The Vision for a Semi-Automated Surveillance System to Complement Protocol-Based Product Assessments

Patrick Archdeacon, MD
Medical Officer, Office of Medical Policy, FDA January 31, 2013
An Analogy to Healthcare

• A comprehensive healthcare system includes both preventive health maintenance and also specialized health interventions
• A preventive program may include vaccines, cholesterol screening, colonoscopy, mammograms, etc.
• Appropriate preventive program is chosen according to patient (age, gender, history, lifestyle, etc)
• May still be necessary to follow with specialized assessments and interventions
What constitutes a comprehensive safety surveillance system?

• Semi-automated routine surveillance, applying general tools with minor adaptations to address the specific product

But also...

• Ability to bring specialized expertise to bear on specific issue(s) that may arise in product lifecycle
Application of this Principle to the Sentinel System

**At Present**

- Infrastructure in place to capture product exposures
- Some experience in measuring a few outcomes (AMI, bleeding)
- Sufficient expertise available to develop programming to apply existing methodologies to specific product:outcome pairs

- Highly specialized system that supports important but restricted range of activities (e.g., the HPV and rotavirus vaccine and dabigatran evaluations described this morning)

**Goal Capacities**

- Increase current capabilities
  - But also...
- Create semi-automated routine surveillance capability
  - Need vastly expanded menu of measurable outcomes
  - Need adaptable modules that can apply general methodologies to many product:outcome pairs
  - Need improved understanding of appropriate application of statistical and epidemiology tools in this setting

- Comprehensive system capable of full range of safety surveillance
Relative Characteristics of Semi-Automated and Protocol-Based Surveillance

<table>
<thead>
<tr>
<th>Semi-Automated</th>
<th>Protocol-Based</th>
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<tbody>
<tr>
<td>• Less resource intensive</td>
<td>• More resource intensive</td>
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<tr>
<td>• Less control of systematic biases</td>
<td>• Greater control of systematic biases</td>
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<tr>
<td>• Able to generate hypotheses</td>
<td>• Able to test hypotheses</td>
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The speakers that follow will describe the ongoing efforts to build the first generation of tools that will support semi-automated surveillance activities through the Sentinel Initiative.