ENGELBERG CENTER for Health Care Reform at BROOKINGS

June 2010

MEETING SUMMARY

BROOKINGS ACTIVE SURVEILLANCE IMPLEMENTATION COUNCIL MEETING #1

Since the Sentinel Initiative was launched in May 2008, the U.S. Food and Drug Administration (FDA) has actively worked to develop and implement the Sentinel System in a transparent and collaborative manner. To ensure engagement from a broad range of experts and stakeholders, FDA awarded a cooperative agreement to the Engelberg Center for Health Care Reform at Brookings to convene a series of expert workshops, public workshops, roundtable webinars, and Brookings Active Surveillance Implementation Council (BASIC) meetings. BASIC is a small group of senior leaders in government and the private sector convened twice a year to discuss ongoing development of the Sentinel System and related activities.

The first BASIC meeting was held on June 2, 2010 and had two primary objectives: 1) explore how ongoing medical product safety surveillance pilot activities complement one another and related initiatives in health information technology, comparative effectiveness research (CER), and quality measurement; and 2) discuss potential organizational models for the Sentinel System. This document highlights major topics discussed during the meeting.

Pilot Projects and Initiatives

Presenters provided updates on a number of pilot projects and initiatives relevant to the Sentinel System:

- Mini-Sentinel is developing an operational coordinating center to query a distributed system for conducting active medical product surveillance. Currently housed at Harvard Pilgrim Health Care Institute, the coordinating center can serve as a model for other future coordinating centers in the Sentinel System.
- The Federal Partners initiative – a collaboration between FDA, the Centers for Medicare & Medicaid Services, and the U.S. Department of Veterans Affairs – does not utilize a common data model or a distributed system. This initiative is exploring whether developing and using a shared protocol will yield results that could be aggregated for analysis and interpretation.
- The Observational Medical Outcomes Partnership (OMOP) is a public-private partnership that researches, develops, and empirically evaluates methods for analyzing existing health care databases to evaluate the safety and benefit of drugs already on the market.
- Exploring and Understanding-Adverse Drug Reactions (EU-ADR) focuses on developing methods and validating health outcomes of interest. Eventually, data models between the United States and the EU-ADR may be harmonized to allow data sharing.
- The Vaccine Safety Datalink (VSD) has successfully used a distributed network to conduct near real-time vaccine surveillance on a weekly basis, and may serve as a model to Sentinel for developing an operational coordinating center and using a distributed network.
- The Agency for Healthcare Research and Quality is currently conducting a number of initiatives that may help to inform Sentinel's development.

Committee members suggested that these models and pilot initiatives should aim to share lessons learned, maximize synergies, and minimize overlap.

Distinguishing Between Use of the Sentinel System for Public Health versus Research
Currently, the Office of Human Research Protection considers work performed under the purview of FDA's Sentinel Initiative to be exempt from common rule requirements, such as investigational review board approval. FDA anticipates that in the future, Sentinel infrastructure will be used for other purposes, such as CER and quality measurement. It is unclear whether these activities will also be exempt from the common rule requirement.

Communicating Safety Surveillance Findings
Council members discussed ways to communicate results of active surveillance queries to patients and physicians, most of whom have only limited epidemiology knowledge or training. Members proposed that Sentinel communications should emphasize both risks and benefits of the product. Some also suggested engaging patient groups to determine the most effective ways to communicate information to patients in an easily understandable format.

Timing in communicating results poses a potential liability to Sentinel's data partners. FDA must balance the goals of ensuring timely communications with ensuring validity and accuracy of results – an inability to fulfill either may pose a risk to public health. Council members noted that a lack of clarity between identification of a potential signal and dissemination of results may pose a liability risk to data partners who must balance their duty to warn beneficiaries of safety concerns with accurately verifying the results. Data partners look to FDA to provide clarity on when the Agency will communicate findings.

Governance
Attendees discussed case studies of successful and unsuccessful public-private partnerships and complex alliances. It was noted by the presenters that successful partnerships start with modest objectives and expanded their scope as they achieved milestones. It was also noted that many failures were due to overambitious goals, lack of upfront agreement on partner contributions, governance issues, and underestimating technical development requirements.

Based on these case studies, participants discussed the challenges (e.g., liability issues, potential revenue losses for organizations that currently sell data), but also the importance of involving non-government data sources versus only government-owned data sources in the development of Sentinel, especially if the goal is to eventually build upon Sentinel to create a "learning health care system" capable of more than just safety surveillance.

Moving forward, participants noted that FDA will have to consider how private-sector data and analytic partners will benefit from being part of the System, particularly in light of the data holders' concerns about liability. Participants suggested that FDA could encourage private-sector participation by clarifying what constitutes public health activities and organizing the Sentinel System's infrastructure and governance in a way that minimizes data partner susceptibility to liability issues. Lastly, it was suggested that FDA should engage large employers and patient representatives in the Sentinel System's governance and decision-making.