NIH Healthcare Systems Collaboratory

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Overview of Presentation

- Goals of the Health Care Systems (HCS) Collaboratory Program
- Organization of Collaboratory
- Descriptions of 7 Demonstration Projects
- Goals of Coordinating Center and Methodological Work Groups
- Value of Collaboratory to SGC4

Goals of HCS Collaboratory Program

- Strengthen national capacity to implement cost-effective large-scale research studies that engage health care delivery organizations
- Support design and rapid execution of high impact Demonstration Projects that will conducted in partnerships with delivery systems
- Make available data, tools and resources to broaden the base of research partnerships with HCSs and that can be applied in future pragmatic trials

Organization of HCS Collaboratory Program

- Funded through the NIH Common Fund
- Two Phases:
  - UH2: 1-year planning phase to refine methods for subject recruitment and consent, randomization (patient and/or clinic), data collection, and analysis → 7 awards
  - UH3: 4-year trial phase for projects that are successful in achieving UH2 milestones → 3-4 awards anticipated
- Active involvement of NIH ICs in each project: NHLBI, NIDDK, NIAID, NIAMS, NIMH, NCI, NINDS/NIDA

Program Coordination and Oversight

- Overall project management provided by Coordinating Center (Duke)
- Programmatic oversight and guidance from:
  - Executive Committee (Chairs, Josie Briggs & Tom Insel)
  - Collaboratory External Advisory Panel
  - Collaboratory Steering Committee (Project PIs, Work Group Chairs, NIH representatives [Chair, Barry Coller])
  - NIH Implementation Team (NIH project officers [Chairs, Josie Briggs and Mike Lauer])

Required Characteristics of PCTs (per RFA)

- Test interventions that are broadly applicable to multiple health systems
- Address issues of major public health importance
- Engage partnership with health care delivery system
- Utilize information that is captured by EMRs or other extant systems and require minimal adjudication
- Minimal exclusion criteria to maximize diversity and generalizability
- Incorporate rigorous prospectively identified controls (preferably by randomization)

Required Characteristics of PCTs (cont.)

- Maximize external validity by testing generalizability across distinct health care settings and populations
- Address and overcome key barriers to conducting research in healthcare settings
- Test interventions that are relatively simple, do not require a complex infrastructure for implementation, and that can be reliably delivered by providers
- Should allow for interventions to be implemented with flexibility by practitioners to mimic practice

Demonstration Projects

- Nighttime Dosing of Anti-Hyptertensive Medications (University of Iowa)
- Population-Based Prevention of Suicide Attempts (Group Health Cooperative)
- Lumbar Imaging with Reporting of Epidemiologic Data (University of Washington)
- Collaborative Care for Chronic Pain in Primary Care (Kaiser Permanente Center for Health Research)
- Active Bathing to Eliminate Infection Trial (UC Irvine)
- Time to Reduce Mortality in End-Stage Renal Disease (TiME) Trial (University of Pennsylvania)
- STOP Colon Cancer (Kaiser Permanente)

Nighttime Dosing of Anti-Hypertensive Medications (University of Iowa)

Partnering NIH Institute / Center

- NHLBI

Primary Goal

- Determine impact of nighttime dosing of anti-hypertensive medications on rates of adverse cardiovascular (CV) events (AMI, CVA, CHF admissions, and coronary and peripheral revascularization).

Sample

- 1100 patients with HTN and 1 or more other conditions that increase CV risk in primary care, cardiology, and nephrology clinics at the Univ. of Iowa and Duke.

Nighttime Dosing of Anti-Hypertensive Medications (University of Iowa)

Randomization Strategy

- Patient-level

Data Sources

- University of Iowa and Duke EMRs (Epic)
- Personal health records to collect PROs, treatment adherence, and out of system adverse events.

Strategies to Improve Efficiency

- Identification of eligible patients through EMR
- Enrollment of patients through study website or central coordinator accessible via toll free telephone line
- Informed consent obtained using interactive online module

Population-Based Prevention of Suicide Attempt (Group Health Cooperative)

Partnering NIH Institute / Center

- NIMH

Primary Goal

- Examine whether either of two outreach intervention programs reduces risk of suicide attempt among outpatients reporting suicidal ideation

Sample

- Outpatients in four large health systems who report frequent suicidal ideation on self-report depression questionnaires administered during routine visits

Population-Based Prevention of Suicide Attempt (Group Health Cooperative)

Randomization Strategy

- Patient-level

Data Sources

- EMRs (Epic) in four large integrated health systems.

