

**Title of Project:** Health Information Technology and Improving Medication Use

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**Organization:** Brigham and Women's Hospital

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### Structured Abstract

**Purpose:** The Agency for Healthcare Research and Quality funded the Brigham and Women's Hospital (BWH) Health IT CERT program to reduce medication errors and improve patient safety.

**Scope:** The BWH CERT cross-disciplinary cores (Methodology and Data Resources and Translation and Dissemination cores) supported projects on soliciting information from patients on adverse medication events, using clinical decision support (CDS), evaluating new processes for medication reconciliation post-discharge, and assessing the impact of regional health exchange on medication safety.

**Methods:** Multiple methods (qualitative and quantitative) were used to evaluate interactive voice response, CDS, and to analyze medication reconciliation, electronic prescriptions, and medication-related CDS.

**Results:** Findings from these projects include the following (see additional results from each specific project below):

- Quantification of the value of pharmacovigilance for determining the patient perspective on medication related symptoms and cessation.
- Description and specification of quality measures and informatics strategies to minimize errors.
- Identification and description of the following:
  - The roll of primary care providers in identification and amendment of inpatient medication reconciliation errors.
  - The safety benefits associated with support for providers before, during, and after implementation of a new e-prescribing system
  - A starter set of clinically significant rules on medication-related CDS for use in clinical information systems.

These projects demonstrate how current health IT-related interventions can be broadly disseminated and provide a set of tools and programs to assist with therapeutics and health information technology (IT).

**Key Words:** clinical decision support, adverse events, medication errors, patient safety, pharmacovigilance, medication reconciliation, medication safety, e-prescribing, health IT

## Health Information Technology and Improving Medication Use

### Final Report

#### Purpose

The Agency for Healthcare Research and Quality funded the Brigham and Women's Hospital (BWH) Health IT CERT program to reduce medication errors and improve patient safety through the following aims:

- Evaluate the impact of using telephony to ask outpatients identified from electronic health record (EHR) data if they are experiencing adverse effects related to specific medications.
- Evaluate the impact of clinical decision support and automated telephone outreach on antihypertensive and lipid-lowering therapy in ambulatory care.
- Evaluate errors arising from implementation of electronic prescribing.
- Evaluate the impact of implementing a post-discharge ambulatory medication reconciliation intervention.
- Evaluate effects of multiple vendor-based prescribing systems on medication safety among Regional Health Information Organizations in New York and Massachusetts.

#### Project Scope

While HIT has great promise for improving medication use, there are many barriers to utilization, and it is unclear whether applications will include the decision support needed to result in desired benefits. In addition, HIT may cause new errors. Health information exchange is just entering the equation, and while this will likely provide great benefit, it also presents new challenges. The BWH CERT funded projects focused on improved information sharing and efficacy and safety monitoring across settings, improved decision support, assessment of how patients are using medications, and how to educate and improve communication with patients. Specifically, each of the projects builds on existing evidence related to the following six areas: 1) Medication Errors and Adverse Drug Events, 2) Therapeutics and Quality, 3) Improving Information Exchange with Patients, 4) Electronic Prescribing in the Ambulatory Setting, 5) Computerized Decision Support, and 6) Health Information Exchange.

#### ***Medication Errors and Adverse Drug Events***

Medical errors and problems in patient safety are as common outside the hospital as they are inside. For example, in a study that Dr. Bates supervised of over 2000 outpatients, Gandhi and colleagues found that 18% of patients reported problems with their medications and at least 3% had adverse drug events (ADEs) on chart review[1]. In a subsequent study, Gandhi and colleagues reviewed medical records and surveyed patients who had received care at one of four ambulatory practices in the Boston area[2]. Among 661 patients, there were a total of 181 ADEs; one in four patients (25%) experienced an ADE. Among the 181 ADEs, 39% were determined to be preventable or ameliorable. Safety problems after discharge also represent a major problem. In another recent study, Forster and colleagues found that 19% of patients developed adverse events after hospital discharge[3]. More than half of the AEs were judged to be either preventable or ameliorable with specific strategies including EHR's, CPOE, and real-time decision support.

Taken together, these studies and many others informed the Institute of Medicine Report, "Preventing Medication Errors," which concludes that the problems of health care quality and patient safety identified in the outpatient setting are at least as important as those in hospitals and that HIT is a potentially powerful tool for medication error prevention[4].

#### ***Therapeutics and Quality***

The quality of therapeutics could also be much better; in a recent large study only 62% of patients received recommended pharmaceutical care[5]. While performance was lowest in education and documentation (46%), performance was only slightly higher for medication monitoring (55%) and underuse of appropriate medications (63%). Chronic disease management is especially important because of the high frequency and costs of these conditions, but improving chronic disease management with HIT has been challenging, with a few successes

and a number of failures[6] although several factors have been identified that are strongly correlated with success[7].

### ***Improving Information Exchange with Patients***

Especially outside the hospital, patients represent the best source about how medications are affecting them and what medications they are actually taking. Our prior work demonstrated that calling patients and asking them whether they'd experienced an adverse effect related to their medications found an ADE rate nearly 3 times higher than medical record review alone[2].

### ***Electronic Prescribing in the Ambulatory Setting***

Electronic prescribing is defined as the writing of a prescription with the use of a computer. Few studies have measured the effect of electronic prescribing on medication safety in the ambulatory setting. In one study by our group in primary care in which a vendor-developed application with basic computerized prescribing was compared to handwritten prescriptions, there was no significant difference in error rates between the two approaches[1]. However, physician reviewers judged that 97% of the prescribing errors could have been prevented with more advanced electronic prescribing systems with decision support. Thus, further research is needed to determine the effect of advanced clinical decision support in electronic prescribing on medication safety in the ambulatory setting, as well as the differential effects of homegrown and vendor-based systems[8]. It is also clear that computerization of any process can have unintended consequences, including electronic prescribing[9].

There are a multitude of vendor-based ambulatory EHRs and electronic prescribing systems with varying capabilities. The Certification Commission for Healthcare Information Technology (CCHIT) was created in part to standardize the functionality, interoperability and security of vendor-based products. However, the differential effects of vendor-based HIT products on medication safety in the ambulatory setting have not yet been determined, as is true for the types of new errors created.

### ***Computerized Decision Support***

While computerized decision support has been demonstrated to improve therapeutic care in a variety of instances, success has varied as noted above, even though modeling suggests that delivering advanced decision support will be central to receiving value from HIT[10]. One major issue has been that vendor systems vary widely in terms of the decision support included, and that no common repository of decision support rules is available in the U.S. To address this and other issues around delivery of decision support, at the request of the Office of the National Coordinator for HIT (ONCHIT), AMIA commissioned a report on this area, called the Clinical Decision Support Roadmap[11].

### ***Health Information Exchange***

Another key development on the HIT front is the emergence of regional health information exchanges (HIEs), which are designed to facilitate sharing of clinical data across sites and among providers of care. Two of the leading exchanges have been Santa Barbara and Indianapolis, which have allowed data exchange for some time[12]. The benefits of clinical data exchange have been estimated to be \$87 billion to the U.S. per year[13]. Currently, HIEs are springing up around the country. The efforts in New York are particularly exciting. In May 2006, New York State awarded \$52.9 million to regional HIEs across the state, as part of the HEAL NY (Healthcare Efficiency and Affordability Law for New Yorkers Capital Grant) Program, and announced the availability of another \$52.9 million for health information technology (HIT) grants in November 2006. This program invests more money per capita in health information technology infrastructure than any other state, making New York a new national leader in this field. Although HEAL NY grantees are required to evaluate the impact of their initiatives, they vary in the expertise and resources available to conduct high-quality analyses, particularly because grant monies from the state can only be dedicated to capital expenses and evaluation monies must come from institutional matching funds or other sources. Individual, non-standardized, and potentially under-resourced evaluations are unlikely to add substantially to the national dialogue on the role of HIE in improving patient safety, health care quality and efficiency.

