ENGELBERG CENTER for Health Care Reform at BROOKINGS

November 2010

MEETING SUMMARY

Brookings Active Surveillance Implementation Council

In cooperation with the U.S. Food and Drug Administration (FDA), the Engelberg Center for Health Care Reform at Brookings convened a small group of senior public and private sector leaders to discuss development of FDA's postmarket surveillance capabilities. The most recent meeting had two primary objectives: 1) discuss pilot activities of Mini-Sentinel and other distributed data systems; and 2) discuss ways to ensure meaningful collaboration with private sector data and analytic partners. This document highlights the major topics discussed during the meeting.

Updates from Pilot Projects and Related Initiatives

Presenters provided updates on a number of pilot projects and initiatives relevant to developing FDA's postmarket safety surveillance system:

- Mini-Sentinel, FDA's pilot postmarket surveillance system under development by Harvard Pilgrim Health Care Institute and collaborators, has made significant progress in its first year. This includes establishing a coordinating center, achieving access to administrative and claims data on 70 million Americans, developing a common data model and a distributed data system infrastructure for remote querying of the data partners, and developing a privacy policy that ensures that only the minimum necessary amount of data is shared with the coordinating center. Because Mini-Sentinel's activities are conducted in support of FDA's public health mission, institutions collaborating on those activities don't need approval from their respective IRBs or HIPAA waivers to participate. In year two, Mini-Sentinel will begin conducting active surveillance evaluations to monitor the occurrence of acute myocardial infarction in patients taking oral hypoglycemic agents as well as to monitor the safety of two vaccines. In addition, Mini-Sentinel plans to expand their common data model to include selected clinical data, such as vital signs and lab results, from electronic health records.
- The Agency for Healthcare Research and Quality (AHRQ) has focused on building the infrastructure to conduct comparative effectiveness research through multiple distributed data networks and patient registries. Many of these projects were recently funded and are in the early stages of implementation.
- The U.S. Department of Health and Human Services' (HHS) Office of the Assistant Secretary for Planning and Evaluation and Centers for Medicare & Medicaid Services has awarded a contract to develop a multi-payer claims database for conducting comparative effectiveness research. The database will employ a hybrid architecture with both a central repository of de-identified data and a distributed network.
- The National Institutes of Health – HMO Research Network (NIH-HMORN) Collaboratory will utilize HMORN's scientific, data and operational infrastructure as a tool for biomedical research. Several institutes in the NIH, including the National Cancer Institute, the National Institute of Mental Health, and the National Heart, Lung and Blood Institute as well as other government agencies such as AHRQ, will collaborate with HMORN to conduct epidemiology studies, clinical trials, and health services research.
- European Medicines Agency's PROTECT project is a public-private partnership that aims to strengthen the monitoring of benefits and risks of medications in Europe. Through the use of datasets, including spontaneous reports, registries, and other electronic databases, they are in the process of developing and validating innovative tools and methods to achieve this goal.

- Observational Medical Outcomes Partnership (OMOP) is a public-private partnership that quantitatively evaluates methods for postmarket safety surveillance. Methods are assessed based on the ability to detect known associations between exposures and outcomes ("true positives" and negative controls) in a range of databases, both in centrally-held databases and within a distributed system of data partners. Moving forward, OMOP hopes to elucidate specific operating characteristics that affect method performance.

Participants agreed that each of these initiatives can be informative to the others, as all attempt to solve common challenges such as data partner participation, system infrastructure, data quality, analytic methods, privacy protection, and security.

