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ORIGINAL RESEARCH

Medication safety after implementation of a commercial electronic health record system in five safety-net practices: A mixed methods approach

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Abstract

Purpose: This study, conducted in five safety-net practices, including two nurse-managed health centers (NMHCs) and three federally qualified health centers (FQHCs), examined the impact of implementing a commercial electronic health records (EHRs) system on medication safety.
Data source: A mixed methods approach with two sources of data were used: (a) a query of prescription records captured by the EHR retrieving co-prescribed medications with identified drug–drug interaction (DDI) risks, and (b) semistructured interviews with clinicians and leadership about the usability and benefits of EHR-embedded clinical decision support in the form of DDI alerts.
Conclusions: We found an exceptionally low rate of DDI pairs in all five practices. Only 130 "true" DDI pairs were confirmed representing 149,087 visits and 62 providers. Among the 130, the largest categories were related to antihypertensive medications, which are in fact often prescribed together. There were no significant differences between physicians and nurse practitioners on the rate of DDI pairs nor between NMHCs and FQHCs.
Implications for practice: Implementation of an EHR in these five safety-net settings had a positive impact on medication safety. The issue of missing end dates is noteworthy in terms of DDIs and unnecessary alerts that could lead to alert fatigue.

Introduction

Medication errors in both inpatient and primary care settings account for a significant number of adverse events and patient deaths. It is estimated that there are 1.5 million preventable adverse drug events annually in the United States (Institute of Medicine [IOM], 2000, 2006). Electronic health record (EHR) systems hold enormous promise in reducing errors in prescribing in all settings (Kaushal, Shojania, & Bates, 2003; Kuo, Phillips, Graham, & Hickner, 2008; Nemeth & Wessell, 2010). However, much of the research to date has focused more on inpatient settings than on primary care settings (Kaushal et al., 2003; Wang et al., 2009).

At the same time, prescribing errors among community-based providers who do not have EHRs have been documented to be as high as one in every four prescriptions written (Abramson et al., 2012). Other researchers have determined that many of the prescribing errors in these community-based practices could

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Table 1 Description of participating centers

Center name and location	Center type	Annual visit volume	Population served	Type of care
CHC1, Mid-West	FQHC	>42,000	Urban Hispanic and recent Mexican and Puerto Rican	Primary care OB/GYN Internal Medicine Pediatric
CHC2, Mid-West	FQHC	>10,000	Urban, HIV+ gay, lesbian, bisexual, and transgender	Primary care large mental health and substance abuse programs
CHC3, Mid-West	FQHC	>14,000	Urban homeless, migrant, and recent refugee	Primary care mental health OB/GYN
NMHC1, Mid-West	NMHC	9000	College students, staff, and families	Primary care
NMHC2, West Coast	NMHC and FQHC	13,000	Urban, homeless financially disadvantaged	Primary care, mental health complimentary care HIV testing and risk reduction

have been avoided with the adoption of an EHR system that has e-prescribing and decision-support capabilities (Abramson et al., 2012; Kuo et al., 2008). Because of widely anticipated patient safety benefits of EHRs, and known deficiencies with handwritten prescriptions such as poor legibility, the requirement to document and transmit prescriptions has been included as an important component of ambulatory incentive programs such as "Meaningful Use" and Patient Centered Medical Home (PCMH; Blumenthal & Tavenner, 2010; Sia, Tonniges, Osterhus, & Taba, 2004).

And yet, issues related to functionality and usability continue to limit the benefits of EHRs on prescribing errors (Nanji et al., 2011). As an example, findings indicate that alert fatigue is a major problem with the use of EHRs in ambulatory settings (Isaac et al., 2009; van der Sijs, Aarts, Vulto, & Berg, 2006). Overriding drug–drug interaction (DDI) alerts was found to be very common even with high severity alerts in a study based on over 3 million prescriptions, suggesting that current computerized alert functions may actually be inadequate to protect patients (Isaac et al., 2009).

The present study was conducted in five safety-net settings, including two nurse-managed health centers (NMHCs) and three federally qualified health centers (FQHCs), all using the same commercial EHR system. Safety-net settings are critical to addressing the healthcare needs of very vulnerable populations who may seek care more episodically, relocate more often, and have more challenges with the overall healthcare system because of their less consistent access to insurance—all of which can present an escalated level of patient safety issues related to medications. With the literature suggesting high rates of prescribing error among community-based providers who do not have EHRs (Abramson et al., 2012), EHRs hold promise for these settings in terms of managing safer prescribing and clearer documentation of medications. There are only limited data from safety-net providers on the impact of EHRs on prescribing patterns (e.g., Shields et al., 2007); information describing such patterns in NMHCs is nonexistent.

