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A Message from Lilly: Project REPORT: Leveraging Health Information Technology to Improve Patient Safety

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A Message from Lilly

Project REPORT: Leveraging Health Information Technology to Improve Patient Safety

By Kraig Kinchen, MD

With the passage of the Health Information Technology for Economic and Clinical Health Act, the United States has demonstrated a commitment to speeding the adoption of electronic medical records (EMRs) by health care providers.[1] The promise of health information technology (HIT) often focuses on the use of EMRs and health information exchanges to improve the information available to health care providers for the delivery of care to individual patients. Increasingly, the health care community also is recognizing the opportunity to improve service delivery by leveraging HIT to gain population-level insights about targeted interventions.

Post-market medication safety surveillance is an important illustration of the potential utilization of HIT for population-level health care information. While extensive clinical trials prior to a medication's launch provide critical information about the benefit-risk profile of a medication, patient safety is promoted further through information gained once the medication is being used in clinical practice.

Post-market efforts to refine the understanding of the benefit-risk profile of a medication include both passive and active surveillance systems. Recently, the importance of HIT in improving active surveillance has received increased focus as the Food and Drug Administration (FDA) has moved forward with the development of the FDA Sentinel Network Initiative, an effort to utilize large health care databases to actively detect potential medication-related adverse events.[2]

Eli Lilly and Company has worked to contribute to the understanding of HIT-enabled active surveillance through involvement in multistakeholder pilot projects including the Observational Medical Outcomes Partnership[3] and the eHealth Initiative's Connecting for Drug Safety Collaboration.[4]

Complementing active surveillance efforts, the passive surveillance system relies on health care providers and others to voluntarily submit information on suspected medication-related adverse events to the FDA through paper-based or Web-based reports to the FDA's MedWatch program.[5] MedWatch reports include clinical information that helps regulators and manufacturers to evaluate the potential relationship between a marketed medication and an adverse event.[6] However, a number of factors, including perceived time limitations of busy clinicians, may hinder the ability of providers to initiate efforts to populate and submit these forms with the information that would best facilitate evaluation.

Lilly, along with a number of other stakeholders, recognizes that the passive surveillance system also has the potential to be enhanced through HIT. The digitalization of health care information through HIT may offer an opportunity to improve the quantity and quality of MedWatch reports by auto-populating important MedWatch fields with electronic information from the EMR or health information exchanges.

Project REPORT (Reporting Events and Patient Outcomes Related to Therapy) is a recent collaboration between Lilly and Dr. Atif Zafar's team from the Regenstrief Institute and the Indiana University (IU) School of Medicine. For this pilot project, Dr. Zafar's team created a Web-based MedWatch form that could be populated with data from

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the Indiana Health Information Exchange (IHIE). After being made aware of the new system, providers at IU primary care clinics had the ability to prepare MedWatch forms that included imported IHIE data on comorbid conditions, concomitant medications, and relevant lab values. Subsequent to including a brief narrative on the potential adverse event and some additional information, the provider could review the form and have it sent to the FDA through Project REPORT. Reflecting on the Project Report pilot project, Dr. Zafar stated, "The REPORT system provides a mechanism for providers to quickly report important adverse drug events that would otherwise go unreported due to the time burdens associated with the reporting process." His team is in the process of improving the system as well as looking for opportunities for partnerships that would extend the system to other health care providers that participate in IHIE.

What is learned from Project REPORT will contribute to the growing body of information that can be gained from other efforts to leverage HIT to enhance the passive surveillance system. The ASTER (ADE Spontaneous Triggered Event Reporting) Project, a collaboration between Partners Healthcare, Pfizer, and others, represents a significant effort to enable clinicians to auto-populate MedWatch fields using EMR data.[7]

Lilly hopes that such initiatives will stimulate further multistakeholder, collaborative efforts to improve adverse event reporting. The timely evaluation of data can promote a more thorough understanding of a medication's benefit-risk profile and enable clinicians to enhance patient safety at the point of care.

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