## Methods

The Brigham and Women's Hospital CERT-Health IT team was comprised of a methodology and data resources core and a translation and dissemination core. These cross-disciplinary cores supported projects on soliciting information from patients on adverse medication events, using clinical decision support (CDS), evaluating new processes for medication reconciliation post-discharge, and assessing the impact of regional health exchange on medication safety.

**Core A—the Methodology and Data Resources Core** was led by Dr. David Bates and Dr. Francis Cook. The focus of this core was to assist with advising project leaders on study design, study methodologies and analytic strategies. The project leaders met with the Core Directors to discuss the various approaches to data collection and statistical plans for analysis. The Core Directors were also involved in advising on the appropriate allocation of programming resources to help insure each project's analysis proceeds according to study timeline. The Methodology Core helped develop standard data collection and analyses processes which included obtaining IRB approval, creating an analysis plan, identifying data elements and definitions for collection, iterative processes with the sources of the data to refine data required, developing the dataset design with documentation, determining the methods for data collection and transfer, and receipt and storage in secure servers.

**Core B—the Translational/Dissemination Core**, was led by Dr. David Bates, and focused on promoting interchange and cross-fertilization across projects, the dissemination of research findings, and the translation of findings into practice through initiatives at the local, regional, and national level. Dr. Bates and other members of the Translational Core have widely presented findings from the CERT projects at the CERT Steering Committee Meetings, local, national and international meetings and in peer review publications (see product lists included with each project summary).

## BWH CERT PROJECTS

### A. e-Pharmacovigilance: Integrating Patient Reports of Side Effects with Electronic Health Records for Surveillance of Recently Approved Drugs

#### Purpose

The interactive voice recognition (IVR) based e-pharmacovigilance system addressed a critical need to increase the sensitivity, and accuracy of ADE ascertainment in the ambulatory setting.

**Objective:** To evaluate the impact of using telephony to ask outpatients identified from electronic health record (EHR) data if they are experiencing adverse effects related to specific medications. Target medications were selected based on date of FDA approval, as drugs are more likely to have unrecognized adverse events noted within 7 years of introduction to the market, and/ or particular concern about side effects.

#### Scope:

**Background/context:** This 4 year project had three phases: (1) development and pilot testing of a pharmacovigilance system that is integrated with an EHR; (2) implementation of the prototype; and (3) assessment of the translation and dissemination of the system.

**Setting:** Brigham and Women's Primary Care-Based Research Network (BW-PBRN) in the greater-Boston area. Brigham and Women's Hospital is a founding member of Partners Healthcare (PHS). These primary care clinics use the Longitudinal Medical Record (LMR), an internally developed, web-based, fully functional EHR that includes notes from primary care and subspecialty practices; coded problem lists; a "health maintenance grid" for documenting preventive counseling and health habits; structured medication prescriptions; and medication allergies.

**Participants:** Adult, English-speaking patients were eligible if they recently been started on one of the target medications by a participating primary care physician (PCP) at a visit during the study period (2008-2010). A patient was eligible only for the first medication prescribed during the study period to reduce

respondent burden. If a patient was prescribed more than one of the target medications during a visit, one medication was randomly selected for monitoring

## Methods

**Study Design:** The first year of the project was used for the development and pilot testing of the e-pharmacovigilance system using qualitative methods. The content of the IVR script/logic was derived from our prior surveys examining patient-reported symptoms and ADEs among ambulatory patients. In addition, formative research was based on qualitative methods.

Once the e-pharmacovigilance system was integrated with the Partners EHR, a prospective cohort study was performed. Patients who were potentially eligible to participate were identified from LMR bi-monthly. As approved by the Partners Healthcare IRB, patients were then mailed an informational letter describing the study from the practice director of the clinic where they receive their care and the principal investigator. The letter included directions for a dedicated toll-free number that could be called to “opt-out” of participation. Patients who did not opt-out within a 2-week period were assigned a unique study ID and their contact information was uploaded to the IVR system. The IVR system made outbound calls during preset calling hours, varying the time of the call to maximize contact. Once contact was made, the spoken script greeted the patient by name, authenticated the respondent’s identify, repeated a brief description of the study purpose and protocol, ascertained whether the patient was willing to participate, and (if yes) asked the patient the programmed questions. For each call, the IVR script ascertained: whether the recipient was taking the medication of interest (if not, we collected information about the reason for stopping, whether they had discussed this issue with their PCP, and if they had not discussed the issue an email was generated to their PCP); whether s/he has experienced a pre-specified list of symptoms since their PCP visit (typically the call occurred 4 – 6 weeks following the visit). Patients who reported a medication-associated symptom were asked: (1) the severity (mild, moderate, severe), (2) how long ago the symptom started, (3) the longest duration of the symptom, (4) whether they thought the medication was related to the target drug, and (5) whether the symptoms were discussed with or treated by a physician. Information reported during the call was automatically documented for all patients in the EMR using a templated note. In addition, the system sent a single email to the PCP if the patient: (1) reported that they had stopped taking a medication intended for chronic use and said they had not discussed this with their provider, (2) reported a pre-defined list of symptoms, specific to each drug, that were of clinical concern or (3) requested that we send an email to their provider.

**Data Sources:** Several data sources were used:

- (1) *IVR system.* Call outcomes were stored by the database (e.g., call completed, no side effects reported, call completed, side effect reported, never reached, refused).
- (2) *EHR.* We reviewed the records of the patients who participated in the survey to identify ADEs, medication allergies, comorbidities, specific lab results (e.g., renal function, liver function) and demographic characteristics (e.g., age, sex).

## Measures:

- **RE-AIM Measures:** Our primary outcomes reflect our goal of evaluating the feasibility, effectiveness and acceptability of this e-pharmacovigilance prototype, specifically the: (1) **Reach** (e.g., the proportion of patients who were dialed who were reached; the proportion who completed the phone call); (2) **Effectiveness** (stopped the target medication, as documented in the EMR by a health care provider; visited a PCP or specialist physician; or experienced a combined outcome of ED visit, hospitalization, or death); (3) **Adoption** (differential use by different patient populations); and (4) **Implementation** (e.g., technical barriers).

## Results (Summary)

Pharmacovigilance provides important information related to the patient perspective. Analysis identified that automated phone pharmacovigilance provides important information about adherence. Compared to those who agreed to participate but did not complete the pharmacovigilance call, subjects who completed the call had greater rates of EMR-documented medication cessation and use of planned primary or specialty care,

but similar use of acute care services or death. Of participants, 50.2% reported >1 symptom; of these, 22.0% thought the symptom was medication-related. Our work found that there were differences in participation by patient demographics and drug class. During the study period, two of the target drugs received particular attention in the lay press for concerns about adverse effects (varenicline and zolpidem). We performed an analysis of symptoms reported by patients taking one of these medications compared to the package inserts and found that patients taking varenicline were significantly more likely to report confusion, depression, fatigue, hallucinations, muscle aches, and sexual dysfunction than noted in the package insert. Elicited rates of depression and hallucination were similar to those reported in package insert for patients taking zolpidem. Automated phone pharmacovigilance can provide estimates of possible ADEs in clinical practice. In the case of varenicline, these data support some of the safety concerns that have come to light post-marketing, while others such as depression and hallucination related to zolpidem were not detected.

**Implications:** These data highlight the potential value and of innovative ways of collecting information about possible ADEs directly from patients.

