*IGI PUBLISHING* **ITJ3766**

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This paper appears in the publication, **International Journal of Healthcare Information Systems and Informatics**, Volume 2, Issue 3 edited by **J. Tan © 2007, IGI Global**

# An Information Technology Architecture for Drug Effectiveness Reporting and Post-Marketing Surveillance

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## ABSTRACT

*Adverse drug events impose a large cost on the society in terms of lives and health care costs. In this article, we propose an information technology architecture for enabling the monitoring of adverse drug events in an outpatient setting as a part of the post marketing surveillance program. The proposed system architecture enables the development of a Web-based drug effectiveness reporting and monitoring system that builds on previous studies demonstrating the feasibility of a system in which community pharmacists identify and report adverse drug events. We define the key technical requirements of such a monitoring and reporting system, identify the critical factors that influence the successful implementation and use of the system, and propose information technology solutions that satisfy these requirements.*

*Keywords:* *adverse event reporting; community pharmacy safety network; postmarketing surveillance*

## INTRODUCTION

Adverse drug reactions have been estimated to result in more than 2.1 million injuries and 100,000 deaths each year in the U.S. alone (Lazarou, Pomeranz, & Corey, 1998). The annual economic cost of adverse drug events is estimated to be more than $75 billion (Johnson & Bootman, 1995). Mitigating the impact of adverse drug events requires the implementation of a comprehensive mechanism for monitoring and detecting adverse drug events. Such a mechanism can save lives and reduce health care costs.

Reliable detection adverse drug events is a difficult problem. Although some adverse drug reactions are detected early on during clinical trials, serious adverse drug effects can still go undetected during this phase due to the practical

limitations associated with the size and duration of the clinical trials. Recent examples of such cases include Rofecoxib and Cerivastatin (Fontanarosa, Rennie, & DeAngelis, 2004). The FDA monitors for adverse drug events in the post-marketing phase through the MedWatch program (www.fda.gov/MedWatch/report.htm). The MedWatch program, which is mainly a voluntary reporting program, suffers from several limitations, the most critical of which are the under-reporting of adverse events and the lack of a denominator reflecting magnitude of exposure.

In a 1996 article titled "The Clinical Impact of Adverse Event Reporting," the FDA estimated that only 1% of the adverse drug events are reported through the MedWatch program (Food and Drug Administration [FDA], 1996, p. 5). An alternative mechanism for detection of adverse drug events is the use of longitudinal medical records and hospitalization records. However, the availability of data from such records has been limited and obtaining longitudinal medical records is an expensive and time-consuming process. In addition, the extraction of meaningful conclusions from such data is difficult due to data integrity, heterogeneity, and missing data problems.

Several information technology-based solutions have been suggested to help monitor and reduce the adverse drug event problem. Most of the proposed solutions and studies conducted have been limited to inpatient hospital settings. Although a major part of drug dispensing and medications takes place in an outpatient setting, there is limited literature on the detection of adverse drug events in an outpatient setting. In this article, our focus is on methods for the detection of adverse drug events in an outpatient setting and in the post marketing phase using a Web-based reporting system. Specifically, our focus is developing the IT architecture for enabling a large-scale data collection mechanism to support the detection and quantification of previously unrecognized side effects and drug interactions for drugs, especially those newly introduced into the market. We propose an IT architecture for enabling a Web-based reporting and surveillance solution called the Drug Effectiveness Reporting and Monitoring System (DERMS). The DERMS system is based on a community pharmacy-based safety network and proposes the participation of community pharmacies for the collection of clinical response and adverse drug event information from patients. We describe the information technology architecture that forms the supporting infrastructure for the surveillance system and discuss the requirements and success factors necessary for successful implementation of the system.

This article is structured as follows. In the second section, we describe the post marketing effectiveness and safety surveillance program and discuss the limitations of the system in its current form. In the third section, we review previous literature discussing technological solutions to the adverse event detection problem. We briefly describe the Drug Effectiveness Reporting and Monitoring System and propose the enabling IT architecture in the fourth section, and discuss the success factors for its implementation in the fifth section. We discuss the limitations of the system in the sixth section, and make concluding observations in the seventh section.

## POST-MARKETING SURVEILLANCE

An effective surveillance process that follows the introduction of a new drug into the market requires the efficient flow of information among the different affected entities including patients, drug companies, the FDA, and healthcare professionals such as doctors, nurses and pharmacists. This should include information on drug usage, patient exposure, interactions, adverse effects, and treatment outcomes. At present, the primary mechanism of disseminating information from the drug companies and FDA are through sales representatives, visiting lecture series, press releases. At present, the primary mechanism of disseminating information from the drug companies and FDA are through press releases, information services, and pharmacy databases that enable timely dissemination of information on drug interactions and labeling information.