May 20th, 5:00 PM - 7:00 PM

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Cutrona, Sarah L.; Toh, Darren; Iyer, Aarthi; Foy, Sarah; Cavagnaro, Elizabeth; Forrow, Susan; Goldberg, Robert J.; and Gurwitz, Jerry H., "Validation of Acute Myocardial Infarction (AMI) in the FDA’s Mini-Sentinel Distributed Database" (2011). UMass Center for Clinical and Translational Science Research Retreat. 2.
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Validation of Acute Myocardial Infarction (AMI) in the FDA’s Mini-Sentinel Distributed Database

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Background

The Food and Drug Administration’s (FDA) Mini-Sentinel is a pilot program that aims to conduct active surveillance to detect and refine safety signals that emerge for marketed medical products.

The purpose of this Mini-Sentinel AMI Validation project was to:

(a) develop and design an abstraction and adjudication process to use when full text medical record review is required to confirm a coded diagnosis; and

(b) to test this approach by validating a code algorithm for acute myocardial infarction (AMI).

Design

(1) AMI Case Identification

Goal: Establish ICD-9-CM-based algorithm to identify patients hospitalized for AMI within the Mini-Sentinel Distributed Database

Approach: Reviewed previous validation studies. Considered using a broad algorithm (incorporating Acute Coronary Syndrome codes, or codes to capture death after ER discharge).

Algorithm: Include ICD-9 hospital discharge codes (a principal or primary discharge code only) of 410.x0 and 410.x1.

(2) AMI Case Retrieval

Goal: Establish and carry out procedure for chart retrieval and extraction, creating patient privacy, collecting and transferring the minimal amount of de-identified information needed to validate potential cases of AMI.

Approach:

1. Identify required chart components (examples: EKGs, cardiac biomarkers, dictated doctor notes).
2. Determine whether chart abstraction would take place centrally or in a locally distributed fashion. (Centralized approach was chosen).
3. Establish protocols for ensuring the privacy and security of data and for explaining the status of this effort as a public health surveillance activity not under the oversight of IRBs.

(3) Abstraction

Goal: Design abstraction form and train 2 nurse abstractors to gather key data for AMI validation.

Approach: 36-item abstraction form included demographic information, brief medical history, biomarker data, EKG copies, cardiac test results and disposition at discharge.

(4) Adjudication

Goal: Develop protocol-driven Adjudication process.

Approach: Protocol developed based on American Heart Association Universal Definition of MI. Two UMass Cardiologists independently reviewed each case and identified as (1) Definite MI; (2) Probable MI; (3) No MI; or (4) Unable to Determine. Cardiologists met to reach consensus in cases where they differed.

(5) Calculation of PPV (Positive Predictive Value)

Goal: Calculate PPV of algorithm (ratio of confirmed AMI cases to all identified cases)

Approach: PPV = Definite + Probable MI

Available data and charts, EKG copies, cardiac test results and disposition at discharge.

Subgroup PPVs:

- age <75 (74 charts) = 94.6% (95% CI 86.9 to 97.9)
- age 75+ (33 charts) = 79.2% (66.5 to 88.0)
- females (67 charts) 77.6% (63.3 to 85.9)
- Lower PPV for females driven by the women in 75+ age group

Women <75 (29 charts) 93.1% (78.0 to 98.1);
Women 75+ (27 charts) 70.4% (51.5 to 84.1)

Conclusions

A PPV of 86% may be considered adequate for some surveillance activities relevant to medication and device safety, but not for others.

Further research may be merited examining between-age group and between-gender differences in the positive predictive value of this AMI identification algorithm.