### **List of Publications, Products, and CERT Leveraged Products**

1. Haas, Jennifer. "Pharmacovigilance." Presentation at the Annual Meeting, International Society for Quality in Health Care, Boston, MA, October 3, 2007.
2. Haas, Jennifer. "Early Experience with E-Pharmacovigilance." Invited Speaker, Centers for Education and Research on Therapeutics, Agency for Healthcare Research and Quality, 2009.
3. Haas, Jennifer. "Participation in an E-Pharmacovigilance System to Monitor Ambulatory Patients for Adverse Drug Events." Panel Speaker, Consumer Applications of Health Information Technology, at the Annual Meeting, AcademyHealth, Boston, MA June 29, 2010.
4. Haas, Jennifer. "Update on E-Pharmacovigilance." Invited Speaker, Centers for Education and Research on Therapeutics, Agency for Healthcare Research and Quality, September, 2010.
5. Haas JS, Iyer A, Orav EJ, Schiff GD, Bates DW. Participation in an ambulatory e-pharmacovigilance system. *Pharmacoepidemiol Drug Saf.* Sep 2010;19(9):961-69.
6. Haas, Jennifer. "Participation in an E-Pharmacovigilance System to Monitor Ambulatory Patients for Adverse Drug Events." Presentation at the Annual Meeting, International Society for Quality in Health Care, Paris, FR, October 10-13, 2010.
7. Haas, Jennifer. "Do Package Inserts Reflect Side Effects in Practice? The Examples of Varenicline and Zolpidem." Presentation at the Annual Meeting, International Society for Quality in Health Care, Hong Kong, September 16, 2011.
8. Linder JA, Haas JS, Iyer A, Labuzetta MA, Ibara M, Celeste M, Getty G, Bates DW. Secondary use of electronic health record data: spontaneous triggered adverse drug event reporting. *Pharmacoepidemiol Drug Saf.* 2010 Dec;19(12):1211-5.
9. Haas JS, Amato M, Marinacci L, Orav EJ, Schiff GD, Bates DW. Do package inserts reflect symptoms experienced in practice?: assessment using an automated phone pharmacovigilance system with varenicline and zolpidem in a primary care setting. *Drug Saf.* 2012 Aug 1;35(8):623-8.
10. Haas JS, Amato M, Orav EJ, Schiff GD, Bates DW. Assessment using an automated phone pharmacovigilance system with varenicline and zolpidem in a primary care setting. *Drug Saf.* [in press].

## **B. A Multimodal Intervention to Improve Antihypertensive and Lipid-lowering Therapy**

### **Purpose**

The purpose of this project was to evaluate the effectiveness of clinical decision support (CDS) compared to automated telephone outreach (ATO) to improve the use of antihypertensive and lipid-lowering medications in community-based primary care practices.

**Objective:** 1) to characterize challenges facing physicians in their efforts to control blood pressure and lower cholesterol levels in community practices; and 2) to evaluate the effectiveness of CDS compared to ATO to improve the use of antihypertensive and lipid-lowering medications in community-based primary care practices.

## Scope

**Background/context:** “Care-gaps” exist in the management of blood pressure and lipids due to barriers in optimal practice at the system, provider and patient levels. Computerized clinical decision support and automated telephone outreach interventions designed and evaluated in this study promise to help overcome physician and patient barriers to effective hypertension/hyperlipidemia treatment.

**Setting:** Our original proposal aimed to recruit physicians from the three Massachusetts eHealth Collaborative (MAeHC) communities for focus groups. However, many of the practices using eClinicalworks that originally were associated with the MAeHC had become affiliated with Beth Israel Deaconess Physician Organization (BIDPO ). By extending our recruitment to the BIDPO, we were able to include these former MAeHC practices as well as many other eligible practices in our study beyond the three MAeHC communities. This change provides for broader representation of physician practices in our study and should lead to wider generalizability.

**Participants:** Physician practices in the MAeHC, one community-based primary care practice in Brockton, MA, and two Take Care New York (TCNY) practices (affiliated with the New York City Department of Public Health and Mental Hygiene). All participating practices are using the eClinicalWorks EHR system.

**Project Status:** Project is active but was closed to enrollment in June 2012. Data analysis and manuscript preparation are currently underway.

## Methods

To complete Aim 1, we changed our qualitative method from focus groups to in-depth interviews based on our experience in conducting focus groups for a similar study in the MAeHC practices. Moreover, we have used in-depth interviews in other settings with much success, so we therefore chose that methodology for this study. An interview guide/script was developed: *Achieving Benchmarks in Treating Hypertension and Hyperlipidemia: Barriers and Best Practices Physician Interview Guide*. Twenty in-depth semi-structured phone interviews were completed with physicians in Beth Israel Deaconess PO practices. Roberta Goldman, PhD interviewed the physicians about barriers to and facilitators of achieving treatment goals for hypertension and hyperlipidemia in primary care. A manuscript reporting the results of this component of the study was published (see Project Products below).

To complete Aim 2, one community-based primary care practice in Brockton, MA was recruited to implement the EHR hypertension and hyperlipidemia alerts of interest using a randomized design. We had originally intended to recruit as many as 10 practices for this component of the aim. However, because of changes in the organizational structure of the MAeHC, as well as delays in their implementing the required software systems to participate in the study, we were limited to only one eligible practice. There was considerable delay in getting the alert system up and running with this practice. Support from the vendor to get the alerts turned on was complicated by the acquisition of the practice by a for-profit healthcare system that was interested in controlling the interface between the vendor system and practices. As a consequence, the vendor was not supposed to directly support the practice and instead support was to come from the technical staff at the healthcare system. This introduced extended delays. The intervention period ended in August 2012. Baseline data were previously collected and final intervention data from the EHR vendor to support study analyses are expected in December 2012.

To complete Aim 3, Two Take Care New York (TCNY) practices were recruited to participate in the ATO/IVR intervention using a randomized design. The study was originally intended to be conducted in the MAeHC practices. However, because of the changed organizational affiliations mentioned above in two of the three communities, as well as a change in organizational priorities in the third community, we were unable to carry out this research in any of the three MAeHC communities. As a result, we sought out another set of primary care practices using eClinicalWorks and were fortunate to establish a collaboration with the New York City Department of Public Health and Mental Hygiene. Through this partnership, we identified potentially eligible primary care practices who had adopted eClinicalWorks. Recruitment was challenging as there was considerable resistance among community-based physicians to doing research in general, and in particular, studies involving telephone calls to their patients. Due to difficulties obtaining data electronically for the two

practices in NY, the PI and staff visited the practices multiple times to manually extract the data needed to identify the patient population meeting study criteria and collect clinical data. Approximately 300 patients were identified between the two practices to be recruited for participation in the automated telephone outreach and were sent an opt-out letter. We checked our research phone line for two weeks, removing patients who did not want to be contacted. Enrollment of patients concluded on 6/26/2012. The finalized list was sent to our automated telephone call vendor who proceeded to contact patients using the healthy living script prepared. Telephone calls ended mid-July and an analysis of call success was provided by the ATO vendor. Data collection of intervention data to evaluate the impact of these calls on study outcomes was being completed in October 2012 as it has required onsite manual collection of data by study staff.

### **Interventions:**

- *Qualitative Study (Focus Groups):* This study tested the effect of CDS (i.e., alerts) to physicians via the EHR compared to IVR to patients. To develop the interventions with maximal potency, we carried out a qualitative study of the challenges facing physicians in their efforts to control blood pressure and lower cholesterol levels.
- *Clinical Decision Support (CDS) Intervention:* Alerts for both hypertension and hyperlipidemia were implemented in the EHR system one community-based primary care practice.
- *IVR Intervention.* The intervention was based on previous interventions we developed for an American Diabetes Association study (7-04-JF-46, Simon, PI) to improve the care of patients with diabetes and shared many features with the e-pharmacovigilance intervention described in section A above. Each patient was notified in advance to expect the automated call. The call was tailored to each patient based on data from the EHR. The call educated the patient about the importance of undergoing regular laboratory monitoring and of reaching treatment goals for the target condition (either hypertension or hyperlipidemia) and elicited specific barriers that the patient may be facing. The main message of the call was to urge the patient to talk with his or her doctor about initiating or increasing medication treatment for the specified condition.

### **Data Sources**

The qualitative data sources are discussed above. For the quantitative analysis, we used diagnoses from the problem list in the EHR, augmented by additional assessment of blood pressure and lipid levels, to identify eligible patients. We used EHR data for pre- and post-intervention measurements of process and outcomes of care. We measured rates of testing for lipid levels and renal function, levels of blood pressure and lipid levels, blood glucose and hemoglobin A1c levels), as well as dosage of medications prescribed for hypertension and hyperlipidemia. We also captured process data from the IVR calls (e.g., proportion of patients reached, time spent on the call, proportion of patients requesting follow-up action during the call).

