Data Needs for Signal Refinement: A Mini-Sentinel Perspective

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From Thought Leadership to Clinical Practice

Mini-Sentinel

Agenda

- Brief overview of Mini-Sentinel and the Distributed Database (MSDD)
- Using the MSDD for signal refinement in 2 scenarios
  - Oral diabetes medication→acute MI
  - Injectable antibiotic drug (inpatient)→acute liver injury

Sentinel Network Prototype (Mini-Sentinel)

- 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

J. Woodcock, Dec 16, 2009

Mini-Sentinel Distributed Database (v1)

- 34 million individuals
  - Kaiser, HMORN, Healthcore, Humana
- Quality-checked administrative/claims data
  - Enrollment
  - Demographics
  - Utilization (diagnoses, procedures)
  - Outpatient pharmacy dispensing
- Distributed approach
- Quarterly updates

Distributed Approach to Signal Refinement

- Review request with MSCC and Data Partners for viability
- MSCC develops SAS programs
- Programs distributed to Data Partners
  - Creation of permanent analysis file
- Results data set and log files returned to MSCC

- Data Partners have complete control over all uses of their data and approve all transmissions

Scenario #1: Oral Diabetes Medication and AMI

- Exposure: Oral diabetes medication
  - Prescription dispensing or claim (longitudinal)
    Days supplied, amount dispensed
  - Continuous enrollment with drug and medical coverage
- Outcome: Acute MI
  - Hospital, ED discharge diagnoses codes (410.x0, 410.x1)
    PPV 88-97% in other systems

Scenario #1: Potential Confounders

- Comorbidities—ICD9 codes (dx and px)
- Obesity—ICD9 code only, not BMI
- Race/ethnicity—variably populated
- Smoking/SES—not available

Scenario #1: Issues

- Principal discharge diagnosis not available at all sources
  - First diagnosis as surrogate
- Censoring at death
  - Inpatient deaths immediately available
  - Other sources have variable lags

    Social Security Administration Master Death File (weeks)

    Tumor registries, state files (months)

    National Death Index (years)

Scenario #2: Injectable Antibiotic and Acute Liver Injury

- Option 1: MSDD v1
- Option 2: MSDD v1 Augmented

Scenario #2: Injectable Antibiotic and Acute Liver Injury—MSDD v1

- Exposure: Antibiotic injection (inpatient setting)
  - Antibiotic injection recorded as a procedure

    Injection procedure may be coded, but unlikely that all injections would be coded
- Outcome: Acute liver injury
  - Diagnosis, procedure codes

    Many ICD-9 codes identify acute liver injury

Scenario #2: Injectable Antibiotic and Acute Liver Injury—MSDD Augmented

- Exposure: Antibiotic injection (inpatient setting)
  - Identification via EHR
  - Incorporate relevant EHR information into MSCDM
- Outcome: Acute liver injury
  - Identification via codes (dx, px) or EHR

If exposure and outcome are expected during the same hospitalization → rely on hospital Data Partners

If outcome is expected to occur after hospitalization → inpatient EHR linked to an insurer

Signal Refinement in Mini-Sentinel

- MSDD v1 is well suited for questions for which exposures, outcomes, and key confounders are reliably coded in administrative data
- MS infrastructure enables us to augment the MSCDM to address specific questions