging for mailed FIT program, Latino-serving FQHC, funded by NIMHD
- **KP Navigation (2017-2018)**
Predictive modeling for patient navigation, KPNW, funded by KP (pilot)
- **PRECISE (2018-2023)**
Predictive modeling and patient navigation following abnormal FIT, funded by NCI

Regional D&I of STOP CRC

- Additional clinics that implemented STOP CRC
 - Washington: 81 clinics (8 health centers)
 - Oregon: 68 clinics (35 health centers)
 - California: 5 clinics (1 health center)
- Oregon and Washington spread supported by state health department contracts with CDC
 - Project PI provided technical assistance and consultation to clinics implementing STOP CRC program




National D&I of STOP CRC

- EHR tools and training videos made available to all health systems affiliated with OCHIN (100+ systems, 18 states)
- All program materials and corresponding implementation guide are publicly available online
 - Currently working with CDC to update guide for national dissemination efforts



STOP CRC Implementation Guide

KAISER PERMANENTE
Center for Health Research

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Research > Our People > Gloria D. Coronado > mailedfit > Maile FIT - Implementation Guide

Implementation Guide

The STOP CRC Implementation Guide discusses clinic capacities needed to run the Mailed FIT Program and decisions clinic administrators and staff must make along the way.

The Guide describes the Mailed FIT Program and how to orient a clinic to the program. Clinics that implement the STOP CRC program need to address technical, workflow, and policy questions before launching it. This guide is intended to address these questions.

[Download the Implementation Guide](#)

Mailed FIT Program Implementation Guide: Guide for Clinics

- Why CRC Screening Programs Are Important
- Fecal Immunochemical Testing vs. Colonoscopy
- Advantages of Direct-Mail FIT Programs

Implementation Guide

[MailedFit](#)

[Why Do It?](#)

[Research Projects](#)

[Program Materials](#)

[MailedFit News](#)

[Workflows](#)

 NIH PRAGMATIC TRIALS
COLLABORATORY
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ABATE Infection

- Cluster-randomized trial of 53 hospitals affiliated with HCA healthcare
- Compared chlorhexidine to routine bathing to prevent hospital-associated infections in general medical and surgical units
- Results showed benefit for a subset of patients with devices



Active Bathing to Eliminate Infection Project

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D&I of ABATE Infection Results

- Toolkit and IT modules converted to operations for intervention sites that chose to continue intervention while awaiting results
- Once results known, presented to health system, prompting health system-wide launch
- Toolkit published with manuscript
- Team currently working with AHRQ to develop toolkit, educational video for national dissemination



The screenshot shows the AHRQ website interface. At the top is the AHRQ logo and the text 'Agency for Healthcare Research and Quality Advancing Excellence in Health Care'. Below this is a navigation bar with categories like 'Health Care Information', 'For Patients & Consumers', 'For Professionals', 'For Policymakers', 'Research Tools & Data', 'Funding & Grants', 'Centers, Portfolios & Initiatives', and 'News & Events'. A breadcrumb trail reads: 'Home > For Professionals > Hospitals & Health Systems > Hospital Resources > Universal ICU Decolonization Protocol'. Below the breadcrumb are links for 'Previous Page', 'Table of Contents', 'Download', and 'Next Page'. The main content area features a sidebar with 'Hospitals & Health Systems' selected, containing 'Hospital Resources' and 'Emergency Department Tools and Resources'. The main heading is 'Universal ICU Decolonization: An Enhanced Protocol' with the sub-heading 'Introduction and Welcome'. The text below states: 'This enhanced protocol is based on materials successfully used in the REDUCE MRSA Trial (Randomized Evaluation of Decolonization vs. Universal Clearance to Eliminate Methicillin-Resistant *Staphylococcus aureus*), which found that universal decolonization was the most effective intervention. Universal decolonization led to a 37 percent reduction in MRSA clinical cultures and a 44 percent reduction in all-cause bloodstream infections.' To the right is a thumbnail for 'Publication # 13-0052-EF' titled 'Universal ICU Decolonization Toolkit: An Enhanced Protocol'. At the bottom of the page is the URL: http://www.ahrq.gov/professionals/systems/hospital/universal_icu_decolonization.html and the NIH PRAGMATIC TRIALS COLLABORATORY logo.