### **Measures**

The main outcome measure was the proportion of patients at treatment goal. We used goals advocated by nationally recognized evidence-based guidelines (e.g., JNC and ATP) in force at the time of the intervention. We also captured the proportion of patients for whom a medication change (initiation or dose increase) occurred.

**Limitations:** This project faced many barriers that caused some delays in completing the project within original timeline including the following:

1. Research review by multiple institutional review boards proved a formidable barrier to our timeline. We experienced significant delays in recruitment and evaluation due to the coordination of approvals from all IRBs.
2. We also encountered barriers to conducting research in Massachusetts community practices. Despite good relations between our research team and these communities, two of the three MAeHC communities decided to stop participation in all research activities. The principal reason they reported for their discontinuation was competing priorities and initiatives. Thus, our enrollment was delayed while we pursued additional practices through TCNY and Good Samaritan in Brockton, MA.



3. We experienced delays while implementing the necessary software upgrades for CDS alerts for the alerts intervention. An eClinicalWorks software engineer visited the practice to resolve vendor-related challenges associated with implementing the CDS rules. In addition, changes in community-based health care systems – ownership changes, changes in priorities, and technology changes – made it very challenging to conduct research in this setting.
4. Another significant barrier we overcame included developing a strategy for identification of patients in control practices (one practice is completely paper-based). To overcome these barriers, the PI and staff made multiple trips to the intervention and control practices in 2012.
5. Though we have a good relationship with our vendor, there were a series of extensive delays with scheduling extracting data from eClinicalWorks as their focus was, understandably, foremost on operational priorities.

## Results

Aim 1: This study of hypertension and hyperlipidemia management by primary care physicians in a Boston-area accountable care organization found that while physicians generally struggle to get patients to goal for these two diseases, they have developed particular perspectives and practices that enhance their success. About half find that it is more difficult to get patients to goal for hypertension; the remainder claims that hyperlipidemia is more difficult. Few physicians felt that their own style of management impacts whether patients get to goal, placing chances of success more dominantly in the patient domain. Similar barriers are cited for both diseases, including factors emanating from patient attitudes, motivation, knowledge, and resources. Many of the physicians felt strongly about the impact of their good relationships with patients in terms of overcoming barriers to success, including the obstacle of limited time with patients. The issue of whether to intensify treatment when a patient is close to goal generated many comments from physicians. Some felt strongly that efforts to get to goal are critical; others claimed that the treatment and management of these two diseases is too complex and dependent on the circumstances of individual patient cases to be able to declare commitment to achieving goal.

Aims 2-3: Still being completed.

## List of Publications, Products, and CERT Leveraged Products

1. Goldman RE, Simon SR. Automated Telephone Outreach Scripts for Hypertension and Hyperlipidemia Healthy Living. Available upon request, [SRSimon@partners.org](mailto:SRSimon@partners.org).
2. Goldman RE, Simon SR. Treating hypertension and hyperlipidemia in an emerging Accountable Care Organization: physicians' perspectives on health information technology, financial incentives and the patient-doctor relationship. *International Journal of Person Centered Medicine*, North America, 2, sep. 2012. Available at: <http://www.ijpcm.org/index.php/IJPCM/article/view/248>. Date accessed: 11 Oct. 2012.
3. Goldman RE, Simon SR. Physician Interview Guide: Achieving Benchmarks in Treating Hypertension and Hyperlipidemia: Barriers and Best Practices. Available upon request, [SRSimon@partners.org](mailto:SRSimon@partners.org).

## C. Unintended Consequences of Electronic Prescribing

### Purpose

The purpose of this project was to employ a mixed-methodology approach to dissect the unintended consequences of electronic prescribing in the community setting.

**Objective:** To evaluate errors arising from implementation of electronic prescribing.

### Scope

**Background/context:** This project reviewed prescriptions from commercial pharmacies to identify electronic prescription (e-prescribing) errors. The prescriptions were analyzed to determine the frequency and character of errors and develop recommendations for preventing these errors and other unintended consequences.

**Setting:** We conducted our study in the 3 communities within the Massachusetts eHealth Collaborative that implemented EHRs within ambulatory practices. While practices within the collaborative were free to chose from a list of 6 EHR vendors, the majority of practices chose to implement eClinicalWorks™.

**Participants:** We randomly choose branches of commercial pharmacies within the target communities for data collection. We will also observed physicians' practices that implemented EHRs within these same communities, which serve quite diverse populations.

## Methods

We employed previously used methods of measuring medication errors in the ambulatory setting to measure the rate of errors on electronic prescriptions processed by commercial pharmacy in the community with high penetration of electronic prescribing. Through a detailed analysis of e-prescriptions with errors, we report on the rate of errors introduced by the use of prescribing and the rate of errors due to decision support failures. We then used a combination of semi-structured interviews and direct observations to describe other UC associated with electronic prescribing. Finally, we used these findings to develop recommendations for preventing and/or mitigating the UC's of electronic prescribing.

### Data Sources:

- *Prescriptions:* We collected copies of 3898 prescriptions processed at commercial pharmacies in three states.
- *Interviews and field observations:* We analyzed 40 hours of direct observations and semi-structured interviews with key informants in an independent retail pharmacy in Massachusetts.

### Quantitative Measures:

- *Classification of prescriptions:* All prescriptions collected were classified by the mode of transmission (hand, fax, electronic transmission), and whether it had been generated by an electronic prescribing system.
- *Errors introduced by ePrescribing:* Each prescription with error underwent further detailed review by physician investigators to determine the contributing factors using a classification method we have previously developed. We classified each error as i) error introduced by the use of electronic prescribing, ii) decision support failure, referring to a cognitive error committed by the prescribing clinician that is not intercepted by the decision support features of the electronic prescribing system, or iii) other errors.

The primary outcome was the incidence of errors introduced by electronic prescribing among eClinicalWorks™ prescriptions. Secondary outcomes are: i) the rate of prescribing errors by error type in eClinicalWorks™ prescriptions; ii) the incidence of contributing factors among eClinicalWorks™ prescriptions with errors; iii) the rate of errors caused by decision support failures.

**Qualitative Measures:** We conducted a qualitative study to examine the unintended consequences and unrealized potentials of computer-based electronic prescribing systems from the retail pharmacy perspective.

**Limitations:** As reported previously, the project strategy was modified because we were unable to conduct parts of this study at the ambulatory clinic sites who initially committed to the project. These sites decided during the study period that they could not collaborate with any new research studies, including our study. We did not receive the additional support of a major pharmacy chain that had provided us with the above described sample of ePrescriptions to conduct observational studies in one or more of these retail pharmacies.

## Results

**Quantitative Results:** We reviewed 3,898 prescriptions obtained from commercial pharmacies in three states. Of the prescriptions we reviewed, 452 (11.6%) contained a total of 466 errors, for an average of 1.03 errors per script. We classified 163 (35.0%) of these errors as errors with the potential to cause patient harm also known as potential adverse drug events (ADEs). Of the potential ADEs, 95 (58.3%) were significant and 68 (41.7%) were serious. The medications with the most errors by type of medication were anti-infective

agents (40.3%), nervous system agents (13.9%), respiratory system drugs (8.6%) and dermatological agents (6.9%). We identified four main types of errors among the computer-generated prescriptions and created a framework to describe these errors. The most common errors by type of error were omitted information (60.8%) - which most commonly included omitted duration, dose or frequency - unclear information (16.1%), conflicting information (15.7%) or clinically incorrect prescriptions (7.6%). We were unable to determine which vendor or home grown ePrescribing systems were used in our deidentified set of prescriptions for the majority of reviewed prescriptions. However we did attempt to stratify the prescriptions by the type of ePrescribing system based on pattern recognition of look-alike ePrescription formats – each ePrescribing system has a “fingerprint” or format unique to that system. We found that 6 unique appearing ePrescribing systems generated 1910 or 49% of prescriptions reviewed by our group. One of the more interesting findings was that different systems were associated with different error types. For example, the proportion of omitted duration errors ranged from 7.7% to 63.2%, omitted dose errors ranged from 8.3% to 30.8% and inappropriate abbreviations ranged from 0 to 30.8%. These findings suggest that ePrescribing systems are associated with unique error patterns and that are likely quite amenable because other systems do not share the similar error patterns.

