

SPAN for CER

Scalable Partnering Network (SPAN) for Comparative Effectiveness Research (CER)

Presentation to GIM Grant Rounds

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Overview

- **Funding:** AHRQ R01 (Steiner, PI)
- **ARRA-funded, \$8 M**
- **Project Period:** 09/30/2010 – 09/29/2013
- **Builds on prior research to develop portal for distributed research network, and FDA Mini-Sentinel Initiative**—efforts led by Harvard Pilgrim
- **Goal:** use distributed research network (DRN) to conduct CER (ADHD & obesity treatments) with HMORN sites & community partners

Overview (cont'd)

- **Lead Organization:** KP Colorado's Institute for Health Research
- **Partner Organizations:**
 - **KP sites:** Georgia, Hawaii, Northern Calif, Northwest (also acts as Data Coordinating Center)
 - **Other HMORN sites:** Geisinger, Group Health, HealthPartners, Harvard Pilgrim
 - **Community sites:** Denver Health & Essentia Institute for Rural Health
- **Contractor:** Lincoln Peak Partners (LPP)

What is the HMO Research Network?

**Consortium of 15 US and 1 foreign HMO
research departments (6 KP regions)**

Over 12 million members in aggregate

“Rich clinical data in defined populations”

**Externally funded research networks (cancer,
CVD, vaccine safety, therapeutics, mental
health, etc.)**

**Sites develop and maintain a “virtual data
warehouse” with common data elements,
variable names and data definitions**

How to combine data from multiple sites?

Central database (e.g. Colorado all-payer claims DB)

- **requires deidentification**
- **assumes local knowledge unnecessary, but facilitates data access by multiple users**

“Distributed” data network

- **each site controls own data**
- **assumes privacy protection, local knowledge are critical, but restricts access**

Specific Aims of SPAN: CER embedded in an informatics grant

- 1. Design and implement a distributed data network for CER**
- 2. Database development and expansion**
- 3. Governance**
- 4. Proof-of-Concept Projects: ADHD and Obesity**

SA 1: Design and implement a distributed data network for CER

- **Why is it important?**
 - **Build scalable infrastructure to securely query data distributed across 11 sites**
 - **Assess potential to conduct multiple variable analysis**
 - **Near-real time data collection may enhance research translation**
- **Challenges**
 - **Some questions not easy to structure as simple queries with drop-down menus and aggregated data tables, e.g. temporal relationships**
 - **Methodology for distributed analyses not fully developed**
 - **Near real-time data collection is often not necessary, may be incomplete**

SA 2: Database development and expansion

- **Why is it important?**
 - Takes advantage of common virtual data warehouse (VDW)
 - Community sites add generalizability
 - Expands VDW by adding patient-reported data elements
 - Creates a platform for future CER studies
- **Challenges**
 - Expanding to community sites without existing VDW
 - No standard for collection and storage of patient reported outcomes