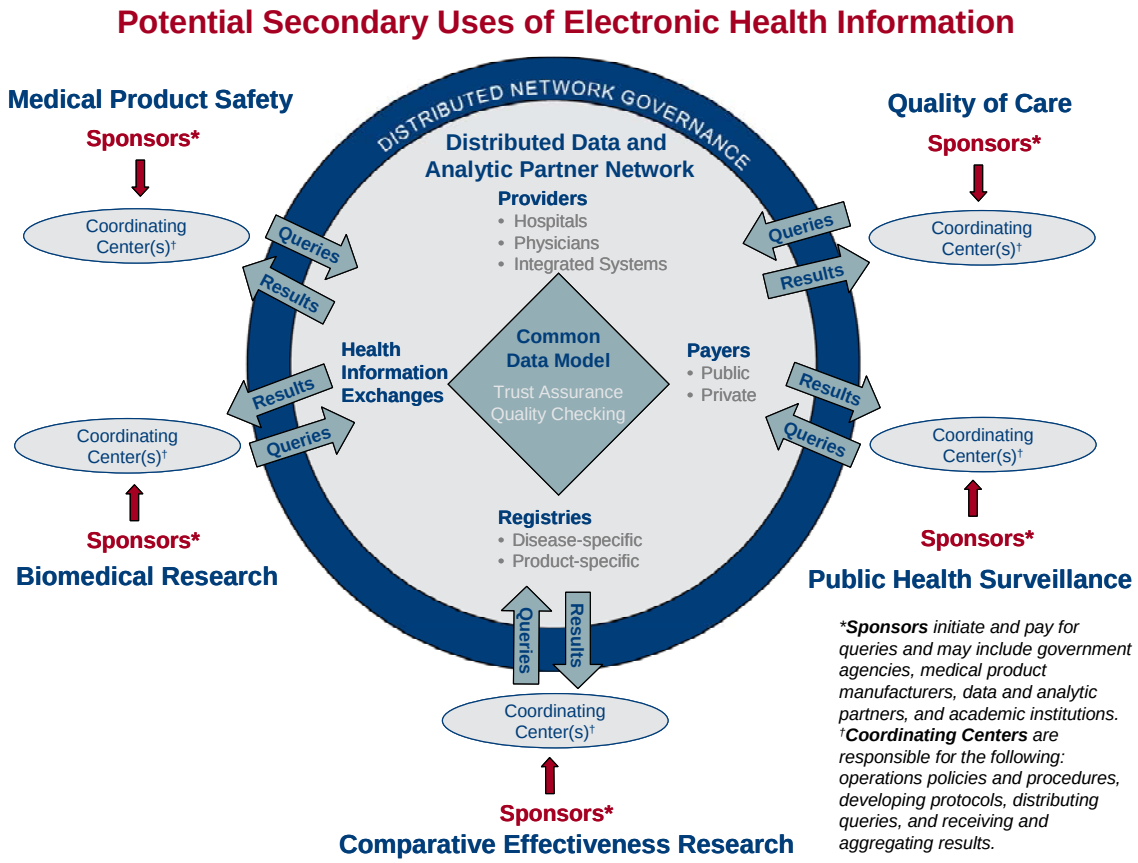
Ensuring Meaningful Participation of Data and Analytic Partners in Sentinel

Janet Woodcock, director of FDA's Center for Drug Evaluation and Research (CDER) and Senior Executive Sponsor of FDA's Sentinel Initiative, stressed the importance of developing and maintaining meaningful collaborations with private sector data and analytic partners. FDA's Sentinel Initiative is developing in parallel with many other efforts to provide better evidence for medical decision making. As a result, there will be more frequent requests of private sector data and analytic partners (D&AP), such as health plans, hospitals, and integrated delivery systems, to evaluate their data. Creating a sustainable business model for D&APs to participate in these efforts is essential for ensuring the viability of a national infrastructure for evidence development.

Key elements for creating a sustainable business model for a distributed database system like Mini-Sentinel include:

- establishing an effective public-private partnership to govern the activities of the system;
- building capacity to link and analyze different data sources while protecting patient privacy; and
- ensuring that all stakeholders have appropriate roles in each of these activities.

