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TITLE

The Effect of EMR on Medication Safety: A SPUR-Net Study

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ABSTRACT

PURPOSE

The primary objective of the study was to determine the frequency, type, severity, and preventability of medication errors (MEs) in primary care settings that used an electronic medical record (EMR) with computerized provider order entry (CPOE) that had clinical decision-support system (CDSS) features at the point of care compared with primary care settings where a paper medical record (PMR) without CPOE and CDSS features was used.

SCOPE

Little information about the effect of EMR on outpatient primary care medication safety had been available. This project assessed MEs in four primary care outpatient clinics affiliated with the Southern Primary Care Urban Research Network (SPUR-Net);two clinics used an EMR, and another two used a PMR.

METHODS

This cross-sectional observational study included three study phases: 1) patient recruitment and eligibility screening during an index visit; 2) phone assessment for medication therapy information; and 3) chart review for medication-related information.

RESULTS

Our preliminary data analyses showed a total of 3,041 or 25% MEs (11% from EMR clinics and 14% from PMR clinics). Medication discrepancy was 82% in EMR clinics and 33% in PMR clinics. The overall MEs were classified into four types:prescribing (6%), dispensing (1%), administering (2%), and monitoring (15%). The EMR appeared to help prevent certain MEs (e.g., documentation or monitoring errors) while creating other types of MEs (e.g., prescribing errors due to missing information or errors in spelling). The EMR was associated with increased medication counseling in primary care clinics.

KEY WORDS

Computerized Medical Records System; CPOE or Computerized Physician Order Entry; Medication Error; Outpatient or Ambulatory Care

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PURPOSE

The primary objective of the study was to determine the frequency, type, severity, and preventability of medication errors (MEs) in primary care clinics that used an electronic medical record (EMR) with computerized provider order entry (CPOE) that had clinical decision-support system (CDSS) features at the point of care compared with primary care clinics where a paper medical record (PMR) without CPOE and CDSS features was used.

SCOPE

BACKGROUND

Every year, 44,000 to 98,000 people in the US die as a result of medical errors. A medication error (ME) is a common type of medical problem in both the outpatient and the inpatient settings.¹ It is estimated that 770,000 people each year experience adverse drug events (ADEs) that result in injury or death, and the costs of such events are estimated to total \$2 billion, or more than \$2,000 per event (excluding the cost of litigation and the patient's economic losses). These data are derived predominantly from the hospital inpatient setting, where it is easier to monitor such problems and identify patients experiencing ADEs. The path from the time a prescription is ordered to the time the patient actually receives the medication can be better traced in the inpatient setting because of its closed circuit. However, most patients in the US obtain prescriptions from primary care physicians. In 2001 alone, 3 billion prescriptions were dispensed in US pharmacies, with retail prescription drug expenditures totaling \$166 billion.² Researching medication safety in the outpatient setting is challenging because it involves separate entities, including the prescriber, the dispenser, and the patient/ consumer, in an open circuit.

The National Coordinating Council for Medication Error Reporting and Prevention³ defines a "medication error" as follows: "A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use." An ME is different from an ADE in that not all MEs result in an ADE. On the other hand, an ADE may have resulted from an ME or from adverse drug reactions not associated with an ME.^{4, 5}

MEs in busy outpatient clinics could come from:

- Communication errors (e.g., illegible handwriting)
- Failure to maintain an accurate list of current medications or history of drug allergies
- Failure to order the appropriate medication (including selection, dose, route of administration, frequency, and directions)
- □ Failure to detect adverse drug-drug, drug-disease, or drug-dietary supplement interactions at the point of care (i.e., at the prescribing stage)
- Failure to order appropriate toxic/therapeutic monitoring tests (e.g., laboratory tests, EKGs)
- Writing prescriptions that are not on the formulary for the insurance company, which wastes time, because corrections must be made, so the initiation of therapy is delayed.

