

## Health Information Technology Center for Education and Research on Therapeutics

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<b>Organization:</b>	Brigham and Women's Hospital
<b>Mechanism:</b>	RFA: HS11-004: Centers for Education and Research on Therapeutics (CERTs) (U19)
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**Summary:** The Centers for Education and Research on Therapeutics (CERTs) demonstration program is a national initiative to conduct research and provide education to advance the optimal use of therapeutics (i.e., drugs, medical devices, and biological products). The program consists of six research centers and a CERTs Scientific Forum. The Health Information Technology CERT (HIT-CERT) is building on existing CERT resources and infrastructure and on Dr. Bates' previous work related to health information technology (IT). The HIT-CERT is focusing research on issues related to health IT use and impact on therapeutics. In particular, the project work involves health IT research and its translation into clinical practice for pharmacosurveillance and medication-related clinical decision support.

The HIT-CERT will address therapeutics issues related to appropriateness, safety, and efficacy in the outpatient, inpatient, and transitions in care settings within the context of health IT. Two cores—the methodology and data resources core and the translation and dissemination core—oversee various aspects of all projects conducted within the HIT-CERT. The former core provides study design, data collection and management, and analysis support for all projects. The latter core promotes the dissemination of research findings and facilitates the translation of findings into practice and policy. Currently, the HIT-CERT has three projects underway for the 5-year duration of the Center.

1. *e-Pharmacovigilance II: Surveillance for Safety and Effectiveness.* This project is developing and will implement an e-Pharmacovigilance system that integrates and interoperates with the Partners Healthcare electronic health record (EHR) system. The e-Pharmacovigilance system will interface with patients by an interactive voice response (IVR) system to monitor the safety and effectiveness of treatment with Food and Drug Administration-approved medications for common chronic conditions. This project is being conducted in three phases over 5 years. Phase 1 involves the development and pilot testing of the integrated pharmacovigilance system. Phase 2 is implementation of the system. Phase 3 involves assessment of the translation and dissemination of the system using the Reach, Effectiveness, Adoption, Implementation, and Maintenance or RE-AIM framework.

2. *Physician-Level Variation in Medication Overrides of Computerized Decision Support.* This project is assessing, describing, and characterizing physician-level variations in response to computerized decision-support safety issues and efficiency suggestions for both the inpatient and outpatient settings. The project involves evaluating variations in medication overrides at baseline, followed by two cluster-randomized

trials. A set of recommendations for improving decision support system safety and efficiency will be based on the findings.

3. *Examining Human Factors Principles in the Design and Implementation of Medication-Related Decision Support Alerts*. This project will develop and evaluate a tool for assessing whether a medication-related decision support alert is appropriate relative to human factors principles. Over a 3-year period, an existing human factors instrument will be validated relative to override rates. Outcomes such as user's satisfaction with alerts will be assessed. Additionally, a set of recommendations on the best way to design medication alerts will be developed.

The HIT-CERT and its projects will provide information, strategies, and tools for utilizing health IT to improve clinical practices related to medication safety, effectiveness, and cost.

#### Specific Aims:

- Leverage new technologies to improve pharmacosurveillance. **(Ongoing)**
- Use new sources of data from clinical decision support to identify physician-level variation and use these results to improve safety and efficiency. **(Ongoing)**
- Improve medication-related clinical decision support. **(Ongoing)**

**2012 Activities:** Project development activities for each of the three projects continued during 2012. Activities for the *e-Pharmacovigilance II: Surveillance for Safety and Effectiveness* study included developing the IVR system; writing, testing, and programming a script; testing the IVR platform; and building a database for the IVR call and counseling protocol that will be part of the study. Additionally, Dr. Bates redesigned the study to be a randomized, controlled trial, as he feels this will strengthen the study. Institutional review board approval was received in December 2012, and the team planned to open the study to recruitment in early 2013.

*The Physician-Level Variation in Medication Overrides of Computerized Decision Support* project work for 2012 involved developing criteria for medication overrides and pilot testing the computerized decision support system. The project team also completed evaluating variations in medication overrides at baseline for the outpatient setting and is in the process of doing so for the inpatient setting.

Activities for the third project, *Examining Human Factors Principles in the Design and Implementation of Medication-Related Decision Support Alerts*, involved developing a study protocol, identifying and confirming study sites, and developing surveys. The project team confirmed nine study sites in total—six in the United States and three located internationally. Upon confirming participation in the study, the nine sites provided screen shots from their respective EHR systems, which will later allow the team to assess the compliance of the medication-related decision support alerts with human factors principles. Some sites also provided the team with their EHR alert logs.

**Preliminary Impact and Findings:** For the *Physician-Level Variation in Medication Overrides of Computerized Decision Support* study, the project team developed criteria for evaluating the appropriateness of medication overrides. The criteria demonstrate good reliability. The team also found that the rate of inappropriate overrides varied by the type of alert, with the highest rates being for renal substitutions, drug-drug interactions, and age-related substitutions. There was a much lower rate for duplicate suggestions, formulary substitutions, and patient allergies.

Preliminary findings for the *Examining Human Factors Principles in the Design and Implementation of Medication-Related Decision Support Alerts* project include learning that: 1) study sites had difficulty sharing the screen shots of their EHRs due to contractual obligations with their EHR vendors and the reluctance of the vendors to share the screenshots; and 2) many of the study sites were not able to produce alert logs from the EHR, indicating a gap in functionality offered by EHR vendor systems.

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**Target Population:** Adults, Chronic Care\*

**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

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\* *This target population is one of AHRQ's priority populations.*