NIH Pragmatic Trials Collaboratory

Enabling pragmatic clinical trials embedded in health care systems
The 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 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

- Study designed with input from health system stakeholders
- Intervention incorporated into routine clinical workflow
- Data collected through EHR in healthcare settings
- Diverse, representative study populations
- Outcomes important to decision-makers
The Collaboratory began as an NIH Common Fund–initiated program. It includes centralized operational support for its pragmatic trial Demonstration Projects from a Coordinating Center and its Core Working Groups.
Starting in 2017, individual NIH Institutes and Centers began providing funding for Demonstration Projects and the Coordinating Center, along with the Common Fund.
Starting in 2019, the NIH HEAL Initiative began providing some Coordinating Center and Demonstration Project 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
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
## Completed Demonstration Projects

<table>
<thead>
<tr>
<th>Project</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABATE</td>
<td>Non-ICU patients</td>
<td>Decolonization strategies</td>
<td>MRSA and VRE clinical cultures</td>
</tr>
<tr>
<td>EMBED</td>
<td>Patients with opioid use disorder</td>
<td>User-centered computerized clinical decision support</td>
<td>Rate of emergency department–initiated buprenorphine/naloxone; referral for ongoing medication assisted treatment</td>
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<tr>
<td>LIRE</td>
<td>Low back pain</td>
<td>Insertion of epidemiologic benchmarks in lumbar spine imaging reports</td>
<td>Relative value unit for spine-related interventions</td>
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<tr>
<td>PPACT</td>
<td>Nonmalignant chronic pain</td>
<td>Multidisciplinary behavioral care management</td>
<td>Brief Pain Inventory</td>
</tr>
<tr>
<td>PROVEN</td>
<td>Nursing home residents</td>
<td>Advance care planning video (behavioral program)</td>
<td>Hospitalizations; presence of advance directives</td>
</tr>
<tr>
<td>SPOT</td>
<td>Suicidal ideation or depression</td>
<td>Collaborative care behavioral program (care management &amp; skills training)</td>
<td>Suicide attempts</td>
</tr>
<tr>
<td>STOP CRC</td>
<td>Adults aged 50-75 years</td>
<td>Direct mail colorectal cancer (CRC) screening program (FIT kit)</td>
<td>CRC screening rates</td>
</tr>
<tr>
<td>TiME</td>
<td>Patients initiating dialysis</td>
<td>Dialysis session of at least 4.25 hours</td>
<td>All-cause mortality, hospitalization</td>
</tr>
<tr>
<td>TSOS</td>
<td>Traumatic injury</td>
<td>Collaborative care management program</td>
<td>PTSD checklist; PHQ-9 scale; alcohol use disorders; SF-12/36</td>
</tr>
</tbody>
</table>
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
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
Cluster trial evaluating whether inserting epidemiologic benchmarks into lumbar spine imaging reports reduces subsequent tests and treatments

- 98 clinical sites
- 246,289 patients
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
PROVEN: Pragmatic Trial of Video Education in Nursing Homes

- Evaluating the **effectiveness of advance care planning video** shown in nursing homes of 2 large health care systems
  - 359 nursing homes
  - 211,469 patients
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
Cluster trial testing a culturally tailored, health care system–based program to improve CRC screening rates in community-based collaborative network

- 30 clinical sites
- 62,155 patients
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
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
Data and Resource Sharing

- Completed projects expected to share data and resources publicly
  - Study tools
  - Datasets and documentation
- Materials added to Collaboratory website at project closeout