This study was undertaken to better understand the prevalence of medication errors in community primary care settings where a commercial EHR system had been newly implemented. The study utilized access to a centralized research database populated by the EHRs used in five primary care practices to measure the extent to which drug pairs with potential harmful interactions were prescribed simultaneously to the same individual (hereafter, DDI pairs). In addition, semistructured interviews with provider informants were conducted and qualitative analyses were performed to develop themes relating to role of EHR use on medication safety. Study protocols were approved by institutional review boards with Federal Wide Assurance at the Michigan Public Health Institute, University of Michigan, and relevant sites.

Methods

This study was part of a larger project on EHR implementation, clinician utilization, and quality of care funded by the Agency for Healthcare Research and Quality (AHRQ) that began in September 2007 and concluded in September 2011. The characteristics of the five safety-net settings studied are reported in Table 1. These participating heath centers provide primary care services to a variety of populations and are located in multiple states (Illinois, Michigan, and California). All of them utilize a common EHR via a Health Center Controlled Network supported by Alliance of Chicago Community Health Services, a funding partner of the Chicago Health Information Technology Regional Extension Center. Study protocols were approved by institutional review boards with Federal Wide Assurance at the Michigan Public Health Institute, the University of Michigan, and relevant sites.

Table 2 Drug–drug interaction classifications[a]

Severity—the medical risk of the interaction	
3—Major	Interaction may be life threatening or cause permanent damage
2—Moderate	Patient's condition may deteriorate because of interaction, requiring additional care
1—Minor	Designates an interaction that is bothersome, but otherwise not medically detrimental
0—None	Interaction has no documented clinical effect, according to published literature
Certainty—quality and quantity of medical literature supporting the existence of a detrimental interaction	
5—Established	Interaction proven in well-controlled human studies
4—Probable	Pharmacokinetic changes documented and known to be of sufficient magnitude to alter the therapeutic response
3—Suspected	Pharmacokinetic changes possibly documented in well-controlled studies, but relationship between plasma concentrations and pharmacologic effect not confirmed
2—Possible	Pharmacokinetic data, demonstrated pharmacologic response, or case reports suggest a possible interaction. However, quality or quantity of supporting clinical data do not substantiate predictability of interaction
1—Doubtful, unknown	Clinical documentation is of poor quality, or well-controlled studies refute case reports of interaction

[a]From Drug Therapy Monitoring System (DTMS) Reference Manual, Chapter 2—Clinical Definitions and Terminology (Published 05/97, Revised 03/01).

The model for EHR implementation in our project is described elsewhere (removed for review, 2011) and was developed based on the following three premises: (a) an engaging and sustaining relationship with the technology team is the only way to shield healthcare practices from adoption difficulties and uncertainties (i.e., partnership-based); (b) adopting practices should think and act collectively as a community in order to lower purchase and maintenance costs and jointly develop best practices for implementation and use (i.e., community-oriented); and (c) it is central to have strong commitments by all parties to managing EHR implementation as a long-term, continuous quality improvement process, as opposed to a one-time software installation effort. The EHR utilized the Medi-Span drug therapy monitoring system popularly used in commercial EHR products, which provides multiple levels of DDI and allergy alert sensitivity based on an internal twofold classification of potential interactions: (a) the severity of interaction outcomes (Major, Moderate, Minor, None), and (b) level of evidence for interactions (Established, Probable, Suspected, Possible, Doubtful/Unknown). Table 2 defines the categories.

This article draws on two sources of data: (a) a query of prescription records captured by the EHR retrieving co-prescribed medications with identified interaction risks, and (b) semistructured interviews with clinicians and leadership about the usability and benefits of EHR-embedded clinical decision support in the form of DDI alerts. The study operationalized the concept of a "DDI pair" as an instance in which a patient record showed two drugs with documented potential interaction effects and overlapping or partially overlapping in time. Therefore, the DDI pairs used in this research study were obtained through the following two sources. First, the project utilized the DDI Quality Tool developed by the Centers for Medicaid and Medicare Services (CMS) that measures "the percent of Medicare Part D beneficiaries who received a prescription for a target medication during the measurement period and who were dispensed a prescription for a contraindicated medication with or subsequent to the initial prescription" (CMS, 2007). The second set of DDI pairs was compiled by documenting all instances during a preload of medical records into the system at one of the participating health centers, which produced a list of interacting drugs that approximates the DDI database used in Medi-Span. For this method, a DDI pair was identified when the EHR-generated alert met the threshold of a "probable" or "established" "major" interaction (Table 2).

