Overview of the NIH HCS Research Collaboratory Program

PRISM Kick-Off Meeting, November 19, 2019

Catherine M. Meyers, M.D., FAHA
NIH/NCCIH, Director, Office of Clinical & Regulatory Affairs
Overview of the NIH Collaboratory

- A bit of history
- What is the NIH Collaboratory?
- What has the NIH Collaboratory accomplished?
- What’s next?
Contemporary Challenges for Clinical Research

- New approaches & strategies for the clinical trial enterprise
  - Stakeholder interactions & leveraging multidisciplinary expertise
  - Methods for preserving randomized trial design & optimizing use of available data
  - Dissemination and Implementation

Lauer MS, Collins FS. JAMA 2010;303:2182-3
Clinical trials get practical

Many clinical trials don’t help doctors make decisions. A new breed of studies aims to change that

By Jennifer Couzin-Frankel, in Philadelphia, Pennsylvania

Trials will involve more women, more minorities, a range of incomes,” says Monique

• Need for trials that inform practice & policies
• Decision makers include patients, clinicians, payers, & policy makers

Pragmatic Trials

Ian Ford, Ph.D., and John Norrie, M.Sc.
NIH Health Care Systems Research Collaboratory

*Launched in 2012*

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

**Aim:** To provide a framework of implementation methods and best practices that will enable the participation of many health care systems in clinical research. Research conducted in partnership with health care systems is essential to strengthen the relevance of research results to health practice.
Opportunities for the NIH Collaboratory – circa 2012

Focus on trials that inform practice - problems of high interest to clinicians, health care systems and patients

Embed research into routine health care environment – real world setting

Engage integrated health care systems with electronic infrastructure to:
  - Utilize cluster and other efficient designs
  - Preserve randomization as the standard
  - Test systems and delivery interventions
  - Enable easier follow-up
NIH Collaboratory PCT

• 19 Pragmatic clinical trials

• Diverse clinical settings, across 15 NIH Institutes, Centers and Offices

• >850 clinical sites, >85% of the US, >20 Health Care Systems, >800,000 participants
NIH Collaboratory Trials—Completed

- Time to Reduce Mortality in End-Stage Renal Disease (TiME) - NIDDK
- Active Bathing to Eliminate Infections (ABATE) - NIAID
- Strategies & Opportunities to Stop Colorectal Cancer (STOP CRC) - NCI
- Collaborative Care for Chronic Pain in Primary Care (PPACT) – NINDS, NIDA, NCCIH
- Lumbar Image Reporting & Epidemiology (LIRE) – NIAMS, NCCIH
- Pragmatic Trial of Video Education in Nursing Homes (PROVEN) – NIA, NINR
NIH Collaboratory Trials Completing 2020

- Trauma Survivors Outcomes & Support (TSOS) – NIMH, NIAAA
- Suicide Prevention Outreach Trial (SPOT) - NIMH
- Improving Chronic Disease Management with Pieces (ICD-Pieces) – NIDDK, NHLBI
NIH Collaboratory Trials
Launched in 2018

- Clinical decision support to implement EMergency department-initiated BuprenorphinE for opioid use Disorder (EMBED) - NIDA
- Guiding Good Choices for Health (GGC4H) – NCCIH, NIDA, OBSSR, ODP
- Primary Palliative Care for Emergency Medicine (PRIM-ER) – NCCIH, NIA
- Personalized behavioral nudges to improve adherence to cardiovascular medications (NUDGE) - NHLBI
- Improving Advance Care Planning in Oncology (ACP PEACE) - NIA, NINR
- Management of Phosphorus in ESRD (HiLo) - NIDDK
NIH HEAL/PRISM - Collaboratory Trials - Launched in 2019

- Non-pharmacological Options in postoperative Hospital-based and Rehabilitation pain Management (NOHARM) pragmatic clinical trial – NIA, NICHD
- Fibromyalgia TENS in Physical Therapy Study (FM TIPS): an embedded pragmatic clinical trial – NIAMS, NINR
- Group-based mindfulness for patients with chronic low back pain in the primary care setting (OPTIMUM) - NCCIH, NIA
- Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults (AcuOA) – NCCIH, NIA
NIH Collaboratory
Participating Institutes, Centers & Offices

NCCIH  NIA  NIDA
NIAMS  NICHD  NCI
NIMH  NIDDK  NINR
NINDS  NIAID
NHLBI  NIAAA
ODP  OBSSR
NIH Collaboratory
Partnering Health Care Systems

- Kaiser Permanente
- (Group Health Cooperative)
- Mayo Clinic
- Henry Ford Health System
- HealthPartners Institute
- Parkland Heath System
- Texas Health Resources
- ProHealth CT
- Hospital Corporation of America
- Yale-New Haven
- UNC – Chapel Hill
- Duke Health
- Northwell Health
- University of Colorado
- Denver Health Med Center
- US Level 1 Trauma Care Centers
- Fresenius, DaVita & Dialysis Clinic, Inc.
- Genesis Healthcare
- UHS Pruitt Corporation
- Oregon Community Health Information Network (FQHCs)
- North Texas VA
- Eastern Colorado VA
NIH Collaboratory Coordinating Center

- Provide national leadership and technical expertise in all aspects of research with health care systems
- Support the design and rapid execution of a set of high impact Pragmatic Trial Demonstration Projects conducted in partnerships with health care systems
- Make available data, tools and resources from these, and other, projects to facilitate a broadened base of research partnerships with health care systems
NIH Collaboratory Program

Pragmatic Clinical Trials

Collaboratory Coordinating Center
Expert Core Working Groups

- Biostatistics & Study Design
- Ethics & Regulatory
- Electronic Health Records
- Phenotypes & Data Standards
- Health Care Systems Interactions
- Patient Reported Outcomes

But Wait... THERE'S MORE!
Rethinkingclinicaltrials.org

Experimental Designs and Randomization Schemes
Endpoints and Outcomes
Analysis Plan

Consent, Disclosure, and Non-disclosure Using Electronic Health Record Data
Data and Safety Monitoring

Designing With Implementation and Dissemination in Mind
Assessing Feasibility

ENGAGING STAKEHOLDERS
and building partnerships to ensure a successful trial

What is the NIH COLLABORATORY?

TRAINING RESOURCES
NIH Collaboratory Workshops

**Ethical & Regulatory Issues of Pragmatic Clinical Trials Workshop**

**Pragmatic Clinical Trials**
Unique Opportunities for Disseminating, Implementing & Sustaining Evidence-Based Practices into Clinical Care

**Pragmatic Clinical Trials**
Embedded Pragmatic Clinical Trials of Therapeutic A vs. B Interventions

**Design & Analysis of Embedded Pragmatic Clinical Trials**
Questions?
PRECIS-2 – “WHEEL” Assessment Tool