<table>
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<th>Study Tools</th>
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<tr>
<td>Protocols</td>
<td>+</td>
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<tr>
<td>Ethics and Regulatory Documentation</td>
<td>+</td>
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<tr>
<td>Computable Phenotypes and Analytic Code</td>
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<th>Datasets and Documentation</th>
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<tr>
<td>Datasets and Dictionaries</td>
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<tr>
<td>Data Sharing Checklists</td>
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<td>Study Design Paper</td>
<td>+</td>
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<tr>
<td>Main Outcome Paper</td>
<td>+</td>
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<tr>
<td>Project</td>
<td>Population</td>
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<tr>
<td>ACP PEACE</td>
<td>Patients with advanced cancer</td>
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<tr>
<td>GGC4H</td>
<td>Parents of early adolescents</td>
</tr>
<tr>
<td>HiLo</td>
<td>Patients undergoing hemodialysis</td>
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<tr>
<td>ICD-Pieces</td>
<td>Comorbid diabetes, chronic kidney disease, hypertension</td>
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<tr>
<td>IMPACt-LBP</td>
<td>Adults with low back pain</td>
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<tr>
<td>Nudge</td>
<td>Patients with chronic cardiovascular (CV) conditions</td>
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<tr>
<td>PRIM-ER</td>
<td>Older adults (&gt;65 years)</td>
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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
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
- 10,991 expected patients
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 health care systems
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
• 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
PRISM Demonstration Projects

- Embedded PCTs of non-opioid interventions for treating pain, improving pain management, and reducing reliance on opioids.

- Aim is to improve availability of, effectiveness of, and adherence to evidence-based, nonpharmacologic pain management.

- PRISM is funded through the Helping to End Addiction Long-term\textsuperscript{SM} Initiative, or NIH HEAL Initiative\textsuperscript{SM}, which supports a wide range of programs to develop new or improved prevention and treatment strategies for opioid addiction.
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<td>BackInAction</td>
<td>Older adults with low back pain</td>
<td>Standard and enhanced 12-week courses of acupuncture</td>
<td>Back-related function at 26 weeks; cost-effectiveness</td>
</tr>
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<td>FM TIPS</td>
<td>Fibromyalgia</td>
<td>Addition of transcutaneous electrical nerve stimulation (TENS) to physical therapy</td>
<td>Fibromyalgia symptoms; adherence to therapy; meeting therapeutic goals; medication use</td>
</tr>
<tr>
<td>NOHARM</td>
<td>Postoperative pain</td>
<td>EHR-embedded tools to aid shared decision making about pain management</td>
<td>Postoperative opioid use, pain, function</td>
</tr>
<tr>
<td>OPTIMUM</td>
<td>Chronic low back pain</td>
<td>Group-based mindfulness in outpatient clinical settings</td>
<td>Pain, physical and psychological function; opioid prescriptions for chronic low back pain</td>
</tr>
<tr>
<td>BeatPain Utah</td>
<td>Adults with back pain in federally qualified health centers in Utah</td>
<td>Brief pain teleconsult and phone-based physical therapy</td>
<td>Pain management; reduction of disparities; evaluation of implementation strategies</td>
</tr>
<tr>
<td>GRACE</td>
<td>Patients with sickle cell disease</td>
<td>Acupuncture and guided relaxation</td>
<td>Pain control; effective treatment sequence; evaluation of implementation strategies</td>
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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
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
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
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
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
NIH Collaboratory Project Resources

Publications, Presentations & Study Snapshots available on the Demonstration Project pages of the Living Textbook
Flow of Information

- Demonstration Projects
  - Core Working Groups
  - Teleconferences
  - Steering Committee Meetings
  - Partner Organizations

Lessons

- Living Textbook & Knowledge Repository
- Grand Rounds, Presentations & Social Media
- Guidance Documents & Journal Publications
Partner Organizations

- Grand Rounds
  - Shared PCORnet/Collaboratory forum
  - Frequent presentations by partner organizations
- Collaboration on
  - Workshops
  - Ethics & regulatory publications
- Shared tools & resources
  - Links to external resources in Living Textbook
Distributed Research Network

- Enables investigators to collaborate in the use of electronic health data while safeguarding protected health information.
Weekly webinars on a wide range of research topics
- 420+ presentations since inception
- Average >250 attendees per session
- Timely, high-interest topics such as COVID-19
- Feature Collaboratory work

Podcasts of featured expert interviews
ePCT Training Resources

- Learning modules for self-paced study
- Workshop recordings and materials
- Quick Start Guides for investigators
- Essentials starter kit
- NIH Collaboratory overview
- ePCT factsheet

rethinkingclinicaltrials.org/training-resources
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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- Follow us! @Collaboratory1