

The Sentinel Network

March 7, 2007

Background

- Adverse events due to the use or misuse of medical products are common
- Adverse events may result from the inherent properties of a medical product, a problem with its manufacture, or errors in its prescribing, selection or use

Background, cont'd

- Healthcare practitioners and patients need up-to-date and accurate information about the risk/benefit profile of medical products to use them safely and effectively

Reality Check

- The risk/benefit profile of medical products evolves over time
- Premarket clinical trials cannot identify all potential risks from a medical product
- Therefore, full knowledge of the risk/benefit profile of medical products does not exist at the time of product approval and often not at the time of treatment decision-making

Reality Check, cont'd

- When important information for safe use exists it is not always readily available at the time of treatment decision-making
- Therefore, timely and effective postmarket surveillance and risk communication are critical to reduce the knowledge gap and foster better informed treatment decisions

The Problem

- The effectiveness of Federal government postmarket surveillance and risk communication efforts have been constrained due to limitations in the:
 - Quality of data
 - Quantity of data
 - Timeliness of data receipt and analysis
 - Capacity to rapidly conduct postmarket safety studies, when needed
 - Risk communication tools used
 - Available resources

The Problem, cont'd

- Current efforts are frequently crisis-driven rather than prevention-driven
- Analyses focus on overall population rather than differentiating subpopulations (personalized medicine)
- There is no coordinated systems approach

A Proposed Solution

- The private sector has taken steps that can facilitate our surveillance activities:
 - Developing new information technology tools
 - Exploring informatics methods and applications
 - Creating the capacity to conduct postmarket safety assessments
- Therefore, we should link private and public sector efforts to address these limitations through better integration of the nation's postmarket medical product safety activities to assemble a "Sentinel Network" – a virtual, integrated, electronic Nationwide medical product safety network

Sentinel Network, cont'd

- The Network would foster the seamless, timely electronic flow of medical product safety information from electronic databases and surveillance reporting systems, through risk identification and analysis processes, to healthcare practitioners and patients at the point-of-care while protecting patient privacy
- The Network would be assembled through public-private collaborations and build on existing efforts rather than create a new system
- The Network would use national and international standards adopted by AHIC

Components of the Sentinel Network

- Data Collection
 - Integrate clinical practice and adverse event surveillance
 - EHRs
 - Integrated databases
- Risk Identification and Analysis
 - Integrated research networks
 - Data mining tools
 - Reach agreement on methodologies
 - Conduct subgroup analyses and identify biological/genomic markers
- Risk Communication
 - Leverage medical community's expertise
 - Integrate new risk information into the workflow of clinical practice (e.g., decision support systems)

Objectives of Today's Meeting

- Evaluate current needs in postmarket medical product adverse event data collection and risk identification and analysis
- Identify the obstacles to, facilitators, and incentives for, developing the data collection and risk identification and analysis components of the Sentinel Network
- Identify opportunities for public-private collaborations for assembling the data collection and risk identification and analysis components of the Sentinel Network

Next Steps

- The public docket will remain open until April 5
- We will review the oral and written comments we receive
- We will develop a roadmap for assembling the Sentinel Network