The diagram below illustrates a potential framework for a national distributed data system that supports secondary uses of electronic health care data, and cultivates strong relationships between various participants and users of the system.



One strength of the distributed data system is that it allows D&APs to maintain physical and operational control of their patient-level data, sending only aggregated information to the coordinating center. However, a distributed system also requires responsiveness, maintenance, and analytic capacity on the parts of D&APs. A sustainable business model and governance structure must recognize and address these needs. Dr. Woodcock urged coordination among different secondary use initiatives to promote greater participation among vital D&APs in Mini-Sentinel and other initiatives for evidence development.

Data and Analytic Partner Considerations for Participating in Sentinel

Partners in Postmarket Surveillance

D&APs indicated that they are interested in participating in Mini-Sentinel's active surveillance activities because it benefits public health. Furthermore, participation in such activities offers D&APs an opportunity to improve their data, methods, and analytic capacity. However, they stressed the importance of true collaboration in the active surveillance process rather than being viewed merely as data providers. D&APs are most familiar with the content, quality, and contextual factors affecting their data, so leveraging their expertise as collaborators in the active surveillance process can be crucial for appropriate implementation and interpretation of results.

Liability and Communication Concerns

D&APs would utilize the results from safety surveillance queries to minimize risks to their members. Some indicated they would consider doing so even before official FDA action, since awareness of substantiated safety issues might raise liability concerns stemming from the duty to warn. Other potential D&APs fear that liability concerns could pre-empt their participation. Further legal analysis of the risks to D&APs of participation in FDA-sponsored safety surveillance activities is needed.

In general, these organizations support timely and effective communication of surveillance findings to health professionals and patients. Ensuring that plans are aware of FDA's communication strategy may also help assuage plan liability concerns. Both plans and manufacturers stated that they would like some amount of advance notice before FDA's public announcements, allowing them to create a plan to handle provider and patient concerns.

Coordinating Requests to Data Partners
D&APs described the multitude of requests they receive for evaluation of their patient-level data, noting that each may require different data formats, making the process of evaluating data inefficient and burdensome. Committing resources to public health efforts is a priority, but can be difficult to justify in the face of competing priorities brought about by health care reform. D&APs stressed the importance of coordinating requests from federal agencies, minimizing overlap, and encouraging the creation of standardized measures and processes for evaluating data.

Reliable and Sustainable Funding
Longer term, D&APs need a sustainable business model with a reliable funding stream that can dedicate the needed resources to support active surveillance and other work that stems from secondary use of data. They encouraged participants to think about innovative ways to provide additional financial support to D&APs to incentivize participation.

Governance Structure to Encourage Participation
Multiple parties, including non-participating institutions, will benefit from Sentinel's findings. While everyone – patients, health care professionals and participating and non-participating D&APs – ultimately benefits when health outcomes improve, D&APs expressed concern about the "free rider" problem. Governance of the D&AP system is also critical. They suggested setting clear guidelines delineating who can use data, what level of access participating and nonparticipating institutions receive, and benefits limited to D&AP participants.

Beyond Safety Surveillance

Meeting attendees offered a number of other compelling uses for the infrastructure to be created for FDA's Sentinel System, such as comparative effectiveness research and quality of care research, which interested representatives from D&APs. However, they warned that FDA should focus on its primary purpose of developing its postmarket safety surveillance capabilities. They cautioned that trying to incorporate other uses into the system before its drug safety infrastructure is fully functional may detract from FDA achieving the primary goal of the Sentinel Initiative, creating a quality active surveillance system. An established system for drug safety surveillance will bolster public and D&AP confidence in the Sentinel System infrastructure, and may help increase D&AP willingness to participate in other secondary uses of health care information as well. Coordination and prioritization among federal agencies before requests are sent to D&APs could help ensure active participation. Because cost-cutting and providing higher-quality care is a top priority for D&APs, secondary initiatives that have immediate impact through reducing cost and improving outcomes will have more appeal.