Population Health NEWS

Adverse Event Data Promotes Population-Based Health Analyses

by Brian Overstreet

Every day it seems that new apps, monitors guides and tools are launched with the intention of streamlining patient care through the better collection of health data. While innovations such as Apple Watch and the health dashboard on mobile phones may speed the collection of personalized health data, the real value from these applications won't be fully realized until data can be aggregated from those apps and used for broad, population-based analysis. Unfortunately, it may be many years until most of these new health data sets are robust enough for the necessary types of detailed analysis that produce actionable intelligence. Fortunately, there is one promising exception for "fast-track" population-based, health data analysis and insight: the examination of adverse event data from FDA-approved drugs.

Since 1997, the FDA has collected and made publicly available case reports of serious adverse events caused by prescription drugs in its Adverse Event Reporting System (FAERS). Healthcare providers, patients and pharmaceutical companies file these reports. Of those constituents, only pharmaceutical companies are required to report them. Despite this, the growth in reporting has been exceptional, from 420,000 case reports filed in 1997 to 1.2 million in 2014.[1] Each case report includes key patient demographic and condition data, the drugs prescribed, the specific adverse event reported and patient outcomes.

From a data standpoint, FAERS contains more than seven million case reports[2] and almost 500 million unique data points. In 2013, FAERS' reports included data on 148,000 hospital admissions, 65,000 deaths and 14,000 disabilities caused by adverse drug events (ADEs).

As the Institute for Safe Medical Practices (ISMP) recently noted in a detailed report: "…Despite its limitations, FAERS is the most reliable system for discovering new drug risks that had not been identified in pre-market drug testing. Also, despite additional perspectives on safety obtained from insurance claims and electronic health records, no other system has comparable international scope, sensitivity to detect rare but catastrophic side adverse events effects and the capacity to pinpoint potential injuries that were unexpected."[3]

FAERS was big data before there was "big data." It is the most valuable repository of post-approval, drug safety data available for the U.S. population. And while reporting to FAERS continues to escalate at a significant rate, one of the most notable aspects of these data in this new age of big data is the longevity of the FAERS' data set. With patient data collected over an almost 20-year time period, detailed population-based analysis and insight are possible right now. This opens up a world of possibilities, especially for the pharmaceutical companies that develop new drugs; the providers who prescribe those drugs; and the health systems, insurers and government agencies that buy them.

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While clinical trials will always be an important part of the new medication testing and approval process, they are notably limited in scope. Being able to properly mine FAERS data provides the vitally important ability to easily benchmark the safety of new medicines against the safety profiles of established and proven, post-marketed, comparative drugs. Using FAERS to establish safety standards, the healthcare system and patients can benefit from speeding the time to market and reducing the costs of developing new drugs, while ensuring faster response to newly introduced drug safety concerns.

These same data are already being used to better inform patient care and prescription decisions. Being able to see the differential rate of specific adverse events and outcome types across an array of medicines indicated for the same disease gives healthcare providers access to analysis that previously wasn't possible. While making critical care decisions that can improve a patient's experience and reduce the possibility for a serious negative outcome is a noble and worthwhile endeavor, there also are significant economic advantages.

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A recent study that mapped adverse event and outcome rates to hospitalization costs, based on the Agency for Healthcare Research & Quality's (AHRQ) Healthcare Cost and Utilization Project, indicated that serious avoidable, adverse events are costing the healthcare system as much as $20 billion annually. While every prescription written can result in a negative adverse event, access to broad data that can accurately predict the rates of those adverse events and suggest alternative options based on a number of patient data and usage cases will make a sizable difference in that cost.

Despite all these benefits, FAERS is at a surprisingly critical juncture. ISMP's study recently highlighted a number of shortcomings in FDA's current procedures for collecting and disseminating adverse event data. In addition, a *Wall Street Journal*[4] exposé highlighted that the same pharmaceutical companies charged with collecting these data on FDA's behalf have been busy offshoring the responsibility to the lowest cost bidder overseas. While the FDA is spending modestly to maintain or moderately improve FAERS, it is dumping hundreds of millions of dollars into a yet-to-be-proven alternative system for drug safety monitoring called Sentinel.[5]

For those in the health data world, it is very frustrating that such a high value data set is being so egregiously ignored by key government agencies. Why is FAERS relegated to second-class citizenry? Part of the reason is an industry bias established against FAERS some 15 years ago that alleged that these data, because they were self-reported, were subject to reporting errors, outside bias and differential reporting. All of these "myths" have since been debunked, but unfortunately the bias still exists in some cases. In addition, the pressure from pharmaceutical companies to maintain control over their drug data remains strong, especially as stratospherically priced drugs hit the market.[6] The advantage of controlling the flow of drug safety data for years after a drug is released in the U.S. market is too lucrative for pharmaceutical companies to ignore so they continually push back against data value of FAERS and the needed improvements in reporting guidelines.

Beyond specific issues that some may have with FAERS, there is a bigger issue at play here—namely, that the second stage of big data is still in its infancy—the analysis and insight phase. While many strides have been made to improve the collection of population-based data across all fields, little has been done about this critical "next step." Based on its breadth, depth and longevity, FAERS is a unique health data set that can be positioned to not only aid patient care and health systems' costs, but also to break through the next dimension of big data and help establish a protocol for proper analysis and insight of large data sets throughout the healthcare ecosystem.

To its credit, FDA seems to understand that FAERS' value in this regard exists, but also that the agency is ill-equipped to shepherd it on its own. For those reasons, it created the OpenFDA system that provides open-sourced access to the FAERS data set and others like it. It seems inevitable that the next step in driving meaningful use from these data will fall to private enterprise and non-governmental researchers. But there is a limit that those on the outside can do when direct support from key government agencies is limited.

An easy starting point is for FDA and others within government to actively help increase reporting to FAERS from key reporters—healthcare providers and patients. The current system for reporting an adverse event is laborious and time consuming, which contributes to the low level of overall ADE adverse reporting. That leaves relying on conflicted pharmaceutical companies to self-report problems with their own drugs.

Providing incentives to increase direct reporting from front-line doctors, nurses and pharmacists would not only increase the breadth of these data, but also the quality.

Moreover, improving the interface for direct patient reporting is a critical next step to maximizing the value of FAERS in the social/mobile environment. It seems foolhardy to hinder the efforts of patients with first-hand knowledge of their ADEs from reporting those events quickly, concisely and accurately.

Despite its shortcomings, FAERS is the best—and only—big data set that can have an immediate impact on improving drug safety and patient outcomes. The analysis and insight that can be drawn today from these seasoned, broad population-based data can save the healthcare system billions of dollars and hundreds of thousands of patients from serious harm every year.

Government agencies have an opportunity—some might say an obligation—to invest to maintain and grow the FAERS system, but will they?

[1] "Reports Received and Reports Entered Into FAERS by Year." U.S. Food and Drug Administration. 2013.
[2] *Ibid*.
[3] "A Critique of a Key Drug Safety Reporting System." ISMP *QuarterWatch*. Jan. 28, 2015.
[4] McLain S. "New Outsourcing Frontier in India: Monitoring Drug Safety." *Wall Street Journal*. Feb. 1, 2015.
[5] Meyers J. "Harvard Pilgrim Awarded FDA Contract for Drug Monitoring." *The Boston Globe*. Oct. 1, 2014. .
[6] Actman J. "Sovaldi Pricing Raises Debate Over Drug Costs." MarketWatch. Oct. 1, 2014.

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