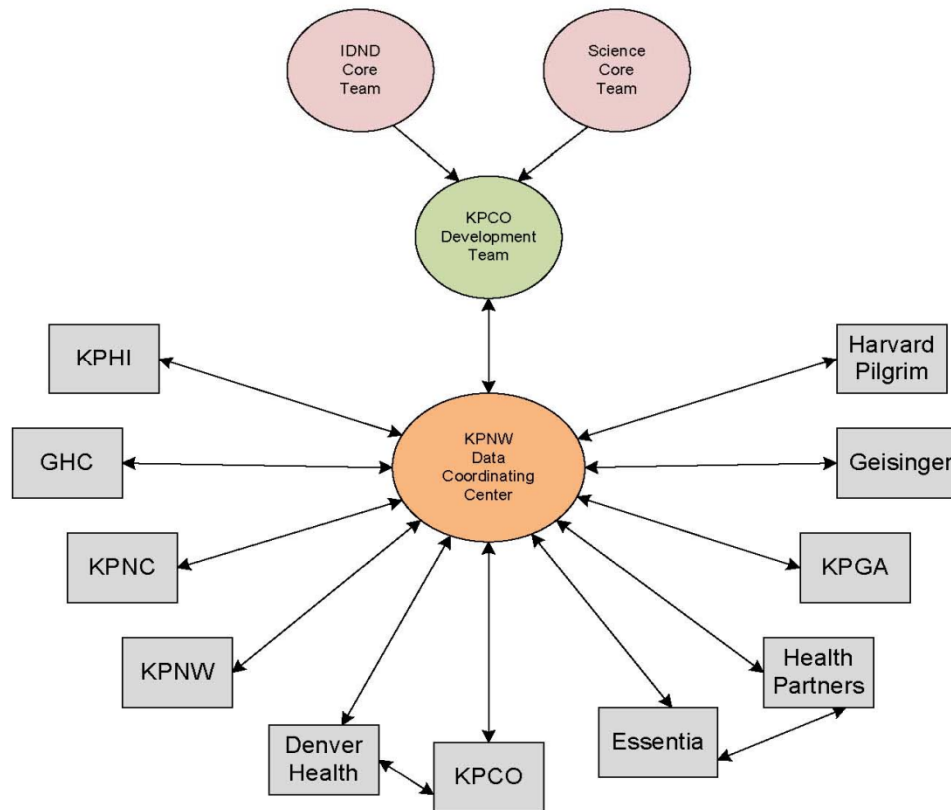
SA 3: Governance

- **Why is it important?**
 - **Privacy & security concerns with data sharing**
 - **CER requires rich data that are not easily deidentified**
 - **Different regulatory environments across sites and funders**
- **Challenges**
 - **Complexity of security/regulatory needs could slow research efforts**
 - **Tension between data privacy vs. efficiency and validity of research**

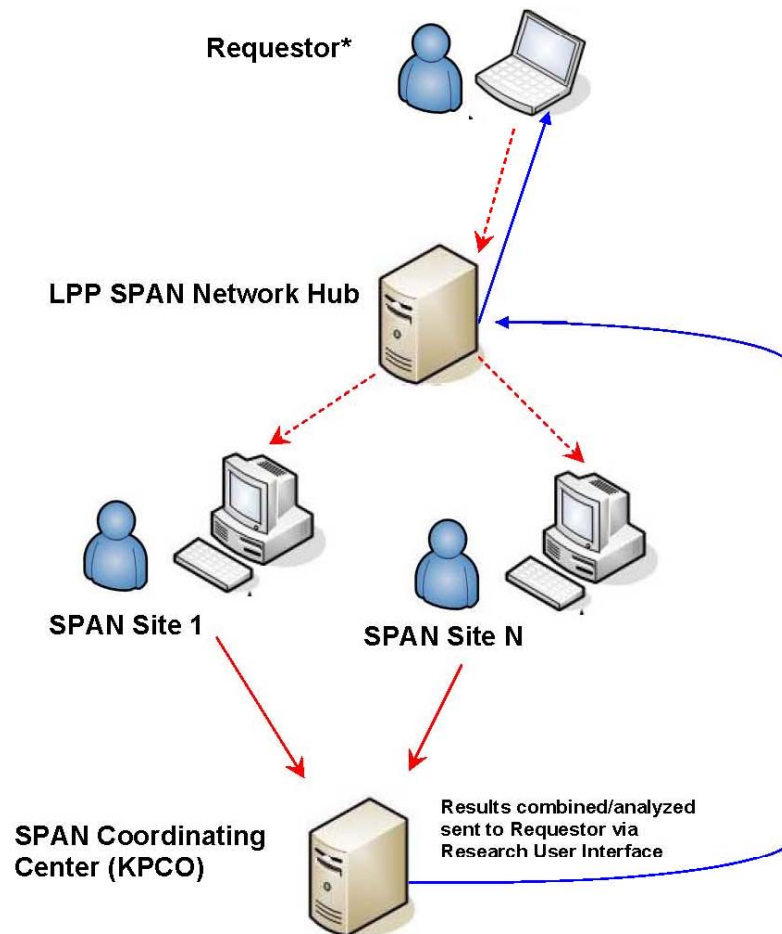
SA 4: Proof-of-Concept Projects: ADHD and Obesity

- **Why are they important?**
 - Mechanism to test distributed research network
 - Test new variable types
 - Utility of near real-time data collection
 - Conditions are public health & AHRQ priorities
- **Challenges**
 - Aligning CER objectives with network capacity
 - Addressing fundamental CER questions using a DRN architecture
 - Collecting PROs on sufficient number of patients in timely manner

Role of the Data Coordinating Center



Steps in a SPAN Query



Governance Core Products

- **Guiding Principles**
- **Research User Interface Principles and Requirements**
- **IRB (KPCO as lead IRB, 9 sites ceded oversight to KPCO IRB, one site's IRB determined not human subjects research, one site retains local oversight)**
- **Reciprocal DUA**
- **Policies and Procedures for Distributed Research**

Data Core Products

- **Data dictionaries developed**
- **Site capacity survey**
 - PROs
 - Restrictions on data sharing (mental health laws vary by State)
- **Programming for initial queries**

Science Core Products

- **Formation of expert panels in ADHD & Obesity**
- **Establish research plan for descriptive & CER studies**

Sustainability

- **How do we maximize *sustainability* beyond grant period?**
 - **System architecture (technology)**
 - **Data structure**
 - **Collaboration (CRN, VSD, CVRN, Mini-Sentinel, other DRNs)**
 - **New research partners**
 - **Expand CER cohorts – new studies**
 - **Governance tools that help DRNs operate with flexibility/efficiency**

What is the vision of the HMORN?

Develop a “collaboratory” with federal funders to address:

- **large observational studies (CER, genomics)**
- **facilitate clinical trials**
- **health care delivery research to inform health care reform**

Questions?



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