

Project Title: Electronic Support for Public Health – Vaccine Adverse Event Reporting System (ESP: VAERS)

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Organization: Harvard Pilgrim Health Care, Inc.

Mechanism: RFA: HS07-002: Ambulatory Safety and Quality Program: Enabling Quality Measurement through Health IT (EQM)

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Project Period: 12/07 – 09/09

AHRQ Funding: \$999,995

Summary Status as of: December 2008

Strategic Goal: Develop and disseminate health IT evidence and evidence-based tools to improve health care decisionmaking through the use of integrated data and knowledge management.

Business Goal: Knowledge Creation

Summary: This project was initiated in December 2007 and has completed the first half of the grant period. The goal of this project is to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS). This project is serving as an extension of the Electronic Support for Public Health (ESP) project, an automated system using electronic health record (EHR) data to detect and securely report cases of certain diseases to a local public health authority. ESP provides a ready-made platform for automatically converting clinical, laboratory, prescription, and demographic data from almost any EHR system into database tables on a completely independent server, physically located and secured by the same logical and physical security as the EHR data itself. The ESP: VAERS project is specifically developing criteria and algorithms to identify important adverse events related to vaccinations in ambulatory care EHR data, and formatting and securely sending electronic VAERS reports directly to the Centers for Disease Control and Prevention (CDC).

Patient data are available from Epic System’s Certification Commission for Healthcare Information Technology (CCHIT) certified EpicCare Spring 2008 system at all ambulatory care encounters within Atrius Health, a large multispecialty group practice with over 35 facilities. Every patient receiving a vaccine is automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions are evaluated for values suggestive of an adverse vaccine event. When a possible adverse event is detected, it is recorded, and the appropriate clinician is notified electronically. Clinicians will be able to preview a pre-populated report with information from the EHR about the patient, including vaccine type, lot number, and possible adverse effect, to inform their clinical judgment regarding whether the clinician wishes to send a report to VAERS. Clinicians have the option of adding free-text comments to pre-populated VAERS reports or to document their decision not to send a report. The CDC’s Public Health Information Network Messaging System (PHIN-MS) software has been installed within the facilities so that the approved reports are securely transferred to VAERS as electronic messages in an interoperable health data exchange format using Health Level 7 (HL7).

The project will evaluate the system by comparing adverse event findings to those in the Vaccine Safety Datalink project—which is a collaborative effort between CDC’s Immunization Safety Office and eight large managed care organizations—and in a randomized trial. The trial will test the hypothesis that the combination of secure, computer-assisted, clinician-approved, adverse event detection and automated electronic reporting will substantially increase the number, completeness, validity, and timeliness of physician-approved case reports to VAERS compared to the existing spontaneous reporting system.

Specific Aims

- Identify required data elements, and develop systems to monitor ambulatory care EHRs for adverse events following vaccine administration. **(Achieved)**
- Prepare and securely submit clinician-approved, electronic reports to the national VAERS. **(Ongoing)**
- Comprehensively evaluate ESP: VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data. **(Upcoming)**
- Distribute documentation and application software developed and refined in the first two aims listed above that are portable to other ambulatory care settings and to other EMR systems. **(Achieved)**

2008 Activities: Dr. Lazarus and his team identified the required data elements and developed systems to monitor ambulatory care electronic health records for adverse events following vaccine administration. A draft document was prepared describing the required data elements, algorithms, interval of interest after vaccination, and actions for broad classes of post-vaccination events. These events include those to be reported immediately without delay (such as acute anaphylactic reaction following vaccination), those never to be reported (such as routine check-ups following vaccination), and those to be reported at the discretion, and with additional information, from the attending physician through a feedback mechanism. The draft document was then widely circulated for comment by relevant staff in the CDC and among the clinical staff at Atrius Health. Feedback received was incorporated, and the document was finalized. The ESP: VAERS case management Web site is currently under construction and will be completed once the more fundamental code is tested and stable. The existing Web site at <http://esphealth.org> will serve as the prototype as planned. In collaboration with the CDC and Constella, the initial HL7 specifications describing the elements for an electronic message to be submitted have been reviewed and approved. Sample test data have been supplied, and the project has begun the design and testing of the computer software needed to generate the messages and installation of PHIN-MS for testing.

Preliminary Impact and Findings: Currently there has been no data collection that would inform preliminary findings at this time.

Selected Outputs

An ESP: VAERS introductory poster was presented at the CDC Vaccine Safety Datalink (VSD) Annual Meeting in Atlanta, GA, in April 2008. A similar presentation was given during the CDC Public Health Informatics Network (PHIN) Conference in August 2008.

Grantee's Most Recent Self-Reported Quarterly Status: Progress in meeting many milestones is stalled. The project is meeting about 30 to 65 percent of its milestones; there is a plan for achieving some milestones but not others. The project team is still grappling with systemic programming delays that were encountered toward the end of the last reporting period (September 2008), due in large part to loss of a few key senior programming staff. These delays have influenced reaching milestones in a timely manner. However, staffing is now back to optimal levels, and the team expects activity to resume once new hires have been adequately brought up to speed with current operating systems and project development thus far. As a result of the delays in installing the PHIN-MS software, the project is somewhat under spent on its budget by 5 to 20 percent. Full use of the budget is anticipated given the increase in project activities during late 2008. The team hired a new programmer early in 2009, and this will help move the programming tasks forward and is covered by the existing budget.

Milestones: Progress in meeting many milestones is stalled.

Budget: Somewhat under spent, approximately 5 to 20 percent.