Defining and Evaluating Possible Database Models to Implement the FDA Sentinel Initiative

Second Annual Sentinel Initiative Public Workshop
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Jeffrey Brown, PhD
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Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute
Contract and Contributors

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**Report Authors:**
- Jeffrey Brown
- Kimberly Lane
- Kristen Moore
- Richard Platt
Project Objectives

- Describe Sentinel System user needs
- Define potential database models (ie, how to organize data)
- Compare & contrast data models with user needs
- Identify environments & systems operating under various models
- Recommend characteristics & capabilities for Sentinel database models
Key Database Model-related Questions

- What does the system need to do?
- What data are needed to meet system needs?
- Where will the data be stored?
- How will the data be analyzed?
- Is a common data model needed
  - What should the model look like?
Selected Primary Uses of Sentinel

- Adverse event surveillance & signal strengthening
- Confirmatory safety studies
- Monitor adoption & diffusion
- Augment registry information
- Calculation of background incidence rates
- Better information regarding appropriate use of electronic data/validity of coding
- Many other potential uses
What Data Are Needed?

- Minimum data needs for primary uses
  - Exposures (with dates)
  - Outcomes and comorbidities
  - Enrollment and demographic information

- Additional desirable data capabilities
  - Linkage across datasets (cross-sectional; longitudinal)
  - Clinical details (lab results, radiology, full-text records)

- Very few data elements are needed for most intended uses of Sentinel

- Needs are distinct from those of payors to pay claims and providers to support care delivery
What Data Are Needed?

- Systems with administrative & claims coupled with EMR data are most useful, but represent a small minority of the U.S. population

**Recommendation:** Initially focus on health insurer administrative & claims databases covering defined populations
Where are Data Stored?

- **Centralized**: data holders send data to a central location; data stored outside the physical control of data holder

- **Distributed**: data holders maintain physical control of their data behind their firewalls, protected by their security procedures and rules

**Recommendation: Distributed Model**

- Allows data holders to maintain physical control over their data and its uses: acceptable to data holders.
- Can accomplish about as much as centralized model; in principle it can do all the same things.
How are Data Analyzed in a Distributed Model?

1. Single analytic program distributed without local modification; requires local datasets to have same format (common data model)

2. Data holders individually implement a single study protocol

**Recommendation: Single Analytic Program**

- Ensures that complex analytic approaches are implemented identically and results comparable across institutions
Implementation of a Common Data Model?

- Common data model: set of definitions for the structure of databases and data elements
- Can be virtual or physical
  - Physical: extract, transform, and load process
  - Virtual: software layer to map local concepts to system concepts; requires real-time data or query transformations

**Recommendation:** Initial implementation should require a physical transformation for all or portion of a population
Types of Common Data Models

- Encounter-based person-level model
- Drug and condition era model (person-level)
- Person-level summary model
- Summary data model

- Many variants to these
- Many ways to enhance functionality through standardization of terminology
Additional Data Model Characteristics of Relevance to Sentinel

- **Linkage: Medical charts**
  - Access to detailed information from the full text records is essential for primary users
    - Allows validation of outcomes & some exposures
    - Provides information on co-existing conditions, indications, and other data to elucidate findings

- **Linkage: External data sources**
  - Can provide data beyond that found in administrative & claims databases or EMRs
Additional Data Model Characteristics of Relevance to Sentinel

- **Linkage: Between institutions**
  - Identify individuals across different care settings
  - Longitudinally identify individuals across data holders

- **Timeliness**
  - Interval until data becomes available for analysis
  - Varies by data source and system
Illustration of Proposed System

Coordinating Center sends a query (program) to all data holders

Data holders review query

Local Datasets
Common Data Model

Review & Return
Results

Institutional Firewall/ Policies

Analysis and Reporting

Review & Return
Results

Institutional Firewall/ Policies

Data holders return results to Coordinating Center
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