

The Sentinel Network

May 9, 2007

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Basic Premise

- 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
- Leveraging health information technology tools can facilitate the acquisition, analysis and communication of new risk information

Premarket/Postmarket Balance

- 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

Premarket/Postmarket Balance

- 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

Current FDA Postmarket Tools

- Passive surveillance tools
- Mandatory reporting by manufacturers and user facilities; standardized forms
- MedWatch
 - Targets all FDA-regulated products
 - Drugs (Rx and OTC)
 - Biologics
 - Medical devices
 - Nutritional products (dietary supplements, infant formula)
- Contracts for use of databases

Current Surveillance Tools - Devices

- MedSun
 - Network of 350 hospitals
 - Share safety “signals” and provide real-time data
 - HeartNet, KidNet
- Vaccine Safety Datalink
- Drugs: Postmarket commitments
- Devices: COA studies, section 522 studies
- FDA disseminates safety information to providers / patients
 - Through labeling changes
 - Through targeted or general safety alerts

The Problem

- Typical postmarket surveillance efforts have been limited by:
 - 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
- Current efforts are frequently crisis-driven rather than prevention-driven
- No systems approach

A Proposed Solution

- The private sector has taken steps that can facilitate our surveillance activities:
 - Developing new information technology tools
 - Creating the infrastructure and 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" – an integrated, electronic Nationwide medical product safety network

Sentinel Network

- Would allow timely electronic flow of medical product safety information from electronic databases and surveillance systems, through risk identification and analysis processes, to healthcare practitioners and patients at the point-of-care while protecting patient privacy
- Would be assembled through public-private collaborations and build on existing efforts
- Would use national and international standards adopted by AHIC

Components of the Sentinel Network

- Data Collection
 - Integrate clinical practice and postmarket safety surveillance
 - Use multiple data sources, e.g., EHRs, lab data, radiological studies, pharmacy records
- Risk Identification and Analysis
 - Develop and validate data mining tools
 - Reach agreement on methodologies
 - Establish integrated research networks
- Risk Communication
 - Leverage healthcare practitioner community's expertise
 - Integrate new risk information into the workflow of clinical practice (e.g., decision support systems)

Sentinel Network Public Meeting

- Federal Register Notice January 2007
- Held on March 7-8, 2007
- 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

Sentinel Network Public Meeting

- Public comments received by April 5
- FDA, along with other agencies, is in the process of writing a white paper that lays out a preliminary roadmap for assembling the Sentinel Network

Prioritized List of Functions

- Rapidly identify known or suspected risks
- Quickly test hypotheses and confirm signals
- Determine whether therapeutic products are appropriately used
- Identify unsuspected risks

Fundamental Principles

- Scientific Credibility
- Independence
- Inclusive Governance
- Transparency
- Privacy Protection and Data Security
- Standards
- Iterative
- Agility

Opportunities

- Enhanced Adverse Event Reporting
 - National standards for reporting AEs
 - Automatic population of reports from EHRs
 - Triggers
 - Real-time queries
 - User-friendly interface for reporting

Opportunities

- Active Surveillance
 - Active surveillance models
 - Bioinformatics infrastructure
 - Data sources
 - Personal Health Records
 - Data mining software development and validation
 - Target events
 - Unique device identifiers
 - Remote monitoring

Opportunities

- Streamlining Confirmatory Studies
 - Economies-of-scale from large standardized datasets
 - Registries
 - Enhanced epidemiologic study capability
 - Safety biomarkers
 - Workforce

Opportunities

- Providing Incentives
 - Business models
 - Shared priorities
 - Encourage healthcare practitioner participation
 - Timely feedback
 - Sense of community
 - Reimbursement
 - Information and expertise
 - Regulatory flexibility