Methods to ensure medication safety include the use of computerized physician order entry (CPOE) features with decision-support tools. CPOE is thought to provide benefits such as decreased medication errors, improved resource utilization, and improved quality of care.⁶⁻¹⁸ Published data thus far are predominantly from studies conducted in the hospital inpatient setting. Summary of the previous studies evaluating the effects of CPOE on MEs and ADEs are listed below:

Reference	Setting	Outcomes	Results
Bates DW, et al. JAMA	Innotiont	Serious ME	Decreased 55% (p=0.01)
1998;280(15):1311-6 ¹⁹	Inpatient	Potential ADEs	Declined 84% (p=0.002)
Bates DW, et al.	Innationt	ME rate	Decreased 81%
JAMIA 1999;6:313-21 ¹¹	Inpatient	Serious ME	Decreased 86%
Gandhi TK, et al. J Gen Intern Med 2001;16(S1):195 (abstract) ²⁰	Outpatient (CPOE without decision support)	ADE	Decreased ADE rate by >50%
Grasso BC, et al. Psychiatr Serv. 2002 Oct;53(10):1325- 6 ²¹	Inpatient (PDA)	ME (before and after)	Decreased from 22% to 8% (>50%)

Table 1. PREVIOUS STUDIES EVALUATING THE EFFECTS OF CPOE ON MEs AND ADEs

Medication safety research in the primary care outpatient setting is in its beginning stage. A recent publication in the New England Journal of Medicine by Gandhi et al.²² reported their patient survey findings from four hospital outpatient clinics and found the incidence of ADEs to be approximately 25%. In another study, Dovey et al. found that US family physicians reported MEs to be among the top-five most commonly reported medical errors, including errors in ordering medications (13%) and errors in implementing medication orders (6%).¹ Literature is lacking in the area of the effect of the EMR on ME epidemiology, type, severity, and preventability in the primary care setting. The frequency of MEs in the outpatient setting is being studied with reporting systems and chart reviews, but direct observation comparing the effect of the EMR and PMR has not been widely applied. Furthermore, the prevention of MEs in primary care clinics may require different strategies from those shown to be effective in inpatient care and is likely to include building effective communication between providers and patients. Computer technologies that check for allergies or drug interactions may be useful in reducing MEs, but such technology has yet to be shown to improve ME rates in the outpatient setting. Furthermore, the process of care in promoting medication safety across multiethnic, multicultural, and socioeconomically diverse patient populations has not been compared.

The primary objective of the study was to determine the frequency, type, severity, and preventability of MEs in primary care clinics that used an EMR with CPOE that had CDSS features at the point of care compared with primary care clinics where a PMR without CPOE and CDSS features was used. Our hypothesis was that the EMR would reduce the frequency, type, and severity of MEs and would help prevent common MEs.

CONTEXT

Medication use in the outpatient setting is ubiquitous; however, little information about medication safety is currently available from this setting. Understanding the severity and type of medication errors will help us design effective strategies in reducing such errors.

SETTINGS

This project assessed the frequency, type, severity, and preventability of ME in primary care outpatient clinics affiliated with an urban, practice-based research network, the Southern Primary Care Urban Research Network (SPUR-Net). At the start of the study, the network had five member organizations, ranging from clinics that provided healthcare to homeless patients and community health centers to clinics that provided care to privately insured patients.

PARTICIPANTS

Though it would be interesting to include all these demographic groups in our study, the study did not include homeless patients because of vast differences in medication prescribing and delivery. Consequently, we recruited four clinics representing each of the remaining health organizations; two clinics used an EMR, and another two used a PMR. Unfortunately, one of the member organizations declined to participate, even though co-investigators and clinicians onsite were enthusiastic about the study. This was because the organization's attorney and members of their education and research board withheld approval for this study out of fear of the potential litigations that could result from study findings. Although we sought advice from various nationally recognized researchers and from lawyers in general counsel offices at AHRQ, the PBRN Resource Center, the Texas Department of Health, out-of-state institutions that conducted research on patient safety, and our home institutions, we were unable to assuage the concerns of the attorney. Despite this setback, we recruited another healthcare organization to join SPUR-Net. Their family medicine clinic, which matched other participating clinics in patient volume and physician numbers, agreed and participated in this study.