The CMS tool contained 26 common DDI pairs. Another eight DDI pairs were further identified from the preload data at the NMHC, resulting in a total of 34 DDI pairs used in this study. The DDI query was run on the EHR data of the participating health centers and covered all of the 34 possible DDI pairs identified as being prescribed to the same patient with overlapping start and end dates during a 24-month period: September 2008–August 2010. Once the DDI pairs were identified, they were also compared to an additional drug to drug checker (Facts and Comparisons) to validate the levels of severity results the EHR alert gave and to review additional advice for each DDI pair. We also reviewed all DDIs with a pharmacist with expertise in primary care to better understand the nature of these interacting drug pairs and how they are handled by providers in typical patient care practices.

Quantitative data were supplemented with 14 provider interviews, which took place 9–34 months after the EHR "went live." Respondents included four physicians, nine nurse practitioners (NPs), and one psychologist. Interviews were semistructured, with questions centering on the following topics: vision and goals for implementing an EHR, the implementation process, leadership and change management, perceived benefits, key challenges to implementing and using, and the usability of clinical

Table 3 DDI[a] pairs total with overlapping end dates ($N = 641$) and DDI pairs identified as "Definitely" or "Likely" ($N = 130$)

DDI pairs	Source of DDI[b]	All DDI pairs identified ($N = 641$)		DDI pairs of "Definitely" and "Likely" ($N = 130$)	
		n	%	*n*	%
ACE inhibitors + potassium sparing diuretics	CMS	125	19.5	17	13
ARBs (angiotensin II receptor blockers) + potassium sparing diuretics	CMS	39	6.1	10	7.7
Beta blockers + alpha agonists (clonidine)	CMS	110	17.2	22	17
Beta blockers + calcium channel blockers	CMS	122	19.0	23	17.7
Warfarin + NSAID	CMS and preload	74	11.5	19	14.6
Warfarin + thyroid hormones	CMS	18	2.8	3	2.3
Warfarin + macrolide antibiotics	CMS and preload	16	2.5	6	4.6
Warfarin + sulfonamide	CMS	12	1.9	1	0.8
Warfarin + amiodarone	CMS	9	1.4	2	1.5
Warfarin + quinolone	CMS	8	1.2	3	2.3
Warfarin + metronidazole	CMS	5	0.8	3	2.3
Warfarin + dicloxacillin	CMS	2	0.3	–	–
Warfarin + tetracycline	CMS	2	0.3	–	–
Statin + antifungal tabs	Preload	46	7.2	–	–
Statin + calcium channel blockers	Preload	20	3.1	5	3.8
Statin + macrolide	Preload	14	2.2	11	8.5
Statin + prevpac misc	Preload	4	0.6	1	0.8
Hydrochlorothiazide + lithium carbonate	Preload	7	1.1	1	0.8
Potassium chloride + spironolactone tabs	Preload	4	0.6	2	1.5
Methotrexate + trimethoprim	CMS	2	0.3	1	0.8
Digoxin + macrolides	CMS	2	0.3	–	–

[a]DDI, drug to drug interaction.
[b]CMS tool versus preload data.

decision support features including medication safety alerts. Nine interviews were conducted in person and five were completed on the phone.

Interviews were recorded, transcribed, coded, and analyzed using NVivo (QSR International, Doncaster, Australia). We performed inductive open coding of the interview transcripts and used the constant comparison approach to identify salient, recurring themes (Charmaz, 2006; Glaser & Strauss, 1967).

Results

Quantitative analysis results

The DDI query revealed a total of 641 potential DDI pairs across all five health centers over the 24-month period, representing 149,087 visits and 62 providers. Of these visits, 130,459 were from the three FQHCs and 18,628 were from the two NMHCs. A large majority of the providers were from the FQHCs ($n = 57$).

