The Collaboratory Story

Initiated through the NIH Common Fund in 2012

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 health care settings
- Diverse, representative study populations
- Outcomes important to decision makers
Core Workgroups

- 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-Reported Outcomes
- Regulatory/Ethics
Demonstration Projects

• Collaboratory pragmatic trials conducted within health care systems to address questions of major public health importance
• Span multiple Institutes & Centers
• 1-year planning phase
• Implementation phase
Reach of Demonstration Projects

869 clinical sites across 80% of the United States

Over 819,000 active subjects
ABATE  Active Bathing to Eliminate Infection

- Cluster trial comparing 2 quality improvement strategies to reduce multidrug-resistant organisms and health care-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
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
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
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
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
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
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
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
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
**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 & 4,500 families expected
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
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
## Summary of UH3 projects

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcome</th>
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</thead>
<tbody>
<tr>
<td>ABATE</td>
<td>Non-ICU patients</td>
<td>Decolonization strategies</td>
<td>MRSA &amp; VRE clinical cultures</td>
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<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>
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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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<td>PPACT</td>
<td>Non-malignant chronic pain</td>
<td>Multidisciplinary behavioral care management</td>
<td>Brief pain inventory scale</td>
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<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>STOP CRC</td>
<td>Adults aged 50-75</td>
<td>Direct mail CRC screening program (FIT kit)</td>
<td>Increased CRC screening rates</td>
</tr>
<tr>
<td>TiME</td>
<td>Dialysis patients</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>
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<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>
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<tr>
<td>HiLo</td>
<td>Patients undergoing hemodialysis</td>
<td>Liberalizing serum phosphate target</td>
<td>Rate of hospitalization</td>
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<td>GGC4H</td>
<td>Parents of early adolescents</td>
<td>Anticipatory guidance curriculum</td>
<td>Behavioral health problems; health service utilization</td>
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<td>Patients with opioid use disorder</td>
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<td>Nudge</td>
<td>Patients with chronic CV conditions</td>
<td>Text messages and chat bot</td>
<td>Adherence to CV medications</td>
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<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>
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Distributed Research Network

Enables investigators to collaborate in the use of electronic health data while safeguarding protected health information.
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
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
The Living Textbook of Pragmatic Clinical Trials

www.rethinkingclinicaltrials.org
Sharing Challenges & Solutions

Collaboratory videos & interviews

Advice to New Pragmatic Trial Investigators

from NIH Research Collaboratory | 1 month ago
PCT Grand Rounds Presentations

- Weekly webinars on a wide range of research topics
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For More Information

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

- **Knowledge Repository**
  - Archives for the Living Textbook including presentations, videos, stakeholder interviews, guidance documents & more

- **Twitter**
  - @Collaboratory1
  - @PCTGrandRounds
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