Strategies to Improve Efficiency

- Automated identification of patients through EMR
- Automatic enrollment & randomization of all eligible patients
- Delivery of interventions through EMR web portals
- Intervention quality assurance tools embedded in EMR
- Assessment of outcome (suicide attempt) using EMR and claims data

Lumbar Imaging & Reporting of Epidemiologic Data (University of Washington)

Partnering NIH Institute / Center

- NIAMS

Primary Goal

- Determine whether inserting a description of the prevalence of imaging findings among asymptomatic subjects into lumbar spine imaging reports decreases subsequent back-related interventions (e.g., imaging, injections, surgeries)

Sample

- Primary care patients undergoing lumbar spine imaging (plain films, CT and MR) at Kaiser Permanente Northern California, Group Health Cooperative, Henry Ford Health System and Mayo Health System

Lumbar Imaging & Reporting of Epidemiologic Data (University of Washington)

Randomization Strategy

- Stepped wedge, cluster randomization at the clinic level

Data Sources

- EMRs (Epic) from participating institutions (includes standardized measures of pain at some sites)

Strategies to Improve Efficiency

- Waiver of consent (minimal risk intervention)
- EMR data for assessing outcomes
- Plan to incorporate pain measures (possibly with PROMIS) into routine clinical care and EMRs at all sites

Active Bathing to Eliminate (ABATE) Infection Trial (UC Irvine)

Partnering NIH Institute / Center

- NIAID

Primary Goal

- Determine whether daily bathing of hospitalized patients with antimicrobial (chlorhexidine) soap prevents healthcare associated infections (HAIs) in hospitalized patients and subsequent readmissions

Sample

- 50 hospitals and their adult non-ICU units from Hospital Corporation of America (HCA)

Active Bathing to Eliminate (ABATE) Infection Trial (UC Irvine)

Randomization Strategy

- Cluster randomization of hospitals

Data Sources

- HCA centralized data warehouse

Strategies to Improve Efficiency

- Uses routine Quality Improvement hospital infrastructure
- Daily electronic nursing prompts for improving and assessing compliance
- Use of centralized data warehouse for all outcomes
- Centralized IRB with reliance agreements encouraged
- Waiver of informed consent anticipated

Time to Reduce Mortality in ESRD Trial (University of Pennsylvania)

Partnering NIH Institute / Center

- NIDDK

Primary Goal

- Evaluate the effects on mortality, hospitalizations and quality of life of an extended duration of thrice weekly maintenance hemodialysis sessions

Sample

- 5100 patients initiating maintenance hemodialysis treatment at participating facilities within two large dialysis provider organizations
- 322 dialysis facilities

Time to Reduce Mortality in ESRD Trial (University of Pennsylvania)

Randomization Strategy

- Cluster randomization of dialysis facilities to extended treatment duration or usual care

Data Sources

- EHRs from dialysis provider organizations
- Quality of life questionnaires

Strategies to Improve Efficiency

- Outcomes ascertained using data available from routine clinical care through data elements common to all sites
- No on-site study personnel required

STOP Colon Cancer (Kaiser Permanente)

Partnering NIH Institute / Center

- NCI

Primary Goal

- Engage FQHCs to implement systems-based transformative approaches to achieve sustainable and large-scale impacts on colorectal cancer screening rates.

Sample

- Patients eligible for colorectal cancer screening in 18 FQHCs

STOP Colon Cancer (Kaiser Permanente)

Randomization Strategy

- Clinic-level

Data Sources

- OCHIN – health information network of 200 FQHCs and 1.2 million patients.

