Communicating Findings from Active Medical Product Surveillance: Medical Journal Perspective

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What do journals offer medical product surveillance studies?

- Independent peer review, can increase confidence in findings
- Improvements in clarity of presentations
- Dissemination to providers and media via a familiar medium
- Mechanisms for comments, corrections, links to related information
- Archiving of reports in common databases

Difficulties journals might pose for surveillance studies?

- Restricted access to full reports
- Delays due to time needed for careful peer review and journal production processes
- Journals often request revisions, these revisions sometimes alter or temper conclusions
- Journal standards for analysis and reporting may differ from FDA standards

How to best balance?

- FDA's need for rapid but responsible communication
- Public's need for valid, reliable information
- Journals' need not to publish "old news"
- Researchers' need for traditional academic publications

Preparing Stakeholders

- Introduce clinicians and others to methods common in studies of medical surveillance and their critical appraisal
- Develop and implement reporting standards for various types of surveillance studies (EQUATOR)
- Educate stakeholders about data limitations, ad hoc queries vs. planned evaluations, non-reviewed vs. peer-reviewed reports, observational vs. experimental data

Stang et al. Annals of Internal Medicine. November 2, 2010.

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Advancing the Science for Active Surveillance: Rationale and Design for the Observational Medical Outcomes Partnership

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The U.S. Food and Drug Administration (FDA) Amendments Act of 2007 mandated that the FDA develop a system for using automated health care data to identify risks of marketed drugs and other medical products. The Observational Medical Outcomes Partnership is a public–private partnership among the FDA, academia, data owners, and the pharmaceutical industry that is responding to the need to advance the science of active medical product safety surveillance by using existing observational databases. The Observational Medical Outcomes Partnership's transparent, open innovation approach is designed to systematically and empirically study critical governance, data resource, and methodological issues and their interrelationships in establishing a viable national program of active drug safety surveillance by using observational data. This article describes the governance structure, data-access model, methods-testing approach, and technology development of this effort, as well as the work that has been initiated.

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When a new drug is approved, understanding of the product's safety profile is limited by the relatively small and narrowly defined study populations in the clinical trials required for approval. Uncommon adverse events are difficult to detect during premarket testing; therefore, developing methods to rapidly detect such events in the postmarket period is an urgent goal of the public health system. Currently, the U.S. Food and Drug Administration (FDA) relies primarily on the submission of spontaneous reports, which are often incomplete, reflect only a small percentage of actual events, and have limited use for outcomes with high background rates (1). Observational databases, containing administrative claims and electronic health records (EHRs), have frequently been used to characterize utilization patterns, track patient outcomes, and conduct formal pharmacoepidemiologic evaluation studies. However, the potential of these observational databases for active surveillance of medical products has not been substantively explored (2), except for vaccines (3). This gap in the understanding of how best to develop and apply active surveillance methods to these databases prompted the Observational Outcomes Medical Partnership (OMOP) project.

An active surveillance system involves a systematic and to validate ways to link and analyze safety data from multiple sources for medical product safety surveillance. An active surveillance system could potentially characterize known side effects, monitor preventable adverse events, and enhance the understanding of safety concerns emerging in the postmarket period by supplementing other sources of safety information (preclinical data, clinical trials, and spontaneous adverse event reporting).

The OMOP (http://omop.fnih.org), a public–private partnership among the FDA, academia, data owners, and the pharmaceutical industry and administered by the Foundation for the National Institutes of Health, was initiated to identify the needs of an active drug safety surveillance system and propose and test scientific methods and data infrastructure to address those needs. The OMOP research program consists of systematic and empirical investigations of the critical methodological and data resource issues within a specific technology architecture and governance model that is probably needed to establish a national medical product safety surveillance system. The ultimate goal of OMOP is to develop the necessary technology and methods to refine the secondary use of observational data for maximizing the benefit and minimizing

Speeding Peer Review

- Pre-submission review of study protocols for more complicated studies
- Develop special formats that allow for rapid publication of simple descriptive studies
- Develop fast track review processes
- Submit protocols, statistical code, and data to journals with manuscripts
- Adequate study staffing to enable rapid response to journal requests for revision
- Routine early e-publication

Strategies for Responsible Reporting

- Develop distinct formats for release of non-peer reviewed results, flag as preliminary
- Avoid sensational language that implies safe/unsafe, communicate safety as a balance of benefits and harms
- Clear reporting with full explication of study limitations, cautions
- Promote data sharing for confirmation of findings and systematic reviews/meta-analyses