

Project Title:	Pharmaceutical Safety Tracking (PhaST): Managing Medications for Patient Safety
Principal Investigator:	Gardner, William, Ph.D.
Organization:	Children's Research Institute
Mechanism:	RFA: HS07-006: Ambulatory Safety and Quality Program: Improving Quality through Clinician Use of Health IT (IQHIT)
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Project Period:	09/07 – 08/10
AHRQ Funding Amount:	\$1,156,142
Summary Status as of:	December 2008

Strategic Goal: Develop and disseminate health IT evidence and evidence-based tools to improve the quality and safety of medication management via the integration and utilization of medication management systems and technologies.

Business Goal: Implementation and Use

Summary: This project was initiated in September 2007 and has completed the first third of the grant period. Pharmaceutical Safety Tracking (PhaST) is a health information system that assists clinicians' management of medications in ambulatory settings. PhaST seeks to protect outpatients taking drugs that have recognized side effect risks even when those drugs are correctly prescribed. PhaST is an automated system for monitoring of medication adherence, side effects, and patient symptoms. PhaST uses research-based assessment procedures administered using interactive voice response (IVR) telephony. When a patient reports a problem with a medication on an IVR call, PhaST alerts a psychiatric social worker trained to triage the problem, to counsel the patient or family, and, when necessary, to contact the patient's prescribing clinician or the hospital emergency services. The goal of PhaST is not to replace clinician visits with telephone calls, but rather to improve safety monitoring and remediate access problems by augmenting channels already available for families to contact clinicians. PhaST is integrated with the mental health system's electronic medical record (EMR) and computerized physician order-entry (CPOE) system, enabling clinicians to have near real-time information on the patient's experience with the medication.

The target medication for this project is the pediatric use of antidepressants. To compare PhaST and usual care, the project is conducting a randomized trial in a large urban specialty mental health system serving a primarily Medicaid population. The project seeks to enroll 800 youths receiving new prescriptions for anti-depressants and is assessing the patients for adverse events during home visits at baseline and 1, 2, and 3 months. The project will compare chart-documented adverse events against adverse events as determined by an examiner blind to the patient's randomization and predicts higher agreement between chart-documented adverse events and examiner-determined adverse events in the PhaST condition. The project is also comparing PhaST and usual care on measures of patient and provider satisfaction, patient outcomes, and measures of the quality of medication management such as rates of patient medication non-adherence.

Specific Aims

- Determine if PhaST is superior to usual care on measures of system process. **(Ongoing)**
- Determine if PhaST is superior to usual care on measures of patient and provider outcomes. **(Ongoing)**

2008 Activities: The project is off to a great start in regards to data collection but needs to increase the rate of recruitment and is therefore expanding recruitment efforts to include the Nationwide Children's Hospital Adolescent Medicine clinic. Rather than conducting an additional pilot study, the project has been incrementally testing the new version of the software as it is rolled out. Teleform documents have been created to record all study data, along with structured query language (SQL) server database tables to receive these data. A policy manual for PhaST triage psychiatric social workers has been created and is online in the form of a wiki. While the manual is complete, it is being continuously updated based on experience with the system. The Institutional Review Board (IRB) would not permit the use of Medication Event Monitoring System (MEMS) caps to collect medication adherence data, as an alternative, self-reports of medication adherence are being used.

Preliminary Impact and Findings: There are no findings to report at this time.

Selected Outputs

The PhaST project. American Academy of Pediatrics Second National Ambulatory Primary Care Patient Safety and Health Information Technology Conference; 2008 October 1-3; Washington, DC.

Grantee's Most Recent Self-Reported Quarterly Status: The project is mostly on track and meeting 80 to 99 percent of its milestones; the project is generally on time. Recruiting has been slower than anticipated, in part because changes in recruitment procedures required by the IRB. The project is somewhat under spent, approximately 5 to 20 percent. There is a revised plan to use members of the Nationwide Children's Hospital Psychiatric Emergency Services team as PhaST triage staff. These staff members will work on an on-call basis; however this reduces the grant expenses.

Milestones: Progress is mostly on track.

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