We had originally planned to conduct the study at the four clinical sites simultaneously, but the unexpected delay necessitated that we begin the study at the three clinics that had IRB approvals. This change in the study protocol affected the total number of patients who completed the study but did not affect the outcomes of the study, because the four study sites were independent clinics that were physically separated from each other. Adopting this strategy also proved to be beneficial because one of the clinics no longer offered onsite residency training after our study was completed; all the other three clinics continued to be residency training sites.

Eligibility criteria for participating patients were:

- Men and women at least 18 years of age
- · Patients receiving a new prescription during the index office visit
- · Patients already taking at least one other prescribed medication
- Patients who signed the study consent form
- Patients who were willing to participate in one telephone follow-up session
- Patient who were English speaking

Our recruitment goal was a total of 500 patients, 250 from EMR clinics and 250 from PMR clinics. The unexpected study delay decreased the participant recruitment to a total of 432 patients: 250 from EMR clinics (125 from Clinic A and 125 from Clinic B) and 182 from PMR clinics (124 from Clinic C and 58 from Clinic D). On average, 10 patients were recruited per week as planned.

Across sites, 2,568 patients were approached for screening; 460 patients were not interested in the study, and another 1,514 patients did not meet the eligibility criteria. Of the remaining 594 patients who were eligible by screening and willing to participate in the study, 432 (73%) patients successfully completed the study between January 2004 and March 2005 (159 patients were lost to follow-up and three patients withdrew from the study).

In total, 432 patients were included in the study analysis. Over two thirds of the 432 participants who completed the study were women (73%), were in their early fifties (average age 52), and were taking seven to eight medications. The EMR and PMR clinics served patients from diverse backgrounds in race/ethnicity (see Table 2), and the race and ethnicity distributions between the EMR and PMR clinics were similar (White 59%, Hispanic 13%, Black 25%, Asian, and other 3%); so were the chief complaint types for the two groups of patients (acute visits 53%, chronic disease management 31%, and health maintenance 16%). However, the majority of EMR patients (81%) had at least some college education compared with half of patients in the PMR group (53%). More EMR patients had received care at their clinics for longer than 3 years compared with PMR patients (47% EMR vs. 38% PMR).

Table 2. ENROLLMENT TABLE

Targeted/Actual Enrollment Table						
Study Title: The Effect of EMR on Medication Safety: A SPUR-Net Study						
Total Planned Enrollment: 500						
TARGETEI	D/ACTUAL E	ENROLLM	ENT: 432			
Ethnic Category	Sex/Gender (Targeted)			Sex/Gender (Actual)		
	Females	Males	Total	Females	Males	Total
Hispanic or Latino	38	38	76	42	15	57
Not Hispanic or Latino	212	212	424	274	101	375
Ethnic Category Total of All Subjects*	250	250	500	316	116	432
Racial Categories						
American Indian/Alaska Native	0	0	0	0	0	0
Asian	10	10	20	4	4	8
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0
Black or African American	52	52	104	90	20	110
White	188	188	376	219	91	310
Racial Categories: Total of All Subjects *	250	250	500	63	27	428

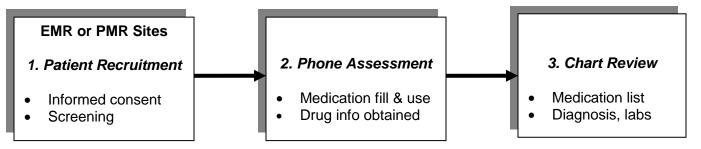
Note: One Hispanic female patient did not answer the question about her racial category; two other female patients and one male patient indicated "other" as their racial category.

