ENGELBERG CENTER for Health Care Reform at BROOKINGS

Expert Workshop:

Statistical and Epidemiological Issues in Active Medical Product Surveillance

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February 16, 2011

Meeting Objectives

- Discuss specific solutions to some pressing methodological issues:
  - Signal refinement in the context of large sample sizes
  - Analyzing horizontally and vertically partitioned data
  - Evaluating the performance of active surveillance methods
- Focus on how solutions may be applied within the context of Mini-Sentinel

Meeting Agenda

Session 1: Signal Refinement in the Context of Large Sample Sizes

Session 2: Meta-Analytic Approaches for Combining Multiple Results to the Same Query

Session 3: Distributed Regression and Related Methods for Signal Refinement

Session 4: Establishing Operating Characteristics of Active surveillance Approaches

Implications of Large Sample Sizes

- Mini-Sentinel is Congressionally mandated to include 100 million people by 2012
- Important advantages:
  - Increased statistical power
  - Expanded ability for subgroup analysis
- Potential concerns:
  - Increased risk of false positives
  - Small/biased effect estimates may appear statistically significant

Horizontal Data Partitioning

Sample Claims Data

Health Plan A's Members

Patient ID #	ICD-9 code	NDC Codes
5402	401.0	54868-1005-1
5673	401.0	00028-0071-10
6007	401.1	54868-1005-1

Same information collected for different patients

Health Plan B's Members

Patient ID #	ICD-9 code	NDC Codes
6056	401.0	0028-0071-10
7051	401.1	0028-0071-10
8057	401.1	54868-1005-1

Vertical Data Partitioning

Sample Vaccine Surveillance Data

State Vaccine Registry

Patient ID #	Vaccination Status
113	Yes
157	Yes
168	Yes
204	Yes
243	Yes

Inpatient Claims Data

Patient ID #	DRG Code
113	179
157	179
168	178
204	N/A
243	203

Same patient, but patient information is held in separate locations

Working with Partitioned Data

- Meta-analysis
- Meta-regression
- Distributed regression
- Other privacy-preserving approaches?

How do we maximize the validity of signal refinement

and

adequately protect privacy?

Evaluating Performance of Methods

- Range of potential operating characteristics
- Variety of methods for active surveillance
- Challenge:
  1. Establish which characteristics are most relevant
  2. Determine how to reliably select methods based on these characteristics