FDA's Mini-Sentinel program

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On behalf of 100+ collaborators

January 11, 2010

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Sentinel Prototype

- Develop a coordinating center for a distributed system
  - Access three or more health data environments with varied attributes to conduct analyses
  - Convene a Planning Board to develop governing documents and establish a Safety Science Committee charged with the day-to-day operations
  - Develop a means for secure communication with contracted data holders
- Evaluate emerging methods in safety science
  - Develop epidemiological and statistical methodologies for signal detection, signal strengthening, and signal validation
  - Test such methodologies in the evaluation of FDA-identified medical product-adverse event pairs of concern

Organizations

- America's Health Insurance Plans
- CIGNA Healthcare
- Cincinnati Children's Hospital Medical Center
- Critical Path Institute
- Brigham and Women's Hospital
  - Division of Pharmacoepidemiology and Pharmacoeconomics
  - Division of General Medicine
- Duke U School of Medicine
- HMO Research Network:
  Group Health Research Institute
  Harvard Pilgrim Health Care Institute
  Henry Ford Research Foundation
  HealthPartners Research Foundation
  Lovelace Clinic Foundation
  Marshfield Clinic Research Foundation
  Meyers Primary Care Inst(UMass / Fallon)
- HealthCore, Inc
- Humana - Miami Health Services Research Center
- Kaiser Permanente:
  Colorado, Georgia, Hawaii, Mid-Atlantic, N. California, Northwest, Ohio, and S. California regions
- Outcome Sciences, Inc
- Risk Sciences International
- Rutgers University Inst for Health
- U of Alabama at Birmingham
- U of Illinois at Chicago
- U of Iowa College of Public Health
- U of Pennsylvania School of Medicine
- Vanderbilt U School of Medicine
- Weill Cornell Medical College

Investigators

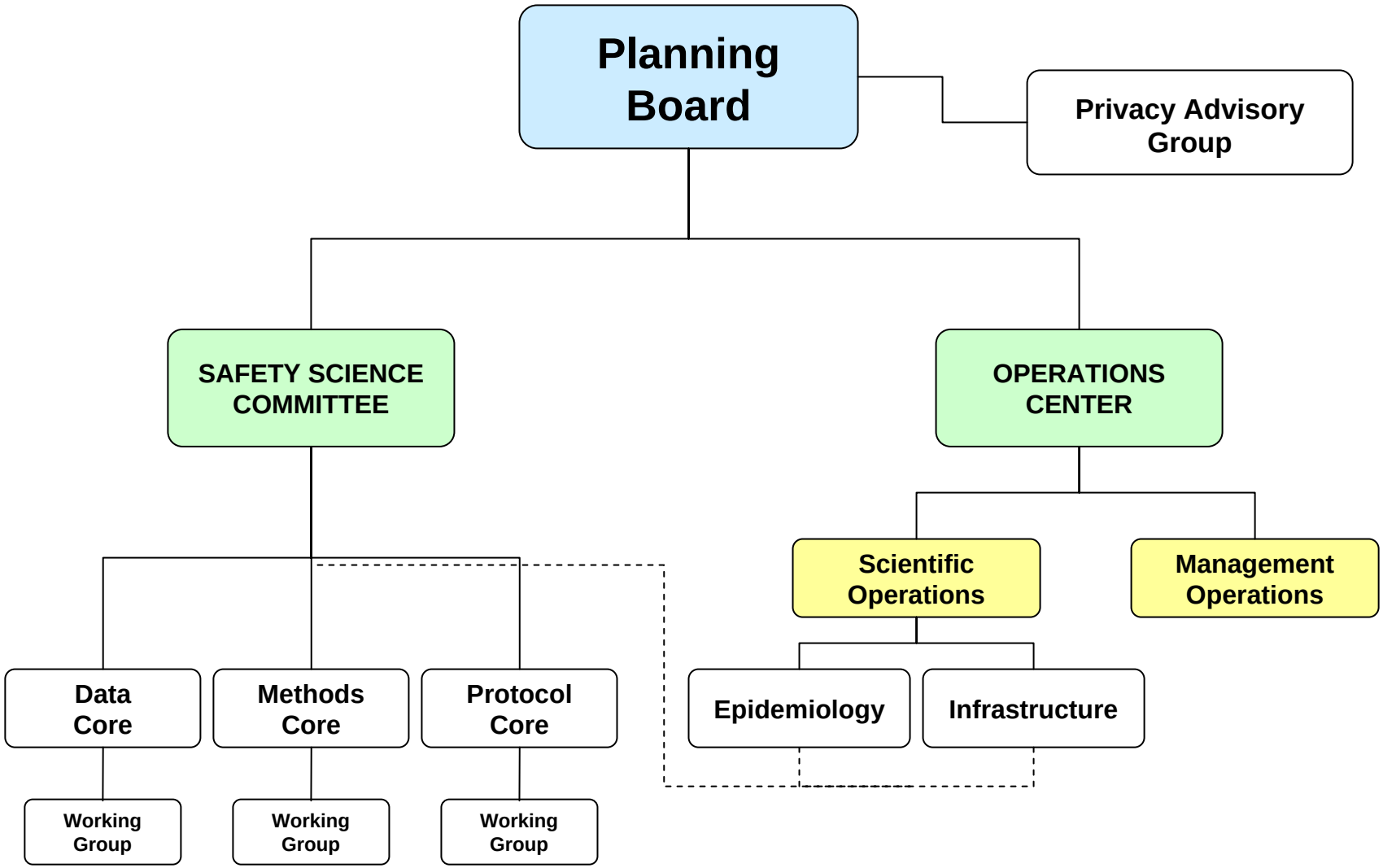
Over 100, including:

