NIH Collaboratory Coordinating Center Overview and Goals

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Today’s Presentation

1. What Are the Goals of the Collaboratory Coordinating Center?
2. How Are We Doing It?
3. How Do We Share What We Have Learned?
4. Conclusions
What Are the Goals of the Coordinating Center?
Millions

Patients **walk through the doors** of hospitals and clinics each year **with questions** about their health and their care.

? How do we **study their experiences** to find answers and **create solutions** that **change care** and **improve outcomes**?
Increasing System-ness

Hospitals and physicians in US health systems
2000: 5810 hospitals
2016: 626 health systems
2020: ?

By the end of 2016, there were 626 health systems* in the United States.

U.S. hospitals and physicians in health systems

- Percentage of U.S. hospital beds in systems
  - 88.2%

- Percentage of U.S. physicians in health systems
  - 44.6%

Note: The hospital figures represent all non-federal general acute care hospitals in the United States.
Data Everywhere

Demographics
- Death data

Diagnoses
- Medication orders

Procedures
- Labs

Patient-generated data
- Geocodes

Tumor registry
- Natural language processing-derived concepts

Biosamples
- Claims

Genomic results
- Social determinants of health

Death data

Claims

Patient-reported outcomes
The NIH 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 healthcare 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 health care settings
- Intervention incorporated into routine clinical workflow
- Diverse, representative study populations
- Outcomes important to decision makers

NIH Collaboratory
Rethinking Clinical Trials
Health Care Systems Research Collaboratory
How Are We Doing It?

Structure of the Coordinating Center
Collaboratory Structure

NIH Centers and Institutes

NIH Project Officers

Advisory Panel

Coordinating Center

Steering Committee

Core Workgroups

Demonstration Projects
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-Reported Outcomes
- Regulatory/Ethics
How Are We Doing It?

Demonstration Projects
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>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>
## Ongoing Projects

<table>
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<tr>
<th>Project</th>
<th>Population</th>
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<tbody>
<tr>
<td>ACP PEACE</td>
<td>Older adults with advanced cancer</td>
<td>Advance care planning program</td>
<td>Completed advance care plans, resuscitation preference orders, palliative care consults, hospice enrollment</td>
</tr>
<tr>
<td>EMBED</td>
<td>Opioid use disorders</td>
<td>Computerized clinical decision support for ED-initiated BUP, referral for ongoing treatment</td>
<td>Rates of ED-initiated BUP</td>
</tr>
<tr>
<td>GGC4H</td>
<td>Parents of early adolescents</td>
<td>Universal evidence-based anticipatory guidance curriculum</td>
<td>Drug use, depression, delinquent behavior</td>
</tr>
<tr>
<td>HiLo</td>
<td>Patients with ESRD receiving maintenance hemodialysis</td>
<td>Higher vs lower serum phosphate target</td>
<td>Hospitalization, mortality</td>
</tr>
<tr>
<td>ICD-Pieces</td>
<td>Comorbid diabetes, CKD, hypertension</td>
<td>Collaborative primary care program</td>
<td>Hospitalization for 3 conditions</td>
</tr>
</tbody>
</table>
## Ongoing Projects (continued)

<table>
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<tr>
<th>Project</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIRE</td>
<td>Low back pain</td>
<td>Insertion of epidemiologic benchmarks in lumbar spine imaging reports</td>
<td>RVU for spine-related interventions</td>
</tr>
<tr>
<td>Nudge</td>
<td>Chronic cardiovascular conditions</td>
<td>Text message reminders and AI-based interactive chat</td>
<td>Medication adherence</td>
</tr>
<tr>
<td>PRIM-ER</td>
<td>Older adults in EDs with serious, life-limiting illness</td>
<td>Primary palliative care program in EDs</td>
<td>ICU and hospital admissions; inpatient days; discharge to home and palliative care service; use of home health and hospice; survival</td>
</tr>
<tr>
<td>PROVEN</td>
<td>Nursing home patients</td>
<td>Advance care planning video (behavioral program)</td>
<td>Hospitalization, presence of advance directive</td>
</tr>
<tr>
<td>SPOT</td>
<td>Suicidal ideation or depression</td>
<td>Collaborative care behavioral program (care management and 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, alcohol use disorders, SF-12/-36</td>
</tr>
</tbody>
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## PRISM Demonstration Projects

<table>
<thead>
<tr>
<th>Project</th>
<th>Population</th>
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<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>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>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>
</tbody>
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How Are We Doing It?

