NIH Health Care Systems Research 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
Collaboratory Structure: 2012-2017

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.

FUNDING

NIH Common Fund

OPERATIONS

Coordinating Center

Core Working Groups

Demonstration Projects

OVERSIGHT

Advisory Panel

Steering Committee

NIH Institutes & Centers

NIH Project Officers
Collaboratory Structure: 2017-2019

Starting in 2017, individual NIH Institutes and Centers began providing funding for Demonstration Projects and the Coordinating Center, along with the Common Fund.

FUNDING
- NIH Common Fund
- NIH Institutes & Centers

OPERATIONS
- Coordinating Center
- Core Working Groups
- Demonstration Projects

OVERSIGHT
- Advisory Panel
- Steering Committee
- NIH Institutes & Centers
- NIH Project Officers
Collaboratory Structure: 2019-Present

Starting in 2019, the NIH HEAL Initiative began providing some Coordinating Center and Demonstration Project funding, in addition to existing funding mechanisms.
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
Reach of Demonstration Projects

>1,200 clinical sites across 90% of the United States

Over 752,000 active subjects
## 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>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>
</tr>
<tr>
<td>PPACT</td>
<td>Nonmalignant chronic pain</td>
<td>Multidisciplinary behavioral care management</td>
<td>Brief Pain Inventory</td>
</tr>
<tr>
<td>STOP CRC</td>
<td>Adults aged 50-75 years</td>
<td>Direct mail 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>
</tbody>
</table>

---

**Congratulations!**

NIH 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
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
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
- 2000 expected patients
STOP CRC Strategies and Opportunities to Stop Colorectal Cancer

- 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
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
• 7053 patients
Data and Resource Sharing

• Projects expected to share data and resources publicly
  • Study tools
  • Datasets and documentation
• Materials added to Collaboratory website at project closeout
## Summary of UH3 Projects

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACP PEACE</td>
<td>Patients with advanced cancer</td>
<td>Clinician communication skills training and patient video decision aids for advanced care planning</td>
<td>Advance care plans completion; medical orders for resuscitation preferences; palliative care consultations; hospice use</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>
</tr>
<tr>
<td>GGC4H</td>
<td>Parents of early adolescents</td>
<td>Anticipatory guidance curriculum</td>
<td>Behavioral health problems; health service utilization</td>
</tr>
<tr>
<td>HiLo</td>
<td>Patients undergoing hemodialysis</td>
<td>Liberalizing serum phosphate target</td>
<td>Rate of hospitalization</td>
</tr>
<tr>
<td>ICD-Pieces</td>
<td>Comorbid diabetes, CKD &amp; hypertension</td>
<td>Collaborative primary care program</td>
<td>All-cause hospitalizations for 3 conditions</td>
</tr>
<tr>
<td>Nudge</td>
<td>Patients with chronic CV conditions</td>
<td>Text messages and chat bot</td>
<td>Adherence to CV medications</td>
</tr>
<tr>
<td>PRIM-ER</td>
<td>Older adults (&gt;65 years)</td>
<td>Palliative care education; simulation-based workshops; clinical decision support; provider audit and feedback</td>
<td>Healthcare utilization and survival</td>
</tr>
<tr>
<td>PROVEN</td>
<td>Nursing home patients</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>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>
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
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
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
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
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
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 expected 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
• 16,000 expected 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 expected patients
New 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, nonpharmacological pain management
## PRISM Demonstration Projects

<table>
<thead>
<tr>
<th>Project</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>AcuOA</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 week, cost-effectiveness</td>
</tr>
<tr>
<td>FM TIPS</td>
<td>Fibromyalgia</td>
<td>Addition of transcutaneous electrical nerve stimulation 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>
</tbody>
</table>
AcuOA 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
- 6 physical therapy 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-pharmacological 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
NIH Collaboratory Resource

Study Snapshots available on Living Textbook

Access the handouts from Demonstration Project Pages
Partner Organizations

Grand Rounds
• Shared PCORnet/Collaboratory forum
• Frequent presentations by partner organizations

Collaboration on
• Workshops
• Regulatory/ethics 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.
PCT Grand Rounds Presentations

- Weekly webinars on a wide range of research topics
- 300+ presentations since inception
- Podcasts of expert interviews available on iTunes
ePCT Training Resources

- Self-paced study
- Workshop recordings and materials
- ePCT factsheet
- Essentials starter kit
- NIH Collaboratory overview

rethinkingclinicaltrials.org/training-resources
For More Information

- **Living Textbook**
  - Comprehensive information on design, conduct, and dissemination of embedded PCTs
  - [rethinkingclinicaltrials.org](http://rethinkingclinicaltrials.org)

- **Monthly Newsletter**
  - Convenient monthly wrap-up of NIH Collaboratory news
  - [rethinkingclinicaltrials.org/newsletter-subscribe](http://rethinkingclinicaltrials.org/newsletter-subscribe)

- **Twitter**
  - @Collaboratory1