- All Vaccine Safety Datalink Principal Investigators
- 12 AHRQ CERTs PIs
- 7 AHRQ DEcIDE center PIs
- 12 current/former FDA advisory committee members
- 3 IOM “Future of Drug Safety” committee members
- 4 International Society of Pharmacoepidemiology presidents
- Critical Path Institute leadership

Data Environments

- 60 million individuals (administrative & claims)
- 10 million also have EMRs
- 88 inpatient facilities
- Device and disease registries

Mini-Sentinel Coordinating Center



Coordinating Center Leaders

- Operations Center
  - Platt, Brown, Lane
- Safety Science Committee
  - Strom (chair), Ray (co-chair)
- Data Core
  - Curtis, Weiner (co-leads)
- Methods Core
  - Nelson, Schneeweiss (co-leads)
- Protocol Core
  - Chrischilles, Hennessy (co-leads)

Antecedents

- Sentinel contractors' reports
- OMOP (Observational Medical Outcomes Partnership)
- FDA's post-market safety programs
- CDC's Vaccine Safety Datalink
- PRISM project (Post-licensure Rapid Immunization Safety Monitoring)
- Meningococcal Vaccine Safety Study
- AHRQ Distributed Research Network

Challenges

- Many different exposures
- Many different outcomes
- Many patient types
- Many and diverse data environments

- Need for timeliness in both detection and followup
- Need to avoid false alarms
- Need for multiple simultaneous activities
- Need for surge capacity

Key features

- Contract
- Target agents
- Data sources
- Coordinating center
- Distributed network
- Active surveillance
- Rapid response to new queries
- Methods development
- Policy development

Key features

- Contract
  - FDA determines all priorities
  - FDA has ultimate decision making authority

Key features

- Contract
- Target agents
  - Drugs
  - Biologics: vaccines, blood products, tissues
  - Devices

Key features

- Contract
- Target agents
- Data sources
  - Claims, EMR (outpatient and inpatient), registries
  - Current data (how current?)

Data needs

- Usually necessary
  - Enrollment: dates and type of coverage
  - Demographics
  - Claims – inpatient, outpatient
  - Pharmacy dispensing
  - Access to a limited number of full text medical records
- Sometimes necessary
  - Electronic medical records
  - Linkage to external registries, e.g., devices, birth, death, immunization

Key features

- Contract
- Target agents
- Data sources
- Coordinating center
  - Scientific and technical expertise
  - Management capacity
  - Computing and analysis capability
  - Networking structures
  - Policies and procedures
  - Contracts and data use agreements
  - Libraries of protocols, computer programs

Key features

- Contract
- Target agents
- Data sources
- Coordinating center
- Distributed network
  - Common data model
  - Balance local decision-making and central control

Key features

- Contract
- Target agents
- Data sources
- Coordinating center
- Distributed network
- Active surveillance
  - Develop and test methods for near real time evaluation of accumulating experience
  - Ability to confirm signals

Key features

- Contract
- Target agents
- Data sources
- Coordinating center
- Distributed network
- Active surveillance
- Respond to new queries
  - Time sensitive ad hoc requests

Key features

- Contract
- Target agents
- Data sources
- Coordinating center
- Distributed network
- Active surveillance
- Rapid response to new queries
- Methods development
  - Statistics and epidemiology
  - Networking and linkage between data sources
  - Performance characteristics of detection algorithms

Key features

- Contract
- Target agents
- Data sources
- Coordinating center
- Distributed network
- Active surveillance
- Rapid response to new queries
- Methods development
- Policy development
  - Privacy
  - Research vs public health practice

Mini-Sentinel's key features

- **Contract**
  - FDA determines all priorities
  - Has ultimate decision making authority
- **Target agents**
  - Drugs, biologics, devices
- **Data sources**
  - Claims, outpatient and inpatient EMR, registries
  - Current data
- **Coordinating center**
  - Create and maintain scientific and technical expertise, computing and analysis resources, policies, procedures, inter-institutional agreements, libraries of protocols and analysis programs
- **Distributed network**
  - Claims, EMR (outpatient and inpatient), registries
- **Active surveillance**
  - Develop and test methods
- **Rapid response to new queries**
  - Time sensitive ad hoc requests
- **Methods development**
  - Statistics, epidemiology, performance characteristics of detection algorithms, linkage between data sources
- **Policy development**
  - Privacy
  - Research or public health practice

Coming soon

www.mini-sentinel.org