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

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

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**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
- Data collected through EHR in healthcare settings
- Intervention incorporated into routine clinical workflow
- Outcomes important to decision-makers
- Diverse, representative study populations
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.
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.
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.

FUNDING
- NIH Common Fund
- NIH Institutes & Centers
- NIH HEAL Initiative

OPERATIONS
- Coordinating Center
- Core Working Groups
- Demonstration Projects

OVERSIGHT
- Advisory Panel
- Steering Committee
- NIH Institutes & Centers
- NIH Project Officers
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><strong>ABATE</strong></td>
<td>Non-ICU patients</td>
<td>Decolonization strategies</td>
<td>MRSA and VRE clinical cultures</td>
</tr>
<tr>
<td><strong>LIRE</strong></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><strong>PPACT</strong></td>
<td>Nonmalignant chronic pain</td>
<td>Multidisciplinary behavioral care management</td>
<td>Brief Pain Inventory</td>
</tr>
<tr>
<td><strong>PROVEN</strong></td>
<td>Nursing home residents</td>
<td>Advance care planning video (behavioral program)</td>
<td>Hospitalizations; presence of advance directives</td>
</tr>
<tr>
<td><strong>STOP CRC</strong></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><strong>TiME</strong></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><strong>TSOS</strong></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

**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 Kleiman, Julia Moody, Jason Hickok, Lauren Heim, Adriana Corbesev, Talsen R Avery, Katherine Haffner, Lauren Shulman, Mary K Hoyden, Robert A Weinstein, Careen Spencer-Smith, Rebecca M Kaganov, Michael V Murphy, Tyler Foxhead, Julie Lonkevitz, Micaele H Coodt, Lena Portillo, Jalpa Sarup-Patel, John A Jenmigan, Jonathan B Perlin, Richard Platt, for the ABATE Infection trial team
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
- 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
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

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
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 Moodiar, 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
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
## UG3 Demonstration Project

<table>
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<tr>
<th>Project</th>
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<tr>
<td>IMPACt-LBP</td>
<td>Adults with low back pain</td>
<td>Primary Spine Practitioner (PSP) Model using doctors of chiropractic and physical therapists as first-line providers</td>
<td>Improve physical function, decrease pain, decrease opioid prescriptions, improve patient satisfaction, and decrease costs and utilization of health care services when compared with usual medical care</td>
</tr>
</tbody>
</table>
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
## Summary of UH3 Projects

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<tr>
<td><strong>ACP PEACE</strong></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><strong>EMBED</strong></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><strong>GGC4H</strong></td>
<td>Parents of early adolescents</td>
<td>Anticipatory guidance curriculum</td>
<td>Behavioral health problems; health service utilization</td>
</tr>
<tr>
<td><strong>HiLo</strong></td>
<td>Patients undergoing hemodialysis</td>
<td>Liberalizing serum phosphate target</td>
<td>Rate of hospitalization</td>
</tr>
<tr>
<td><strong>ICD-Pieces</strong></td>
<td>Comorbid diabetes, chronic kidney disease, hypertension</td>
<td>Collaborative primary care program</td>
<td>All-cause hospitalizations for 3 conditions</td>
</tr>
<tr>
<td><strong>Nudge</strong></td>
<td>Patients with chronic cardiovascular (CV) conditions</td>
<td>Text messages and chat bot</td>
<td>Adherence to CV medications</td>
</tr>
<tr>
<td><strong>PRIM-ER</strong></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><strong>SPOT</strong></td>
<td>Suicidal ideation or depression</td>
<td>Collaborative care behavioral program (care management &amp; skills training)</td>
<td>Suicide attempts</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
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
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℠ Initiative, or NIH HEAL Initiative℠, which supports a wide range of programs to develop new or improved prevention and treatment strategies for opioid addiction.
## UH3 PRISM Demonstration Projects

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<tr>
<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 week; cost-effectiveness</td>
</tr>
<tr>
<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>
</tr>
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</table>
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
- FQHCs 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
- 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
- 350+ 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

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

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