Upon inspection of initial results, the research team questioned the extent to which individual instances are true DDI pairs, or whether apparent DDI pairs may be an artifact of system use. Specifically, examination of these data revealed that 564 of the 641 DDI pairs (88%) had a missing end date on one or both drugs—labeled by the DDI query as "potentially overlapping"—leaving only 77 DDI pairs that were "definitely" overlapping in time (12% of the total 641 DDI pairs) during the study timeframe. Of the 564 DDIs that had one or more missing end dates, 511 (80% of total DDIs) were categorized as "unlikely" because of the fact that their start dates were greater than 1 month apart and/or they were prescribed prior to the beginning of our study period (September 1, 2008). The 53 remaining DDI pairs (8% of total DDIs) with missing end date(s) were considered "likely," as both drugs were prescribed on or after September 1, 2008 and had start dates within 1 month of each other, indicating a higher likelihood that the prescriptions overlapped during the study period. We ultimately decided to restrict our query to include the 77 "definitely" DDI pairs with specifically documented start and end dates and the 53 "likely" DDI pairs for a total of 130 DDIs for 149,081 patient visits. The distribution of all 641 DDI pairs and the distribution of the 130 "definitely" and "likely" pairs are presented in Table 3. Of the 34 possible DDI pairs queried, we found 21 DDI pairs in the 641 sample and 14 DDI pairs in the 130 sample (Table 3).

Of the 77 "definite" DDI pairs, six were from one NMHC and 71 were from the three FQHCs. For the "likely" category, eight of the 53 DDI pairs were from one NMHC and the other 45 were from the three FQHCs.

Relative to visit volume, there were no statistically significant differences in the numbers of DDI pairs/between the NMHCs and FQHCs ($p = .74$).

Among the 130 "definitely" and "likely" DDI pairs, we found the largest categories of DDI pairs were related to antihypertensive medications ($n = 72$, 55.4%) and warfarin ($n = 37$, 28.4%) (Table 3). Although there may be potential interacting effects, beta blockers are often prescribed together with calcium channel blockers and alpha agonists with careful monitoring. Warfarin prescribed with antibiotics, synthroid and antiarrythmics may be a clinical necessity requiring close monitoring. However, warfarin prescribed with nonsteroidal anti-inflammatory drugs (NSAIDs) has a higher level of potential interaction. In an additional review with an expert pharmacist, we found that most of the DDI pairs were drugs that could be prescribed together—and in fact are often prescribed together because both may be either needed clinically for a short period of time (e.g., warfarin and certain antibiotics) or their interacting effects can be managed with close and appropriate monitoring (e.g., beta blockers and calcium channel blockers, warfarin and thyroid hormone). All interactions except those for warfarin and NSAIDs and ace inhibitors and potassium sparing diuretics were identified as often or frequently prescribed together with close monitoring, or clinically necessary for short periods of time.

Qualitative analysis results

Four main themes relevant to computer-generated DDI alerts were identified in interviews. These themes are (a) high sensitivity setting, (b) incomplete medication list or expired drugs not being removed from the list, (c) alert overriding and tolerance of interacting effects, and (d) general appreciation of the value of computerized DDI alerts.

High sensitivity setting. A majority of the end users we interviewed deemed the sensitivity of the EHR's DDI alerting function was set too high. As one respondent put it, "sometimes it overkills." Users further commented that it is very difficult to avoid interactions for mental health patients who are on psychiatric drugs, and that it is of little value for the system to alert on antibiotics and birth control pills and food and alcohol.

Incomplete medication list or expired drugs not being removed from the list. End users acknowledged that the value of the system's DDI alerting function is largely undermined because many patients do not have a complete medication list in the system: "we tend sometimes not to update it as efficiently as we should." In addition, inactive drugs are not routinely removed from the list, or are sometimes kept on the list purposefully to provide a speedy view of the patient's entire medication history. Many interviewees also commented that in ambulatory care settings it is practically difficult to maintain a complete and accurate medication list of patients. At one study site that services many "drop-in" visits, for example, providers do not perceive maintaining the mediation list for those patients who have a very low likelihood of returning to the clinic the best use of their clinical time.

Alert overriding and tolerance of interacting effects. End users acknowledged that they commonly overrode DDI alerts generated by the system because certain DDIs are oftentimes unavoidable: "we tell patients there are interactions of this and this, but we have to weigh the consequences ... [we] do have a large number of patients with psychiatric medications and they do interact with a lot of other drugs." They further commented that they are consciously aware of the interacting effects of certain pairs of drugs but they believe the effects can be tolerated by the patient or can be alternatively managed: "I have a lot of patients on purposeful interactions, a lot ... you know if you're putting somebody on for a short period of time, you take that risk."