**Qualitative Results:** We conducted a qualitative study to examine the unintended consequences and unrealized potentials of computer-based electronic prescribing systems from the retail pharmacy perspective. We analyzed 40 hours of direct observations and semi-structured interviews with key informants in an independent retail pharmacy in Massachusetts. Five major themes emerged from a detailed analysis of the field notes and transcribed interviews including: 1) communication issues, 2) workflow issues, 3) opportunities for new errors, 4) cost issues and 8) technical system issues.

**Outcomes/Discussion/Significance:** Our findings suggest that prescribing errors vary significantly according to which computerized prescribing system is used. Furthermore, our data show that different systems are associated with different error types. The pharmacy observation work will provide additional insight into the ePrescription workflow. We learned about unintended consequences resulting from ePrescriptions and their amelioration and management by pharmacists. Our findings will help inform the design and implementation of the electronic prescribing system infrastructure and workflow processes within retail pharmacies

**Implications/Recommendations:** The implications of this work are that informatics strategies can be used to minimize electronic prescribing errors. Recommendations based on our findings include the following: 1) Implement CDS with maximum dose checkers; 2) automate the amount to be dispensed to prevent inconsistent quantity errors by eliminating the redundant entry of the final medication quantity; and 3) use the dispense forcing functions that create constraints in data entry to prevent errors such as structured data entry with mandatory data fields to prevent omitted information.

### List of Publications, Products and CERT Leveraged Products

1. Ash JS, Sittig DF, Campbell E, et al. An unintended consequence of CPOE implementation: shifts in power, control, and autonomy. *AMIA Annu Symp Proc.* 2006; 2006: 11–15.
2. Poon, Eric. “Errors Associated with the use of e-Prescribing.” Tutorial at the Annual Symposium, AMIA, Chicago, IL, November, 2007.
3. Ash JS, Sittig DF, Poon EG, et al. The extent and importance of unintended consequences related to computerized provider order entry. *J Am Med Inform Assoc* 2007;14(4):415-23.
4. Nanji, KC, Rothschild JM, Salzberg, C, et. al. Errors Associated with Electronic Prescribing [abstract]. In: American Medical Informatics Association 2010 Annual Symposium; 2010 November 13-17; Washington, DC. 2010. p. 1190.
5. Nanji, KC, Rothschild JM, Salzberg, C, et. al. Errors associated with outpatient computerized prescribing systems. *J Am Med Inform Assoc.* 18(6): 767-73, 2011
6. Rothschild, JM. Unintended Consequences of Electronic Prescribing. *CERT Education Committee Webinar* conducted Jan 8, 2011.

Rothschild, JM. Unintended *Consequences and Unrealized Potential of Electronic Prescribing in the Outpatient Pharmacy*. Manuscript under development describing the qualitative study conducted in 2011 in a very active urban independent pharmacy. The study included unblinded direct observations and staff interviews.

## D. Ambulatory Medication Reconciliation Following Hospital Discharge

### Purpose

To determine the effects of a post-discharge medication reconciliation intervention, including the use of information technology, on serious medication errors.

**Objective:** The objective of this research is to reduce the incidence of post-discharge medication discrepancies and preventable and ameliorable adverse drug events (ADEs) through the use of health information technology (HIT). The goals of this post-discharge medication reconciliation process are twofold: 1) to verify that the inpatient medication reconciliation process was done optimally according to the physician who is most familiar with the preadmission medication regimen; and 2) to clearly document in the outpatient medical record the new post-discharge medication regimen.

### Scope

**Background/context:** A new medication reconciliation module was designed and studied using HIT to facilitate post-discharge medication reconciliation within the Partners HealthCare System (PHS) ambulatory electronic medical record (EMR). It was accessible for 6 months after a patient was discharged from Brigham and Women's Hospital (BWH) or Massachusetts General Hospital (MGH) or until the reconciliation process was complete.

**Setting:** BWH/MGH Primary Care Based Research Network (PBRN) practices within PHS, a non-profit, regional, integrated health delivery system in Eastern MA.

**Participants:** Nineteen primary care practices at PHS were randomized to receive the post discharge medication reconciliation module or usual care. Eligible subjects included patients admitted to BWH or MGH who planned to follow up with a PCP in one of the 19 primary care practices in the PBRN.

### Methods

**Study Design:** We evaluated the effects of the medication reconciliation module intervention on serious medication errors using a cluster-randomized controlled trial. In addition, a secondary analysis was completed to evaluate the accuracy of medication lists one month after discharge compared with patient report.

**Data Sources:** Prior to discharge, after confirming eligibility criteria and obtaining informed consent, research assistants administered a brief questionnaire to patients to gather information regarding important potential confounders of the outcomes, including self-reported health status, race, ethnicity, language, education, marital status, and household income. Data to assess documented medication accuracy and serious medication errors was assessed by patient interview conducted 30 days after discharge in enrolled subjects. Additional demographic and billing data were obtained from computerized databases at each study site.

**Intervention:** The intervention, a medication reconciliation module, presents the EMR medication list (i.e., from prior to hospital admission) and the discharge medication regimen side by side, sorted by medication class, with identical medications next to each other and differences in dose or frequency highlighted. Changes to the ambulatory EMR medication list could be made with a single click. Medication regimens could be reconciled "in part" (e.g., in the case of specialists only responsible for prescribing some of the medications) or "in full" (as would usually be the case for primary care physicians).

**Measures:** The primary outcome was the number of serious medication errors per patient during the first 30 days after hospital discharge. This is a composite outcome that includes: 1) actual adverse drug events (ADEs) that could have been prevented or reduced in severity (preventable or ameliorable ADEs), and 2) medication

discrepancies with the potential to cause adverse events (potential ADEs). The primary outcome elements were assessed by an adjudication team composed of three clinician investigators, blinded to study arm.

- *Medication Discrepancies:* a research assistant asked patients to name each medication he/she is currently taking. This list was compared to each medication on the discharge medication list. Any discrepancies in dosage, frequency, missing medications, or additional medications were noted and reasons for these discrepancies explored with the patient. Reasons other than changes made by a physician or completion of a prescribed course were counted as a discrepancy.
- *Possible ADEs:* were initially be detected by a screening question for new or worsening symptoms since hospital discharge similar to that used in the e-pharmacovigilance and vendor EHR safety studies. In the event of an affirmative response to this review of symptoms, follow-up questions elicited details of these symptoms and their relation to medications. Research staff prepared de-identified case summaries of possible ADEs using the responses to these answers, the medication lists at admission and discharge, the hospital discharge summary, and any available outpatient visit notes, discharge summaries from ED visits or readmissions, and laboratory test results in the month since discharge.
- *Adjudication of preventable/ameliorable and potential ADEs:* the adjudication team, composed of physician investigators, were presented all the above information for each patient. For new or worsening symptoms (possible ADEs), adjudicators decided whether the injury was related to medication use (i.e., an actual ADE took place) using the Naranjo algorithm[14], a validated scoring system to assess causality. For all ADEs, clinicians then determined whether it was preventable or ameliorable (i.e., able to be decreased in severity, duration, or both) by any change in management. For discrepancies, adjudicators judged whether or not each problem had the capacity to cause patient harm (i.e., was a potential ADE). To avoid double counting, each medication was attributed to one serious medication error per patient. Lastly, for all serious medication errors, severity was judged by the adjudicators as "serious," "life-threatening," or "fatal," using definitions established at BWH[15].
- *Documented Medication List Accuracy:* A "gold standard" medication list was derived by including all discharge medications, removing any planned completions in therapy and incorporating any reported changes made by the patients' physicians since discharge. The documented EMR medication list at the time of the call was compared to this gold standard regimen and the proportion of concordant medications (exact matches in medication, dose, and frequency) was calculated.
- *Covariates:* Patient age, sex, race, ethnicity, primary language, median income by zip code, primary and secondary insurance, self-reported health status (SF12 score), education, hospital discharge diagnosis-related-group (DRG) weight, prior hospitalizations in the prior 12 months and ED visits in the previous 6 months, type of admission to hospital (elective, emergency, transfer), index length of stay, and number of medications at discharge were collected, as was PCP post-graduate year, sex, and patient volume, and practice site.
- *Analyses:* The primary outcome and its subcomponents were assessed using multi-variable Poisson regression, adjusted for all covariates and using general estimating equations to adjust for clustering by PCP. Documented medication list accuracy was assessed using binomial logistic regression.

