ENGELBERG CENTER for Health Care Reform at BROOKINGS

January 2011

MEETING SUMMARY

# Sentinel Initiative Public Workshop

## Update on Mini-Sentinel's Accomplishments

In year one of the Mini-Sentinel pilot, collaborators accomplished a number of tasks leading to the creation of an active surveillance system that will bolster the U.S. Food and Drug Administration's (FDA) current post-market safety capabilities. The Mini-Sentinel Operations Center (MSOC) at the Harvard Pilgrim Health Care Institute formed partnerships with different data and analytic partners to create a distributed data system. The MSOC then developed a coordinating center to manage the activities of data and analytic partners and, through an iterative process, formed guiding principles for participating in the pilot and a common data model to ensure standardization of data format at all participating sites. Collaborators participated in development and evaluation of epidemiological and statistical methods for signal refinement. Although use of a distributed system alleviates many data privacy issues because person-level data generally do not leave their existing, secure data environment, Mini-Sentinel developed a policy that minimizes the amount of person-level data that is shared with the coordinating center and follows HIPAA's "minimum necessary" standard.

## Plans for Mini-Sentinel in Year Two

FDA and the Mini-Sentinel team will begin conducting active surveillance evaluations in the second year of the Mini-Sentinel pilot. The first planned evaluation monitors occurrence of acute myocardial infarction in patients taking oral hypoglycemic agents. A concurrent Phase IV randomized controlled trial being conducted with some of the drugs of interest will allow comparison of Mini-Sentinel results to findings from the trial. The planned evaluation will inform the methods and conduct of future Sentinel evaluations. Beyond conducting surveillance evaluations, the Mini-Sentinel team is focused on expanding the common data model to incorporate selected clinical data, such as vital signs and lab results from electronic health records and other sources. Mini-Sentinel is working to develop a secure and efficient mechanism for the data partners to conduct regular updates of the Mini-Sentinel Distributed Database.

## Stakeholder Expectations for the Sentinel Initiative

***Patient advocates*** indicated that to maintain transparency and trust, FDA communications should convey information clearly, without causing unnecessary concern. It is important for patients and consumers to understand that knowledge of the drug safety profile is accumulated through a continual process. With assistance from health professionals and advocacy organizations, patients and consumers can understand the role of Sentinel's findings in the larger process that FDA undergoes to interpret new safety information about drug side effects.

***Health care professionals*** can facilitate patient understanding of Sentinel's findings and can promote and support informed decision-making.

***Health plans*** are willing to participate in Sentinel-related activities; however, they want to ensure that findings will be used to improve patient outcomes.

***Medical product manufacturers*** would like advance notification of when and how FDA will communicate data to the public so that they are prepared to respond appropriately to patients and health care professionals about the use of their products. They are interested in being able to collaborate with Mini-Sentinel investigators as they hold valuable information about their products. Lastly, manufacturers would like the system to be created in a way that it could be leveraged for continued evaluation of their products in post-market settings.

**The Future for Sentinel and Other Secondary Uses of Data**

Continued open collaboration between public and private stakeholders is an overarching priority of the Sentinel Initiative. Public-private collaboration is essential for the development of the Sentinel System and the development of a broader infrastructure for evidence development activities. The opportunity exists to expand upon the Sentinel System's infrastructure to conduct other types of evidence development such as medical product safety research, biomedical research, quality of care, and comparative effectiveness research. Garnering meaningful and collaborative participation from data and analytic partners is pivotal to the success of such an expansion.

Experts noted that although data and analytic partners are receiving increasing numbers of data evaluation requests, their participation is limited by resource constraints. There is opportunity for federal agencies to minimize burden to data and analytic partners by coordinating and prioritizing data requests and working together to establish common data formatting requirements. Establishing a governance structure that incentivizes participation could also encourage collaboration by data and analytic partners. Sentinel's procedures for managing participation in the system could serve as a model for other types of evidence development.