De-implementation of Ineffective Interventions

- New working group to explore current practices and potential opportunities for de-implementing ineffective interventions after ePCTs

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PRISM Projects: Use of Implementation Research Methods

PRISM Projects

- Group-based mindfulness for patients with chronic low back pain in primary care (OPTIMUM)
- Acupuncture for chronic low back in older adults (BackInAction)
- Fibromyalgia TENS in physical therapy (FM-TIPS)
- Nonpharmacologic options for postoperative pain (NOHARM)
- Guided relaxation and acupuncture for chronic pain in sickle cell disease (GRACE)
- Non-pharmacologic pain management in FQHC primary care clinics (BeatPain Utah)

OPTIMUM

BackInAction

FM-TIPS

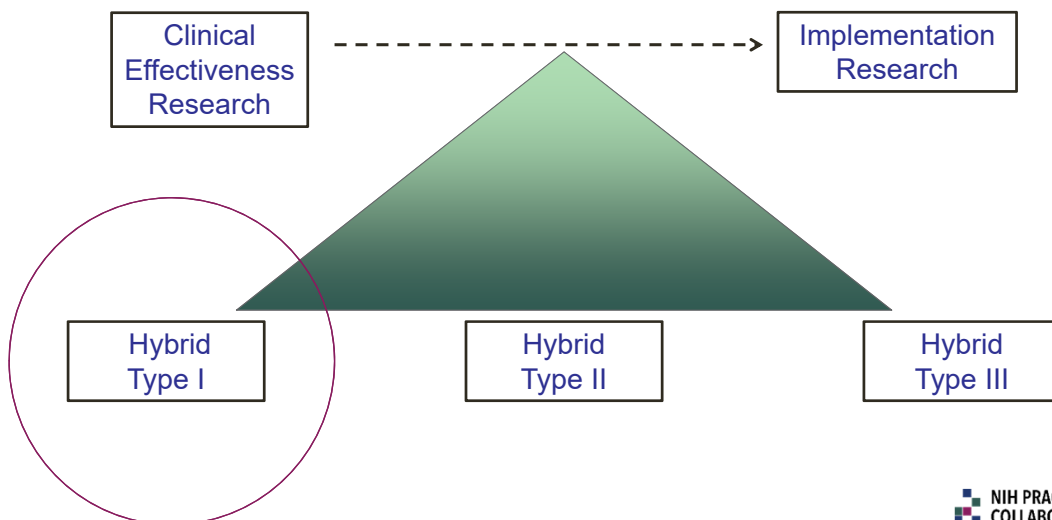
NOHARM

GRACE

BeatPain Utah



Hybrid Effective-Implementation Designs



Hybrid Type I Designs in PRISM

- All include an implementation-related process evaluation guided by an implementation research framework (e.g., CFIR, RE-AIM)
- Most process evaluations use qualitative or mixed methods
- Goals
 - Within projects, understand key implementation barriers/facilitators – guide future design of implementation strategies to support real-world uptake of the intervention
 - Across projects, create generalizable knowledge about key barriers/facilitators associated with implementing non-pharmacologic pain interventions



Learn more about NIH Pragmatic Trials Collaboratory Demonstration Projects at rethinkingclinicaltrials.org

A screenshot of the website's navigation menu. The menu is open, showing options: "NIH Collaboratory", "Coordinating Center", "Demonstration Projects", "Core Working Groups", "Distributed Research Network", "Living Textbook", "Table Of Contents", and "How To Use This Site". A green arrow points to the "Demonstration Projects" option. Below the menu, a section titled "Demonstration Projects" is visible, containing the text: "Our Mission: Strengthen the national capacity to implement cost-effective large-scale research studies that engage healthcare delivery organizations as research partners." The website header includes "Home", "About", "Resources", "Grand Rounds", and "News".



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Potential Opportunities for Synergy Across Collaboratories

Potential Opportunities for Synergy

- Identify common barriers/facilitators associated with implementing nonpharmacologic interventions across disease groups and settings (PRISM and PMC)
- De-implementation of ineffective interventions from ePCTs
- Others?

For More Information

Living Textbook

- Comprehensive information on design, conduct, and dissemination of embedded PCTs
- rethinkingclinicaltrials.org

Monthly Newsletter

- Convenient monthly wrap-up of NIH Collaboratory news
- rethinkingclinicaltrials.org/newsletter-subscribe

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