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Validation of Acute Myocardial Infarction (AMI) in the FDA’s Mini-Sentinel Distributed Database

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Validation of Acute Myocardial Infarction (AMI) in the FDA’s Mini-Sentinel Distributed Database

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2) Harvard Pilgrim Health Care Institute, Boston, MA

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 ICD 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, ensuring 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, death certificate 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: Design protocol-driven Adjudication process
Approach: Protocol developed based on American Heart Association Universal Definition of MI. Two UMass Cardiologists independently reviewed each case and classified 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

RESULTS
Percent of Requested Charts that were Obtained (93% overall)
Availability of Critical Chart Components

Average Size of Chart (Pages)
Availability of Cardiac-Specific Chart Components

Positive Predictive Value of AMI Identification Algorithm

<table>
<thead>
<tr>
<th>DATA PARTNER</th>
<th>YES (%)</th>
<th>NO (%)</th>
<th>TOTAL # OF CHARTS</th>
<th>PPV (%)</th>
<th>95% CONFIDENCE INTERVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>DP1</td>
<td>26</td>
<td>6</td>
<td>32</td>
<td>81.3</td>
<td>64.7, 91.1</td>
</tr>
<tr>
<td>DP2</td>
<td>29</td>
<td>9</td>
<td>38</td>
<td>76.3</td>
<td>60.8, 87.0</td>
</tr>
<tr>
<td>DP3</td>
<td>33</td>
<td>2</td>
<td>35</td>
<td>94.3</td>
<td>81.4, 98.4</td>
</tr>
<tr>
<td>DP4</td>
<td>35</td>
<td>3</td>
<td>38</td>
<td>92.1</td>
<td>79.2, 97.3</td>
</tr>
</tbody>
</table>

OVERALL 123 20 143 86.0 79.4, 90.8

Subgroup PPVs:
age <75 (74 charts) = 94.6% (95% CI 86.9 to 97.9)
age 75+ (53 charts) = 79.2% (66.5 to 88.0)
males (76 charts) = 93.4% (88.5 to 97.2)
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.