**Limitations:** Use of the module was low at the beginning of the trial: in June through December 2008, the module was only used in 18% of visits to study PCPs within 30 days of discharge. We conducted an informal survey of PCPs to determine the reasons for low use. We suspected that low use was because it was a completely new feature to be used in a minority of patients (i.e., only those recently discharged), and that users might not be aware of the module or forget to use it. Our survey confirmed our suspicions: most PCPs were supportive of the module but simply forgot to use it. In addition, several usability issues emerged, including the following: 1) PCPs were confused whether or not every medication discrepancy needed to be resolved, 2) adding medications resulted in extra work to specify the form of the medication (which doesn't exist in inpatient pharmacy information); and 3) modifying medication doses removed prior instructions and refill information.

To manage the issue of PCPs forgetting to use the module, we created an active reminder. Whenever a user was in the EMR medication screen of a patient who needed medication reconciliation, the user received a

pop-up to go to the medication reconciliation module. In addition, we created a passive reminder in the EMR Summary screen, alongside other health care reminders. To address user confusion about how to use the module, we conducted educational visits to each primary care site and supplemented them with email announcements. This approach also allowed for increased publicity about the need for post-discharge medication reconciliation.

**Results**

With these efforts, individual provider use of the medication reconciliation tool increased in the final 3 months of the study period to 44.8% of eligible visits among all patients in the intervention practices. However, among enrolled study subjects throughout the entire study period, the post-discharge medication reconciliation tool was only used in 16% of patients in the intervention arm.

The study included 759 patients: 380 in intervention practices and 379 in usual care practices. Regarding patient characteristics, 52% were female, mean age was 71 years, and 45% had been hospitalized in the previous 12 months. The number of serious medication errors per patient was 0.39 in the intervention arm and 0.48 in the usual care arm (relative rate 0.80, p=0.04; Table 1). In clustered analysis, use of the intervention was associated with a non-significant change in risk (RR 0.80, 95% CI 0.60 - 1.05, p = 0.11). Regarding the subcomponents of the primary outcome, both preventable/ameliorable and potential ADEs were reduced to a similar degree in the intervention arm compared with usual care (21% and 19% relative risk reduction, respectively), although neither was statistically significant (see Table 1, below).

**Table 1. Main Results**

<b>Outcome</b>	<b>Intervention N=380</b>	<b>Control N=379</b>	<b>Relative Risk</b>	<b>P value</b>
# clinically significant errors / patient	0.39	0.48	0.80	0.04
# preventable/ ameliorable ADEs / patient	0.19	0.24	0.79	0.12
# potentially harmful discrepancies / patient	0.19	0.24	0.81	0.16
Accuracy of LMR medication list 30 days post-dc	23%	22%	1.09	0.04

Regarding medication list accuracy, in an intention to treat analysis, the accuracy of the EMR medication list 30 days after discharge was 23% among intervention patients and 22% among usual care patients (adjusted odds ratio 1.09, 95% confidence interval 1.00 - 1.17, p=0.04). Among patients in whom the tool was used, the accuracy of the EMR medication list was 25% (p=0.02 for comparison with patients in whom it was not used). The most common inaccuracy was documentation of medications the patient was no longer prescribed.

**Significance/Implications:**

In this cluster-randomized controlled trial, we found that the accuracy of documented medication regimens 30 days after discharge to be poor (around 22%). If the post-discharge medication regimen is not corrected in the outpatient medical record, it perpetuates the cycle of medication discrepancies (i.e., the next time the patient is admitted to the hospital, errors are made in taking the preadmission medication history because the ambulatory EMR medication list is incorrect, therefore the patient is again discharged on the wrong regimen, post-discharge medication reconciliation is more difficult, and the ambulatory EMR medication list continues to be inaccurate). An electronic post-discharge medication reconciliation tool led to a small improvement in documented regimens and to a modest decrease in serious medication errors (statistically significant in unadjusted analyses). The overall efficacy of the tool was limited in part because the tool was only occasionally used.

In theory, primary care providers (PCPs) are in the best position to identify and correct errors of inpatient medication reconciliation and to make further adjustments to the post-discharge medication regimen based on their knowledge of and relationship to the patient. Therefore, use of a post-discharge medication reconciliation tool should help create a seamless transition by explicitly involving the PCP in the post-discharge medication process. In practice, use of the module was low and its impact on patient safety was modest. Further

improvements to the tool are likely necessary to improve usability, such as: 1) explicitly requiring all discrepancies to be reconciled, 2) addressing issues with adding and modifying medications such it is easy to prescribe these medications in the ambulatory setting, 3) improving the reminder such that it is effective without being intrusive, and 4) accommodating the distribution of effort among office staff (e.g., with some tasks done by physician assistants, nurses, and pharmacists, with physicians verifying information and approving final changes). In addition, policies and procedures likely need to be put in place to increase implementation: 1) distributing effort among office staff, including medical assistants, nurses, and pharmacists (with HIT designed to accommodate distribution of effort, for example, with co-sign functions); 2) sending email reminders to PCPs if medications are not reconciled within 30 days; 3) replacing the existing EMR medication list with the discharge list if patients do not have a Partners PCP. Collectively, these efforts may improve medication safety during and after transitions in care.

### **List of Publications, Products, and CERT Leveraged Products**

1. A web-based slide deck describing the Medication Reconciliation's tool's functionality is now available and has been uploaded onto CERT Central for dissemination.
2. Post- Discharge Medication Reconciliation Electronic Tool
  - An electronic tool that prompts primary care physicians to perform medication reconciliation at the first post-discharge outpatient visit, clearly displays and organizes preadmission and discharge medication regimens, and facilitates the creation of the new post-discharge medication list with just a few keystrokes.
  - Detailed description of functional specifications based on current medication reconciliation module is available on the CERT Website to allow for use/ modification by others.
3. Poon EG, Blumenfeld B, Hamann C, et al. Design and implementation of an application and associated services to support multi-disciplinary medication reconciliation efforts at an integrated healthcare delivery network. *J Am Med Inform Assoc* 2006;13:581–592.
4. Schnipper, Jeffrey. "Medication reconciliation: successes, failures, and why it is so hard" Invited Speaker, Workshop, Society of General Internal Medicine, Toronto, ON, Canada, April 2007.  
Schnipper, Jeffrey. Chair, Summit on Medication Reconciliation, Joint Commission on Accreditation of Healthcare Organizations, 2007.
5. Schnipper JL, Gandhi TK, Wald JS, et al. Design and implementation of a web-based patient portal linked to an electronic health record designed to improve medication safety: the Patient Gateway medications module. *Inform Prim Care*.2008;16(2):147-55.
6. Turchin A, Hamann C, Schnipper JL, et al. Evaluation of an inpatient computerized medication reconciliation system. *J Am Med Inform Assoc*. 2008 Jul-Aug;15(4):449-52.
7. Schnipper JL. Medication discrepancies and medication reconciliation. In: McKean SCW, Bennett AL, Halasyamani LK, editors. *Hospital Medicine: Just the Facts*. New York, NY: McGraw-Hill; 2008. P. 24-30.
11. Pippins JR, Gandhi TK, Hamann C, et al. Classifying and predicting errors of inpatient medication reconciliation. *J Gen Intern Med*. 2008;23(9):1414-1422.
12. Schnipper, JL. "Reconciling medications after hospital discharge: development and evaluation of an electronic tool." March 6, 2009. <http://clinicalhelp.partners.org/test/DisMedRec.htm>
13. Schnipper JL, Hamann C, Ndumele CD, et al. Effect of an electronic medication reconciliation application and process redesign on potential adverse drug events: a cluster-randomized trial. *Arch Intern Med* 2009;169(8):771-780.
14. Schnipper, Jeffrey. "Electronic medication reconciliation." Roundtable Invited Talk, Canadian Patient Safety Institute, Toronto, ON, Canada, 2009.
15. Schnipper, Jeffrey. "Implementation of Medication Reconciliation at the Practitioner Level." Invited Speaker, Webinar, National Quality Forum, 2009.
16. Schnipper, Jeffrey. "Medication reconciliation and its role in improving patient safety." Invited Speaker at Transitions in Care/Grand Rounds Emerson Hospital, Concord, MA, 2010.

