SPAN for CER

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

Presentation to GIM Grant Rounds

April 19, 2011
John F. Steiner, MD, MPH
Senior Director, KPCO, Institute for Health Research & PI for SPAN

Prepared by the Scalable PArtnering Network (SPAN) for Comparative Effectiveness Research (CER), supported by grant number R01HS019912 from the Agency for Healthcare Research and Quality. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Agency for Healthcare Research and Quality.
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

*SPAN authorized staff or sponsored outside investigator
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
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?

Inquiries:

John F. Steiner (john.f.steiner@kp.org)

Andrea Paolino (andrea.paolino@kp.org)