METHODS

STUDY DESIGN

This cross-sectional observational study included three study phases, as depicted in the following flow chart (see Figure 1).

Figure 1. STUDY FLOW CHART



Phase 1 Patient Recruitment – The research assistant recruited patients at primary care clinics and screened their eligibility during a study index visit to make sure they met study criteria.

Phase 2 Phone Assessment – The research fellow called patients and evaluated their medication therapy (prescription drugs and over-the-counter [OTC] products), including the process of prescription fill at the pharmacy, medication use (e.g., compliance), reactions (side effects and adverse reactions), and any medication counseling they had/had not received from their physicians and pharmacists.

Phase 3 Chart Review – The research assistant and the research fellow reviewed patient charts for information pertaining to medication therapy and management.

DATA SOURCES/COLLECTION

Patient recruitment was conducted at the four participating clinics, with two clinics using the same EMR with CPOE features (Logician) and two clinics using the traditional PMR method for medication prescribing. Data sources came from patient interview (recall) and chart review collected by research assistants and the research fellow.

As we proposed, during the first 3 months, we modified the data intake forms from the Brigham and Women's Hospital Patient Safety Research Group and incorporated the classification system of medication errors from the National Coordinating Council for Medication Error Reporting and Prevention. We also formulated a list of medication categories for coding purposes. In addition, data entry forms with interactive features in Microsoft Access format were successfully designed.

To date, we have completed data collection for 432 patients, including patient recruitment, telephone assessment, and chart review.

INTERVENTIONS

No intervention was introduced in this study. The EMR with COPE features had already been in use for approximately 5 years in the two EMR clinics.

MEASURES

The primary endpoint in the study was medication error. This descriptive study assessed the frequency, type, severity, and preventability of medication errors in primary care clinics. Medication errors between EMR and PMR clinics were compared.

Medication error nodes (i.e., when the error was thought to have occurred) included prescribing, dispensing, administering, and monitoring errors. The prescribing error was evaluated based on the accuracy and inclusion of dose, route, and frequency from the patient's own description of their medication use or the information retrieved on the medication list in the chart by the research assistants; selection of appropriate medications, drug interactions, and medication allergy history were also assessed. The dispensing error was evaluated based on the patient's read back from medication bottles (i.e., instruction on the prescription bottles and directions for OTC or supplement use by the patient). The administering error was evaluated based on the patient's self-report of their medication use patterns and adherence. The monitoring error was evaluated mainly based on any discrepancy between what the patient said they were taking and what was actually recorded in the medical records; laboratory parameters, if available in the medical records, were retrieved and assessed as well.

LIMITATIONS

Because the study approval was withheld by one organization due to fear of potential litigations that could result from the study findings, the study was delayed. Even though we were successful in recruiting another site that matched well with the other three study sites, we only had sufficient time and resources to include 58 instead of 125 patients from the fourth clinic for the study.

In addition, limitations of the study included patient recalls and system-related limitations. We did not scan the original prescriptions (written or printed) given by primary care physicians, nor did we look at the original medication bottle dispensed from pharmacies. Instead, we collected data based on patient recalls, which may not be accurate even though we double checked the information in the patient's medical records and asked the patient to read to us medication instructions printed on the prescription bottle. System-related limitations we discovered during the study included computer fields that were not required fields (e.g., the oral route was systematically missing from the EMR sites) and medication lists kept in the medical charts that were incomplete, particularly in the PMR clinics.

This study might not have accurately estimated any dispensing errors and might have underestimated the monitoring errors. Because the study was not conducted at pharmacies, dispensing errors (potential or actual) could not be captured in the study unless the patient reported having a problem obtaining their medications from the dispensing pharmacy. Monitoring errors pertaining to appropriate laboratory tests were likely to be underestimated, because we did not collect every recommended laboratory test for all the medications (e.g., data regarding INR frequency and levels were not collected).

