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

NIH Collaboratory
Rethinking Clinical Trials®
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.

**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.

**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
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

>1,100 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</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!*
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

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. Thadani,11,12 Wolfgang Winkelmayr,13 Susan S. Ellenberg,5 Denise Cifelli,14 Rosemary Madigan,14 Amy Young,1 Amy White,15,16 Franklin W. Maddux,3 Kevin C. Abbott,17 and J. Richard Landis5
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>
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<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>
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</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
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<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

Study Snapshot

Active Bathing to Eliminate (ABATE) Infection

Study Snapshot

Principal Investigator: Susan Huang, MD, MPH
Sponsoring Institution: University of California, Irvine School of Medicine
ClinicalTrials.gov: NCT01600587

Abstract: Healthcare-associated infections (HAIs) are one of the most frequent causes of death in the United States and incur more than $30 billion annually in healthcare costs. Prevention of HAIs is a national priority for patient safety and cost reduction. The incidence, mortality, and cost of HAIs are caused by common bacteria that normally live on the skin or in the nose and which overcome the body’s normal defenses because of massive medical devices, surgical incisions, or the physiological effects of hospitalization.

Collaborating healthcare systems: hospital corporation of America, Harvard Medical School, University of California, Irvine, school of Medicine, Rush University, John H. Stroger Hospital, Centers for Disease Control and Prevention

NIH Institute(s) of Health: National Institute of Allergy and Infectious Diseases (NIAID)

Studies in intensive care units (ICUs) indicate that decontamination of patients’ skin with chlorhexidine, and nasal wash in neonates, can prevent many HAIs. However, evidence is lacking about the effectiveness of decontamination in non-ICU settings, where the majority of HAIs occur. Decontamination is thus rarely used in these settings, despite its potential to meaningfully decrease the HAIs. ABATE infection is a cluster-randomized controlled trial of hospitals that compares a quality improvement strategy to a standard internal and external review strategy.

Trial Timeline

June 2014 - Nov 2014

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<tbody>
<tr>
<td>Development</td>
<td>Start</td>
<td>Recruitment</td>
<td>Recruitment</td>
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Study Snapshot
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
- 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

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

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