FDA’s Sentinel Initiative — A National Strategy for Monitoring Medical Product Safety

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US Food and Drug Administration
Sentinel Initiative

• Develop a national electronic safety monitoring system
  – Strengthen FDA's ability to monitor postmarket performance of medical products
  – Enable FDA to access existing automated healthcare data by partnering with data holders (e.g., insurance companies with large claims databases, owners of electronic health records, others)

• Will augment, not replace, existing safety monitoring systems
Potential Capabilities of Sentinel

• Improving FDA’s capability to identify and evaluate safety issues in near real time
• Enhancing FDA’s ability to evaluate safety issues not easily evaluated with the passive surveillance systems currently in place
  • Expanding FDA’s access to subgroups and special populations (e.g., pediatrics, geriatrics)
  • Expanding FDA’s access to longer term data
  • Expanding FDA’s access to adverse events occurring commonly in the general population (e.g., myocardial infarction, fracture) that tend not to get reported to FDA through its passive reporting systems
Mini Sentinel
Harvard Pilgrim Healthcare

• Develop and test the scientific operations needed for the Sentinel Initiative.

• Create a coordinating center with continuous access to automated healthcare data systems to enable safety evaluations
Organizations

- America's Health Insurance Plans
- CIGNA Healthcare
- Cincinnati Children's Hospital Medical Center
- Critical Path Institute
- Brigham and Women's Hospital
  - Division of Pharmacoepidemiology and Pharmacoeconomics
  - Division of General Medicine
- Duke U School of Medicine
- HMO Research Network:
  - Group Health Research Institute
  - Harvard Pilgrim Health Care Institute
  - Henry Ford Research Foundation
  - HealthPartners Research Foundation
  - Lovelace Clinic Foundation
  - Marshfield Clinic Research Foundation
  - Meyers Primary Care Inst(UMass / Fallon)
- HealthCore, Inc
- Humana - Miami Health Services Research Center
- Kaiser Permanente: Colorado, Georgia, Hawaii, Mid-Atlantic, N. California, Northwest, Ohio, and S. California regions
- Outcome Sciences, Inc
- Risk Sciences International
- Rutgers University Inst for Health
- U of Alabama at Birmingham
- U of Illinois at Chicago
- U of Iowa College of Public Health
- U of Pennsylvania School of Medicine
- Vanderbilt U School of Medicine
- Weill Cornell Medical College
A. Only those academic institutions with automated data will be recipients of queries.

B. No entities will have access to protected health information that they do not already hold. Instead, those whose queries are accepted by the Mini-Sentinel Coordinating Center for processing will receive results summaries from analyses conducted by each data holder that receives and agrees to respond to those queries. Results summaries will not include protected health information.
Mini-Sentinel major deliverables- 1\textsuperscript{st} year

- A coordinating center with
  - secure communications capability for sharing confidential information between FDA and Mini-Sentinel collaborators
  - communications capability for public sharing of non-confidential work products
- The first version of the Mini-Sentinel Distributed Database, encompassing quality-checked administrative and claims data including at least 25 million lives
- A framework (taxonomy) for safety surveillance methods and a prioritized list of gaps
  - new methods development addressing three methods gaps
- A prioritized list of Health Outcomes of Interest (HOI) for subsequent validation
  - procedures for obtaining full text medical records and case adjudication for HOI
  - validation of one HOI
- A fully developed protocol to use accumulating data for identify excess risk of acute myocardial infarction associated with one or more drugs
Pediatric patients included in the Mini-Sentinel Distributed Database*

<table>
<thead>
<tr>
<th>Age Groups</th>
<th># of Pediatric Patients Captured in Distributed Partners’ Databases as of January 1, 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 4 weeks</td>
<td>24,398</td>
</tr>
<tr>
<td>5 - 52 weeks</td>
<td>284,324</td>
</tr>
<tr>
<td>1 - 4 years</td>
<td>1,924,654</td>
</tr>
<tr>
<td>5 - 9 years</td>
<td>3,042,707</td>
</tr>
<tr>
<td>10 - 19 years</td>
<td>7,029,473</td>
</tr>
</tbody>
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*Distributed partners include HMO Research Network, Kaiser Permanente, Humana, and Healthcore
Federal Partners Collaboration

- An active surveillance initiative via intra-agency agreements with CMS, VA, DoD
  - Pediatric data available in Medicaid and DoD databases
- Small distributed system
  - Each Partner has unique data infrastructure
  - No common data model being utilized
- FDA proposes medical product – AE pairs to evaluate
- Develop a shared protocol
- Evaluate active surveillance methodologies
- Assess interpretability of query findings resulting from a decentralized analytic approach
Pediatric Patients included in DoD’s Pharmacovigilance Defense Application System

<table>
<thead>
<tr>
<th>Age Groups</th>
<th>Pediatric Patients Eligible for Care as of March 2010</th>
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</thead>
<tbody>
<tr>
<td>0 - 21 years</td>
<td>2,872,445</td>
</tr>
<tr>
<td>0 - 17 years</td>
<td>2,074,821</td>
</tr>
<tr>
<td>0 - 4 weeks</td>
<td>8,967</td>
</tr>
<tr>
<td>5 - 52 weeks</td>
<td>114,722</td>
</tr>
<tr>
<td>1 - 4 years</td>
<td>497,833</td>
</tr>
<tr>
<td>5 - 9 years</td>
<td>551,808</td>
</tr>
<tr>
<td>10 - 17 years</td>
<td>901,491</td>
</tr>
<tr>
<td>18 - 21 years</td>
<td>797,624</td>
</tr>
</tbody>
</table>
# Demographic Characteristics of Medicaid FFS Beneficiaries with Drug Coverage and Claims Capturing Health Outcomes - 2009

<table>
<thead>
<tr>
<th>Population (millions)</th>
<th>2009 Continuous FFS Enrollment Period of at Least:</th>
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<tbody>
<tr>
<td></td>
<td>1 month</td>
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<tr>
<td>Total (all ages)</td>
<td>39.8</td>
</tr>
<tr>
<td>0 - 21 years</td>
<td>19.8</td>
</tr>
<tr>
<td>0 - 17 years</td>
<td>16.8</td>
</tr>
<tr>
<td>0 - 4 weeks</td>
<td>1.2</td>
</tr>
<tr>
<td>5 - 52 weeks</td>
<td>2.2</td>
</tr>
<tr>
<td>1 - 4 years</td>
<td>4.9</td>
</tr>
<tr>
<td>5 - 9 years</td>
<td>4.7</td>
</tr>
<tr>
<td>10 - 17 years</td>
<td>6.4</td>
</tr>
<tr>
<td>18 - 21 years</td>
<td>3.4</td>
</tr>
</tbody>
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Other ongoing activities

• Convener on Active Medical Product Surveillance- The Brookings Institution
  – Holds expert panels, active surveillance roundtables, implementation meetings, and annual Sentinel public meeting

• Observational Medical Outcomes Partnership
  – A Public-Private partnership focused on developing the data infrastructure and scientific methods needed for conducting active surveillance in observational data
Conclusions

• Pediatric population is well represented in the Mini-Sentinel Distributed Database (MSDD) and the Federal Partners Collaboration

• Medical product safety issues unique to the pediatric patient population can be addressed within the Sentinel Initiative pilot programs
  – Some questions such as growth-related concerns will need to await the addition of more clinical data to the MSDD

• Broader lessons learned regarding data needs and methods development will benefit evaluations targeted at the pediatric population