

Electronic Support for Public Health–Vaccine Adverse Event Reporting System

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Organization:	Harvard Pilgrim Health Care, Inc.
Mechanism:	RFA: HS07-002: Ambulatory Safety and Quality Program: Enabling Quality Measurement through Health Information Technology (EQM)
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Project Period:	December 2007 – September 2010, Including No-Cost Extension
AHRQ Funding Amount:	\$999,995
Summary Status as of:	September 2010, Completion of Grant

Target Population: General

Summary: Public and professional confidence in vaccination depends on reliable postmarketing surveillance systems to ensure that rare and unexpected adverse effects are rapidly identified. The goal of this project was 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 served as an extension of the Electronic Support for Public Health (ESP) project, an automated system using electronic medical record (EMR) data to detect and securely report cases of statutory notifiable 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 EMR system into database tables on a completely independent server. The ESP:VAERS project specifically developed criteria and algorithms to identify important adverse events related to vaccinations in ambulatory care EMR data, and format and securely send electronic VAERS reports directly to the Centers for Disease Control and Prevention (CDC).

Patient data are available from Epic System's Certification Commission for Health Information Technology-certified EpicCare EMR 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 are able to preview a pre-populated report with information from the EMR about the patient, including vaccine type, lot number, and possible adverse effect, to inform their clinical judgment regarding whether they wish 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).

Specific Aims:

- Identify required data elements, and develop systems to monitor ambulatory care EMRs for adverse events following vaccine administration. **(Achieved)**

- Prepare and securely submit clinician-approved electronic reports to the national VAERS. **(Achieved)**
- Comprehensively evaluate ESP:VAERS performance in a randomized trial and in comparison to existing VAERS and Vaccine Safety Datalink data. **(Not Achieved)**
- 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)**

2010 Activities: During this no-cost extension year, the majority of effort was to build on the work completed in the first year, in which criteria were developed consultatively to implement, validate, and test adverse event definitions identifying case histories that might be suggestive of an adverse effect following vaccination. The grant team has a functioning adverse event detection system capable of being expanded and modified to deal with a wide range of conditions. Testing and initial validation are complete. Additional validation was planned as part of dissemination to other sites.

Functioning source code is now available to share under an approved open source license. Dr. Lazarus has added the ESP:VAERS code, HL7, and other specifications and documentation to the existing ESP Web documentation and distribution resource center <http://esphealth.org>. The existing Web site served as the prototype as planned. The ESP:VAERS case-management Web site has been completed.

Software and identification keys were obtained from the CDC in order to complete PHIN-MS installation on a test server for testing, and secure message transport to the target server has been successfully tested.

The HL7 specification describing the elements for an electronic message to the consultants engaged by CDC for this project has been implemented. Synthetic and real test data have been generated and successfully transmitted between Harvard Pilgrim Health Care and the consultant group.

The team had planned to evaluate the system by comparing their adverse event findings to those in the Vaccine Safety Datalink project—a collaborative effort between CDC’s Immunization Safety Office and eight large managed care organizations. Through a randomized trial, the team had also planned to 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. However, due to restructuring at CDC and consequent delays in terms of decisionmaking, it was ultimately not possible to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial, or to compare ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data, as was described in the third aim. However, the infrastructure is available and Dr. Lazarus is hopeful that the project may generate additional interest to complete this study.

A critical part of many public health functions is to be able to send information back to physicians in a way that is quick and cost effective. The team was able to successfully develop a system which sent a message to physicians in a way that was integrated into the EMR as part of their regular work routine, and that they did not find intrusive.

Grantee’s Most Recent Self-Reported Quarterly Status (as of September 2010): The randomized trial was not achieved, as described above. However, all other aims and milestones were successfully achieved. Budget spending was on target.

Impact and Findings: It is possible to automatically detect adverse events in defined ways, and to electronically report them to CDC’s VAERS. Decision support functions can be repurposed such that

instead of detecting reportable diseases, they can detect events that are related to vaccination, as potential vaccine adverse events.

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