17. Schnipper, JL. Assessment of improvements to IT-based medication reconciliation. (Abstract), Society of Hospital Medicine Annual Meeting, Washington, DC, 2010.
18. Schnipper, Jeffrey. "Medication reconciliation: improving medication safety during transitions in care." Invited Speaker, Division of General Medicine, Vanderbilt University Medical Center, Nashville, TN, 2010.
19. Schnipper JL, Liang CL, Hamann C, et al. Development of a tool within the electronic medical record to facilitate medication reconciliation after hospital discharge. *J Am Med Inform Assoc.* 2011;18(3):309-313.
20. Schnipper JL, Hamann C, Karson AS, et al. Effects of an electronic post-discharge medication reconciliation tool on the accuracy of ambulatory medication documentation. Society of General Internal Medicine 34<sup>th</sup> Annual Meeting, Phoenix, AZ, May 7, 2011.
21. Schnipper JL. "Implementing best practices at your medical center through computerized clinical decision support (CDS)." Society of General Internal Medicine 34<sup>th</sup> Annual Meeting, Phoenix, AZ, May 7, 2011.
22. Schnipper, Jeffrey. "Optimizing medication safety at transitions in care: the value proposition of medication reconciliation." Keynote Address, Canadian Patient Safety Institute, National Summit on Medication Reconciliation, Toronto, ON, Canada, 2011.
23. Schnipper JL. Medication Safety: are we there yet? *Arch Intern Med.* 2011;171(11):1019-1020.
24. Schnipper JL, Gandhi TK, Wald JS, et al. Effects of an online personal health record on medication accuracy and safety: a cluster-randomized trial. *J Am Med Inform Assoc.* 2012; 19(5):728-734.
25. Cohen MJ, Shaykevich S, Cawthon C, Kripalani S, Paasche-Orlow MK, Schnipper JL. Predictors of medication adherence post-discharge: the impact of patient age, insurance status, and prior adherence. *J Hosp Med.* 2012;7:470-475.
26. Kripalani S, Roumie CL, Dalal AK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: a randomized controlled trial. *Ann Intern Med.* 2012;157:1-10.
27. Mueller SK, Cunningham Sponsler K, Kripalani S, Schnipper JL. Hospital-based medication reconciliation practices: a systematic review. *Arch Intern Med.* 2012;172(14):1057-1069.
28. Salanitro AH, Osborn CY, Schnipper JL, et al. Effect of Patient- and Medication-Related Factors on Inpatient Medication Reconciliation Errors. *J Gen Intern Med.* 2012;27(8):924-932.
29. Schnipper JL, Rothschild JM. Improving Medication Safety. *Lancet.* 2012;379(9823): 1278-1280.

## E. Impact of Vendor Systems on Ambulatory Medication Safety

### Purpose

The purpose of this project was to determine the effects of electronic prescribing on medication safety, including medication errors, near misses and preventable adverse drug events (ADEs), in the ambulatory setting.

**Objective:** The specific aim of this study was to compare the effects of different vendor-based electronic prescribing systems on ambulatory medication safety in various settings, including rural and underserved areas, and to determine the effects of electronic prescribing systems on ambulatory medication safety over time, comparing medication safety among recent adopters (who adopted electronic prescribing < 6 months ago) to experienced users (who have been using electronic prescribing for ≥ 1 year).

### Scope

**Background/context:** Medication errors are defined as errors in drug ordering, transcribing, dispensing, administering or monitoring. This study occurred as part of a larger effort to evaluate the impact of health information technology and health information exchange initiatives in the HEAL NY program. This larger effort was conducted by the Health Information Technology Evaluation Collaborative (HITEC), a multi-institutional entity that the investigators of this application were directing. HITEC is working closely with New York State, AHRQ's National Resource Center and the eHealth Initiative. We expected to find variations in the effectiveness of different vendor-based e-prescribing systems for improving ambulatory medication safety.



Variation in the effectiveness of vendor-based electronic prescribing systems has important policy implications. For example, characteristics of effective systems could be used to guide more stringent future certification requirements for e-prescribing, or help in the development of best practices for implementation of systems and training for providers. We expected to find larger effects of e-prescribing systems over time as users became more experienced with system and due to iterative refinement in the clinical decision support.

**Setting:** Our study took place in several communities located in New York. We selected these communities in order to assemble a study population with the following characteristics: use of multiple different vendor-based systems across the communities, communities with providers we could study longitudinally, and inclusion of urban underserved and federally defined rural areas.

**Participants:** We enrolled twenty providers in rural Hudson Valley, New York and seventeen providers in New York City. There are multiple different vendor-based e-prescribing systems being implemented among these communities and various different health information exchange systems within these communities.

## Methods

**Study Design:** Although a randomized design would have been desirable, it was not feasible because individual physicians choose to adopt rather than being assigned to electronic prescribing. Therefore, we utilized a retrospective cohort design, examining providers early after implementation and after more sustained use. We used historical data from providers in the same communities to establish baseline rates.

**Data Sources:** For all providers included in the study, we obtained electronic prescription downloads at 3 months post implementation and 1 year post-implementation.

## Measures:

As per our previous methodology, the first 3 prescriptions per patient (to limit patient clustering) were reviewed for errors by a nurse data collector. Using previously developed standardized forms, the data collector determined the type of error. When an error with the potential for harm was noted or when a drug often used to treat an ADE was prescribed, a chart review was performed to determine any sequelae from the error. The research nurse presented all suspected near misses and ADEs to two physician reviewers, who independently classified them as ADEs, near misses, medication errors, or exclusions. Using the Naranjo algorithm[14], the physicians rated ADEs and potential ADEs according to preventability, and the likelihood that the incident was due to the specific drug. Whenever an error with the potential for harm was noted, the prescribing physician was notified.

## Results

*Hudson Valley, NY:* We analyzed 1629 prescriptions at 3 months post-implementation and 1738 prescriptions at one year post-implementation. Use of e-prescribing resulted in very low error rates (5.9 errors per 100 prescriptions). These low rates were sustained over time but without further improvement (5.9 versus 4.5 errors per 100 prescriptions,  $p = 0.15$ ).

*In New York City:* Prescriptions were analyzed at 3 months post-implementation ( $n=1283$ ) and at one year post-implementation ( $n=1386$ ). Error rates were 10.7 per 100 prescriptions at baseline and 11.7 per 100 prescriptions at 1 year ( $p = 0.37$ ).

We found relatively low overall error rates that were no different early during implementation and after sustained use, supporting our conclusion that extensive support for implementation and training can help minimize patient safety threats early after transitioning to a new e-prescribing system and lead to sustained low rates in the long-term.

## Significance/Implications:

This study found that extensive support for providers before, during, and after implementation may help mitigate potential safety threats from implementation of an EHR system and result in sustained safety benefits over the long-term. Relatively low error rates were found, both during implementation and during sustained use among practices with support for use of a new e-prescribing system.

## List of Publications, Products, and CERT Leveraged Products

1. Abramson, EL, Pfoh E, Barron, Y, Quaresmio J, Kaushal R. The Effects of Electronic Prescribing by Community-Based Providers on Ambulatory Medication Safety. Under Review.
2. Practical Approaches to Using Electronic Health Records for Research: Challenges and Mitigation Strategies. *The Agency for Healthcare Research and Quality*. March 15, 2011.
3. Abramson EL, Pfoh E, Edwards A, Zigmont K, Kaushal R. The Effects of Electronic Prescribing on Prescribing Safety in an Urban, Underserved Setting. In Preparation.