Furthermore, this study was limited by not having sufficient resources and personnel to conduct patient interviews in languages other than the English language. There were quite a few Spanish-speaking patients who were interested in participating in this study but were not eligible.

RESULTS

PRINCIPAL FINDINGS

Based on data collected from 432 patients, 3,069 medications (1,632 medications from EMR clinics and 1,437 medications from PMR clinics) were documented and/or reported for use. Averages of seven (\pm four) medications and eight (\pm five) medications were reported for use by patients from the EMR and PMR clinics, respectively, including an average of five (\pm three) prescription medications from EMR clinics and six (\pm four) medications from PMR clinics.

Our preliminary data analyses showed a total of 3,041 or 25% MEs (1,377 errors or 11% from EMR clinics and 1,664 errors or 14% from PMR clinics). Most medications reported as used by patients were listed in the electronic medical records (82%), whereas only one third of medications reported as used by patients were listed in the paper medical records (33%). The overall MEs that were identified were classified into four types: prescribing (6%), dispensing (1%), administering (2%), and monitoring (15%) (Table 3).

The medication error nodes, when stratified among all the errors, were distributed as follows (Table 3):

ME Nodes	Overall MEs	Within MEs	Within EMR	Within PMR
Prescribing	6%	25%	34%	18%
Dispensing	1%	5%	11%	1%
Administering	2%	9%	13%	5%
Monitoring	15%	61%	43%	76%

Table 3. MEDICATION ERROR NODES

The severity of all errors in relation to causing adverse drug events (ADEs) was as follows: no potential for ADE (5%), potential for significant ADE (68%), and potential for serious ADE (30%). The preventability of the total errors by CPOE features was estimated to be 86% (94% in PMR clinics and 75% by additional CPOE features in EMR clinics).

The overall medication adherence, as reported by patients, was found to be 63% (60% EMR clinics vs. 66% PMR clinics). The use of EMR was significantly related to medication counseling recalled by patients, reported to have been given by primary care physicians at the point of care—particularly written counseling for both indications and side effects and oral counseling for side effects.

The following analyses are in progress:

a. Final checks on all MEs. Certain MEs may need to be discarded from the final analysis. For example, in the preliminary analysis, the omission of medication route in the medical record

was counted as an ME. However, because the majority of medications prescribed in the outpatient setting were intended for the oral route, errors identified from prescriptions or records that did not include an oral route for medications that were only available for oral use will be discarded in final analyses.

- b. Once the final identification of MEs is complete, the comparison of ME rates between patients in the EMR and PMR groups will be conducted using the chi-square test. The median number of MEs per patient will be compared between the two groups using a Wilcoxon rank sum statistic. Error rates adjusting for patient background (gender, ethnicity, age, and educational level), medication class, and number of visits will also be evaluated. A multivariate logistic regression model will be employed. Adjusted odds ratios and 95% confidence intervals will be calculated for each effect in the logistic regression model.
- c. Severity of error will be compared between the two groups using a Mantel-Haenszel chisquare test for trend, which takes into account an ordered response variable (severity of error) between the two groups. Severity of error may be grouped into categories and compared between the two groups using multinomial logistic regression for outcomes that have more than two levels.

OUTCOMES

In the outpatient primary care setting, the use of EMR with some CPOE features is associated with decreasing certain MEs, such as medication discrepancies (i.e., medications patients say they take and medications listed in the medical records). However, it is also associated with increasing certain other types of MEs, such as prescribing errors (e.g., missing information or errors in spelling). The directions printed on medication bottles seemed to have greater consistency with EMR-generated prescriptions. The medication adherence rate was higher for PMR patients than for EMR patients. Additional analyses adjusting for patient characteristics need to be included before conclusions can be drawn.