Process for Identifying and Responding to Issues
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
## Issue Tracker

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Raised by (PI)</th>
<th>Category</th>
<th>Date Reported</th>
<th>Status Updated</th>
<th>Status at Last Check In</th>
</tr>
</thead>
<tbody>
<tr>
<td>Culture: Beginning second set of site visits; culture change is needed around beliefs about infection control.</td>
<td>Huang</td>
<td>Practice norms &amp; workflow</td>
<td>9/12/14</td>
<td>2/25/15</td>
<td>Ongoing – Investigators continuing follow up site visits for facilities struggling with compliance and overuse of CHG.</td>
</tr>
<tr>
<td>A radiologist unhappy with the intervention and how it changes the format of radiology reports. This might lead to a site withdrawing.</td>
<td>Jarvik</td>
<td>Engagement</td>
<td>4/24/15</td>
<td>4/24/15</td>
<td>New challenge: We’re currently doing what we can to work through this issue.</td>
</tr>
</tbody>
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Sharing Challenges & Solutions

Teleconferences, SC Meetings, Collaboratory Videos & Interviews
How Do We Share What We Learn?

Process for Dissemination
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
Simulation Studies

Lessons re: Design & Analysis
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
PCT Training Workshops

- What are Embedded PCTs?
- Engaging All Stakeholders & Aligning With HCS Partners
- Designing With Implementation in Mind
- Design & Analytic Considerations
- Regulatory & Ethical Challenges
- Measuring Outcomes
- Pilot & Feasibility Testing
- Dissemination
- ePCT Team Composition
- Developing a Compelling Application
PCT Grand Rounds Presentations

- Weekly webinars on a wide range of research topics
- >300 presentations since inception
- Podcasts of expert interviews available on iTunes and Soundcloud
For More Information

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

- **Monthly Newsletter**
  - Convenient monthly wrap-up of NIH Collaboratory news, Demonstration Project spotlights, and new Living Textbook content
  - [rethinkingclinicaltrials.org/newsletter-subscribe](http://rethinkingclinicaltrials.org/newsletter-subscribe)

- **Twitter**
  - @Collaboratory1
Conclusions
What’s been contributed

• Significant body of knowledge on ethical & regulatory issues in PCTs
  • Consulted with OHRP
  • Conducted research on clinician & participant attitudes
  • Published special journal issue on challenges & best practices
• Biostatistical guidance in area of cluster randomized trials
• Created functional distributed research network
• Established policies and culture for data sharing
• Developed resources and guidance to support re-use of EHR data, integration of patient-reported outcomes, and partnerships with healthcare systems
• Shared case studies from our Demonstration Projects
What’s Next: Expanded Knowledge

• Develop and disseminate guidelines and lessons learned from the PRISM projects

• Promote synergies with newer Collaboratory programs
  • NIA Imbedded Pragmatic AD/ADRD Clinical Trials (IMPACT) Collaboratory
  • NIH-DoD-VA Pain Management Collaboratory

• Advance the quality and impact of patient-centered outcome measures
  • Using patient engagement activities
  • By understanding and disseminating best practices for assessing pain and related constructs in the context of ePCTs

• Study innovative dissemination and implementation science approaches
What will you contribute...

LESSONS LEARNED
Conclusions

• Take advantage of continued interest in real-world evidence and learning health systems

• Multiple lessons learned from rethinking research integrated with practice

• Cost-effective, large-scale research is possible, and we have the charge to scale it...
  • By learning, sharing, and helping the ecosystem evolve