Strategies to Improve Efficiency

- Automated systems-based strategy (mailed fecal tests)
- System for identifying patients and tracking outcome built into Epic
- No patient consenting is planned

Collaborative Care for Chronic Pain in Primary Care (Kaiser Permanente Center for Health Research)

Partnering NIH Institute / Center

- NINDS / NIDA

Primary Goal

- Determine the impact of a primary care-based interdisciplinary biopsychosocial intervention on pain symptoms, pain-related functioning, use of health care services (including receipt of opioid medications), and health plan cost/savings

Sample

- Patients with complex chronic pain on long term opioid treatment in primary care within Kaiser Permanente in Northwest (Oregon/Southwest Washington), Georgia, and Hawaii regions

Collaborative Care for Chronic Pain in Primary Care (Kaiser Permanente Center for Health Research)

Randomization Strategy

- Primary care clinic-level

Data Sources

- Kaiser Permanente EMR (Epic)

Strategies to Improve Efficiency

- All data collection through EMR /data readily available in health care delivery system where results are applied
- Utilization of clinical care infrastructure/staffing for intervention implementation
- Informed consent process simplified
- Few exclusionary criteria

Goals of Coordinating Center (Duke)

- Develop and adapt technical and policy guidelines and best practices for conducting research studies in partnership with health care systems
- Work collaboratively with Demonstration Projects to develop and test project implementation plans and provide technical, design and coordination support
- Disseminate Collaboratory policies, practices & lessons learned in Demonstration Projects to inform best practices for pragmatic trials and engaging systems, practitioners, and patients in research to improve health & care delivery
- Oversee efforts of methodological work groups
- “Proselytize” to increase enthusiasm for the methods

Methodological Work Groups

- Provider-Health Systems Research Interactions (Eric Larsen, MD, PhD)
- Stakeholder Engagement (Sean Tunis, MD)
- Ethics and Regulatory Issues (Jeremy Sugarman, MD)
- Patient-Reported Outcomes (Kevin Weinfurt, PhD & Amy Abernethy, MD)
- Electronic Health Records (Jeffrey Brown, PhD & Lesley Curtis, PhD)
- Clinical Phenotyping (Edmond Hammond, PhD)
- Biostatistics and Study Design (Elizabeth DeLong, PhD)

Key Issues Addressed by Work Groups (cont.)

Provider Health System Interactions

- Strategies for building productive collaborations with healthcare systems
- Design considerations for systems-embedded research
- Lowering administrative barriers for multi-site studies
- Strategies for reaching, consenting, scheduling & following up with study participants
- Obtaining input from HCS and front-line clinicians regarding prioritization of research topics and implementation strategies
- Incentivizing participation by provides in pragmatic trials
- Communicating results to partners and participants

Key Issues Addressed by Work Groups

Stakeholder Engagement

- Methods for engaging stakeholders (e.g., patient groups, professional societies, regulatory bodies) in HCS research and identification of best practices
- Incorporation of stakeholders' views in implementing demonstration projects and on Collaboratory-endorsed policies & best practice recommendations

Key Issues Addressed by Work Groups

Ethics and Regulatory Issues

- Use of clinical data in research (e.g., privacy, security, appropriate uses of identifiable and de-identified data)
- Standardize institutional IRB practices about informed consent (e.g., opt-in vs. opt-out) for different study designs
- Improve consent documents to increase understanding
- Interaction with FDA on trials regulations
- Managing conflicts of interest

Key Issues Addressed by Work Groups (cont.)