DISCUSSION

Because EMRs are available in different forms, with various features of CPOE and CDSS, medication errors associated with the use of different EMRs undoubtedly will vary. Our finding of an EMR-associated decrease in medication discrepancies suggests that the EMR is an effective tool for medication reconciliation in the outpatient setting. Our finding of an EMR-associated increase in medication counseling given by primary care physicians reported by patients suggests that the EMR is effective in promoting physician-patient communication about medication information. Additional research is warranted to further explore the effect of different versions or improved versions of the EMR on either medication discrepancies or medication counseling.

Data related to an EMR-associated increase in prescribing errors need to be further stratified, particularly those errors pertaining to missing information on oral administration route. Nevertheless, these data suggest that the EMR can create errors if computer entry fields are not forced or required. An EMR with CPOE features that allow physicians to hand-type prescriptions can create errors in spelling. Though there was more consistency between the information on the printed instruction for prescription bottles and printed prescriptions, prescribing errors could also be more easily transferred to dispensing errors. Our finding of an EMR-associated increase in dispensing error suggests that the pharmacy staff may be more likely to "copy and paste" the information from printed prescriptions to the printed directions on prescription bottles.

Therefore, missing information, such as a missing oral route, was frequently found to be omitted on the prescription labels, too.

The difference in medication adherence rates between EMR and PMR patients indicates that patient characteristics need to be adjusted for in the final analyses, and future studies are warranted.

CONCLUSIONS

An EMR helps prevent certain MEs (e.g., documentation or monitoring errors) while creating other types of MEs (e.g., prescribing errors due to missing information or errors in spelling). The EMR has other beneficial effects, such as increasing medication counseling at the point of care in primary care clinics.

SIGNIFICANCE

The research question about how EMRs affected medication safety is significant to SPUR-Net's continuing research efforts, because it provides us a baseline comparison between various primary care practices. In addition, the data are providing us suggestions on ways to implement new EMR systems as well as ways to upgrade existing EMR features that will impact several large healthcare organizations. Furthermore, the study is helping SPUR-Net explore ways to bridge medication-related communication gaps among a diverse group of primary care providers and their patients.

The study also extends our understanding of MEs in a diverse primary care population and highlights what effects CPOE with CDSS has in increasing or reducing such errors. The study addresses an important deficit in patient safety research, because it provides much-needed information about MEs that occur in the primary care setting. The outcomes of this research are significant, because they provide us a more complete understanding of how primary care patients with diverse backgrounds are impacted and how we can design and implement interventions to prevent MEs in the outpatient setting. Moreover, these outcomes will fundamentally advance our knowledge and the promotion of medication safety.

IMPLICATIONS

The research findings from this study are being used by SPUR-Net--affiliated clinicians and clinic administrators to design EMRs in PMR clinics that are starting to implement the use of an EMR; the findings are also helping EMR clinics find ways to improve CPOE features in order to further decrease MEs. These study findings can be compared by other primary care clinicians, outpatient clinic administrators, and researchers to help reduce outpatient MEs in other sites. The study findings also yield additional evidence to help policymakers make decisions regarding the use of EMR in outpatient primary care clinics. Finally, the study findings provide the basis for designing and implementing improved versions of the EMR to further reduce MEs in the outpatient setting.

LIST OF PUBLICATIONS AND PRODUCTS

We are preparing to submit the following manuscripts once the data analyses are finalized:

- 1. Kuo GM, Seger AC, Adams GJ, Danek LCK, Adkison JD, Hawkins CA, Steinbauer JR, Volk RJ, Spann SJ. The comparison of an electronic medical record and a paper medical record on medication errors in primary care clinics.
- 2. Kuo GM, Spann SJ. The effect of EMR on medication reconciliation in primary care clinics.
- 3. Kuo GM, Mullen PD, Adams GJ, Piller L, Rogers JC. The comparison of electronic and paper-based medication prescribing methods on medication counseling in primary care clinics.
- 4. Kuo GM, Mullen PD. Medication counseling in outpatient pharmacies reported by patients.
- 5. Brown J, Kuo GM. Medication adherence by primary care patients.

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