## F. Identification of a Common Set of Clinical Decision Support Rules

### Purpose

The purpose of this project was to convene a panel comprised of expert clinical informaticians, providers (physicians, nurses, and pharmacists) and regulatory agencies, to identify high value clinical decision support rules. The rules were generated from the knowledge base used in one research and practice setting (Boston site). These rules were vetted with the expert panel and the intention was to produce a list that could then be reformulated as needed so as to offer a high likelihood of successful implementation into a variety of other electronic health record (EHR) systems and practice settings.

**Objective:** The specific aim of this study was to produce a starter set of rules of high potential value for safety and quality ready for implementation in EHRs across settings.

### Scope

**Background/context:** The intent of this project was to begin one aspect of the Clinical Decision Support Roadmap as developed and described by the American Medical Informatics Association (AMIA) team in its contract for the Office of the National Coordinator for Health Information technology (ONC).

**Setting:** Partners HealthCare

**Participants:** Working with Dr. Bates and his team in Boston, AMIA assembled a small group of expert clinical informaticians to review a candidate list of perceived 'best practices' decision rules developed over the years for use in the Boston setting. The team focused on preventive care reminders and medication decision support rules related to drug-drug interactions and therapeutic duplications for providing clinical decision support in EHRs.

### Methods

The AMIA team, in collaboration with the Boston group then assessed which of these were perceived by the group to have sufficient value and potential to be incorporated into EHRs. The group offered their assessment based on their expertise and the capabilities available with home-grown and commercially available EHRs and medication knowledge bases

A review of how decision support rules are implemented in the EHRs of major vendor products on the market was undertaken to ascertain which candidate rules were identified for further study.

**Data Sources:** The guidelines and decision support rules developed by Partners Healthcare which have already been catalogued were the subject of the review and these were the primary data sources, though rules developed elsewhere were considered for testing.

**Measures:** Rules were evaluated for their either quantitative or qualitative usefulness in improving quality as defined by the IOM Chasm report features of safety, timeliness, patient-centeredness, effectiveness, efficiency, and equity for both individuals and populations as experienced at Partners Healthcare.

### Results/Implications

This project developed a starter set of clinically significant rules on medication-related CDS that could be implemented in clinical information systems across health care settings. While actual implementation of the decision support rules in other settings testing ease and feasibility of implementation and potential for broad

scalability was beyond the scope of this project, best-practice recommendations were developed with respect to 'how-to' forms, e.g., usability designs, plus a implementation guide containing implementation 'pearls' as well as an educational programs for use in the AMIA 10x10 program. Information about the starter set and associated recommendations have been widely disseminated through published articles in Health Affairs, BMJ Quality & Safety, JAMIA, and the Journal of Patient Safety.

### List of Publications, Products, and CERT Leveraged Products

1. Clinical decision support content related to the paper "Best practices in clinical decision support: the case of preventive care reminders." This is posted online at the Clinfowiki: [http://www.informatics-review.com/wiki/index.php/Preventive\\_care\\_reminders](http://www.informatics-review.com/wiki/index.php/Preventive_care_reminders).
2. Cresswell KM, Bates DW, Phansalkar S, Sheikh A. Opportunities and challenges in creating an international centralised knowledge base for clinical decision support systems in ePrescribing. *BMJ Qual Saf.* 2011 Jul;20(7):625-30. Epub 2011 May 23.
3. Classen DC, Phansalkar S, Bates DW. Critical drug-drug interactions for use in electronic health records systems with computerized physician order entry: review of leading approaches. *J Patient Saf.* 2011 Jun;7(2):61-5. Review.
4. Seidling HM, Phansalkar S, Seger DL, Paterno MD, Shaykevich S, Haefeli WE, Bates DW. Factors influencing alert acceptance: a novel approach for predicting the success of clinical decision support. *J Am Med Inform Assoc.* 2011 Jul-Aug;18(4):479-84.
5. Zachariah M, Phansalkar S, Seidling HM, Neri PM, Cresswell KM, Duke J, Bloomrosen M, Volk LA, Bates DW. Development and preliminary evidence for the validity of an instrument assessing implementation of human-factors principles in medication-related decision-support systems--I-MeDeSA. *J Am Med Inform Assoc.* 2011 Dec;18 Suppl 1:i62-72. Epub 2011 Sep 21.
6. Phansalkar S, Wright A, Kuperman GJ, Vaida AJ, Bobb AM, Jenders RA, Payne TH, Halamka J, Bloomrosen M, Bates DW. Towards meaningful medication-related clinical decision support: recommendations for an initial implementation. *Appl Clin Inf* 2011;2(1):50-62.
7. Dalal AK, Poon EG, Karson AS, Gandhi,TK, Roy C, Lessons Learned From Implementation of a Computerized; Application for Pending Tests at Hospital Discharge, *Journal of Hospital Medicine* (online) 6(1):16-21, 2011 Jan
8. Kesselheim AS, Cresswell K, Phansalkar S, Bates DW, Sheikh A. Clinical decision support systems could be modified to reduce 'alert fatigue' while still minimizing the risk of litigation. *Health Aff (Millwood)*. 2011 Dec;30(12):2310-7.
9. Schiff GD, Galanter WL, Duhig J, Lodolce AE, Koronkowski MJ, Lambert BL. Principles of conservative prescribing [Review]. *Archives of Internal Med* 171(16): 1433-40, 2011 Sep 12
10. Schiff, G. Medical Error: A 60 year old Man with Delayed Care for a Renal Mass: Clinical Crossroads, *Journal of the American Medical Association*. May 11, 2011.

## References

1. Gandhi, T.K., et al., *Outpatient prescribing errors and the impact of computerized prescribing*. J Gen Intern Med, 2005. **20**(9): p. 837-41.
2. Gandhi, T.K., et al., *Adverse drug events in ambulatory care*. N Engl J Med, 2003. **348**(16): p. 1556-64.
3. Forster, A.J., et al., *Adverse drug events occurring following hospital discharge*. J Gen Intern Med, 2005. **20**(4): p. 317-23.
4. Aspden, P., et al., *Preventing Medication Errors*, T.I.o. Medicine, Editor. 2007, The National Academies Press: Washington, DC.
5. Shrank, W.H., et al., *The quality of pharmacologic care for adults in the United States*. Med Care, 2006. **44**(10): p. 936-45.
6. Sequist, T.D., et al., *A randomized trial of electronic clinical reminders to improve quality of care for diabetes and coronary artery disease*. J Am Med Inform Assoc, 2005. **12**(4): p. 431-7.
7. Kawamoto, K., et al., *Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success*. BMJ, 2005. **330**(7494): p. 765.
8. Shekelle, P.G., S.C. Morton, and E.B. Keeler, *Costs and benefits of health information technology*. Evid Rep Technol Assess (Full Rep), 2006(132): p. 1-71.
9. Ash, J.S., M. Berg, and E. Coiera, *Some unintended consequences of information technology in health care: the nature of patient care information system-related errors*. J Am Med Inform Assoc, 2004. **11**(2): p. 104-12.
10. CITL. *HIEI: healthcare information exchange and interoperability*. 2006 [cited 2012 November 1]; Available from: <http://www.citl.org/> .
11. Osheroff, J.A., et al., *A roadmap for national action on clinical decision support*. J Am Med Inform Assoc, 2007. **14**(2): p. 141-5.
12. Finnell, J.T., et al., *Community clinical data exchange for emergency medicine patients*. AMIA Annu Symp Proc, 2003: p. 235-8.
13. Walker, J., et al., *The value of health care information exchange and interoperability*. Health Aff (Millwood), 2005. **Suppl Web Exclusives**: p. W5-10-W5-18.
14. Naranjo, C.A., et al., *A method for estimating the probability of adverse drug reactions*. Clin Pharmacol Ther, 1981. **30**(2): p. 239-45.
15. Bates, D.W., et al., *Incidence of adverse drug events and potential adverse drug events. Implications for prevention*. ADE Prevention Study Group. JAMA, 1995. **274**(1): p. 29-34.