Patient Reported Outcomes

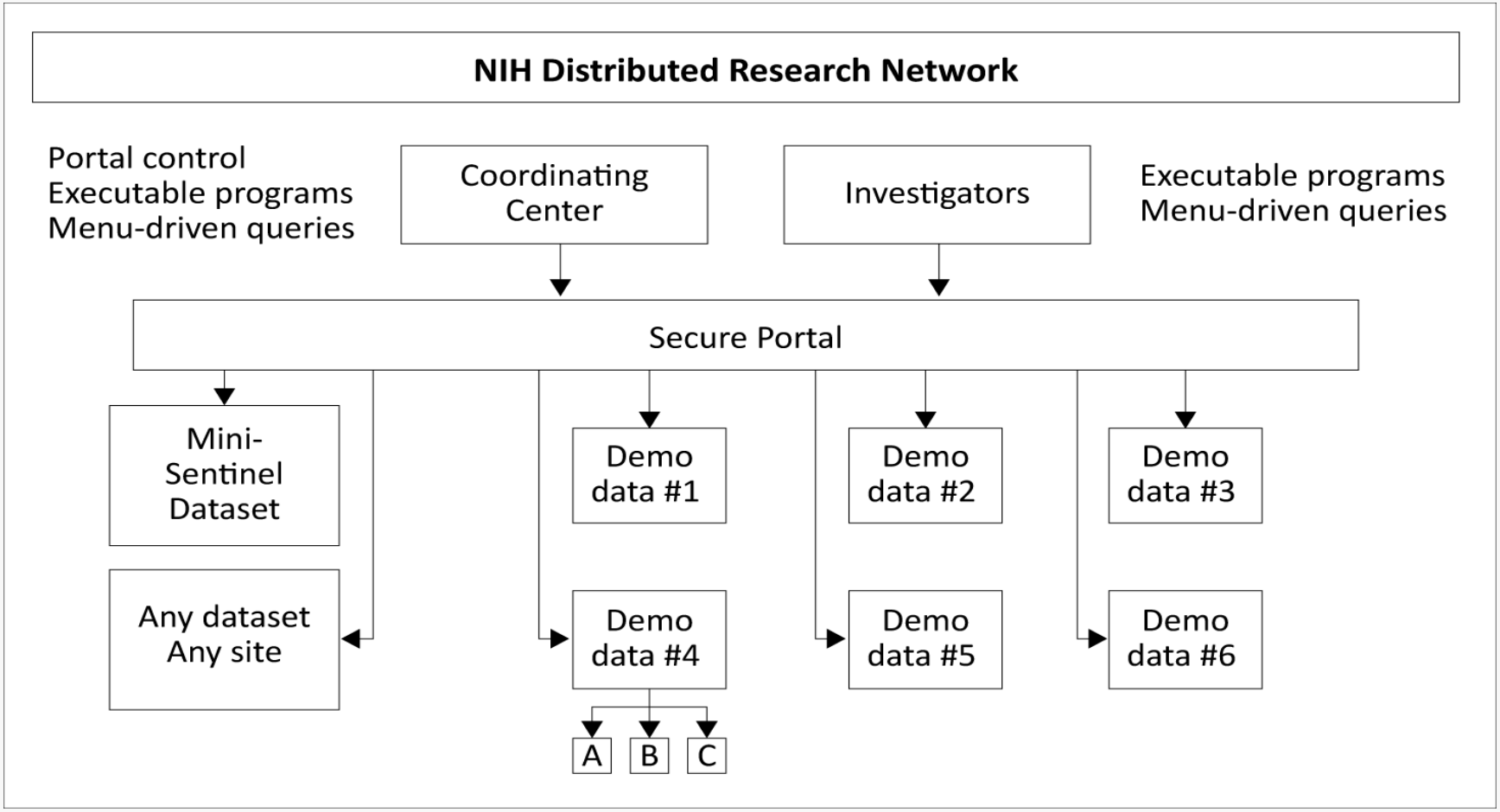
- Selecting, compiling, and curating most appropriate measures
- Developing efficient, high-quality systems for collecting PROs
- Valid and informative statistical analysis of PRO endpoints
- Usability & feasibility testing of PRO assessment systems

Key Issues Addressed by Work Groups (cont.)

Electronic Health Records

- Create NIH Distributed Research Network
- Enable authorized investigators to identify networks and clinical and research data sets of interest
- Allow investigators to submit queries and perform analyses while data remain in the control of their owners
- Create repository of tools to leverage EHRs for research

NIH Distributed Research Network



CTSA Clinical & Translational® Science Awards

Key Issues Addressed by Work Groups (cont.)

Clinical Phenotypes

- Develop library of computable definitions and algorithms to enable phenotyping for the most common and important conditions
- Develop library using the demonstration projects, as well as other ongoing PCTs
- Test phenotype definitions & algorithms against across different data systems and against medical records review data
- Synthesize best practice for identifying and addressing data quality issues

Key Issues Addressed by Work Groups (cont.)

Biostatistics & Study Design

- Optimal use of clustered designs and use of stratification
- Strategies for randomization within hierarchical organizations
- Accounting for contamination of interventions
- Selection of pragmatic, actionable, and meaningful endpoints
- Adaptation to real-time data acquisition
- Consider constraints on equal-probability randomization
- Developing sustainable interventions

Value of HCS Collaboratory to SGC4

- Active engagement and investment of multiple NIH ICs in success of demonstration projects –> ***natural partners for SGC4 in advancing CER & community-based research***
- Development of methodological standards & best practices for designing & conducting pragmatic trials by Collaboratory Work Groups --> ***dovetail SGC4 efforts with Work Groups to build capacity CTSA agendas in pragmatic trials***
- Strategies for overcoming barriers for conducting multi-site pragmatic trials --> ***export to CTSA Consortium***