Appreciation of the value of computerized DDI alerts. Despite concerns, the interviewees generally agreed that computerized DDI alerts could be useful. This is especially among those providers who had prior experiences witnessing severe consequences because of DDI: "one time I felt very grateful that it, you know, saved me."

Discussion

Enhanced medication safety is a much anticipated benefit of widespread adoption of EHRs and e-prescribing capabilities. Our findings, based on five safety-net practices using the same EHR system, suggest that there were indeed very few DDI pairs (0.01%) when accurate true time overlaps were queried. The DDI pairs themselves were also consistent with those reported in the previous literature from primary care in that they were related to cardiovascular medications and warfarin predominantly (Wessel et al., 2010). Moreover, we found that most of the DDI pairs identified were drugs that could be prescribed together—and in fact are often prescribed together. These drugs do present potential DDIs; however, they may be needed clinically for a short period of time, or can be used together with close and appropriate monitoring and patient education if longer term use is needed.

Our qualitative data did confirm the presence of the well-known phenomenon of alert fatigue (e.g., Isaac et al., 2009). Although our rate of DDI pairs was extraordinarily low, some clinicians in our study reported

overriding the alerts and thought they were just too sensitive. At the time of this study, the alert system in the EHR did not require documentation as to why an alert might be ignored or overridden. The upgraded version of the EHR now includes that "forcing function" (Nanji et al., 2011) in which a provider must enter a response as to why an override has been selected.

In addition, the initial DDI alert system of the EHR used in this study—not unlike other commercial products—simply presented the severity and certainty of the DDI. However, to obtain the necessary clinical details about the specific DDI, the provider had to drill down into the alert screen to obtain the particulars and recommended action. A busy provider may not take the time to go further after an initial alert. The authors questioned whether the initial alert message provided sufficient information to be fully helpful to a busy clinician. As Nanji et al. (2011) suggested, "specific drug decision support" would be helpful, and we are suggesting that this occur earlier in the alert process. For example, if a provider prescribed warfarin and an antibiotic and received an alert of "probable/major" yet found prescribing a clinical necessity, an added specific detailed alert would be more useful and helpful. A message such as "if prescription necessary for short term, close monitoring of INR is essential" or "consider prescribing an alternative antibiotic" or "additional patient teaching may be needed." A provider should not have to go into several layers of information to receive a fairly simple alert message that will either increase the possibility of prescribing something else, or monitoring appropriately if it is decided to be clinically necessary.

The current study highlights an additional concern of the inaccuracy of alerts caused by missing end dates. The significant lack of missing end dates may not only overestimate the number of actual DDIs, it may also lead to alert fatigue and discounting alerts because some have irrelevant information. Orrico (2008) found that missing end dates accounted for almost half of medication discrepancies in a study that examined medication list reconciliation in an outpatient setting. In that study anti-infectives and anti-inflammatory agents were found to be the most common discrepancy offenders. In our data, missing end dates involved more chronic disease and cardiac agents as well as anti-infectives and anti-inflammatory agents.

With the growth of e-prescribing and medication reconciliation during care transitions, having accurate medication lists—including end-date entry—is even more critical. By not having accurate end-date information, there may be more unnecessary alerts with confusing and incorrect information resulting in needless phone calls, increased time and cost as well as choosing medications that may not be the drug of choice in a particular situation because of an avoidable DDI alert. Providers may not be aware of the significance of entering end dates, as it is one more step in the data entry process. Much more emphasis during implementation and training in this area may be needed and/or evaluation of the prescribing functions within the EHR from a usability perspective. It may also be important to add a "forced function" as described by Nanji et al. (2011) that requires the provider to enter an end date.

Within the EHR itself it was not possible to track the extent to which providers responded to DDI alerts and chose an alternative prescription, although with the very low rate of DDIs by date overlap, we suspect providers did pay attention to the alerts. While the system does not track the effect of alerts on provider behavior, we know from interviews that they do have some effect—despite the existence of reported alert fatigue. Given the extremely low DDI pairs in this study, we believe the alerts avoided prescriptions that would have created a potential or real DDI. Interestingly in the qualitative interviews, the frequency of psychiatric medication alerts frustrated providers in one setting, yet when reviewing DDI pairs, there were no such interactions among the pairs (and those pairs were in the CMS 26 DDI pairs) indicating that the alerts may have impacted prescribing choices. Having said that, the sensitivity of the alert can be adjusted at both the practice level and the user level. We do think giving individual providers the ability to adjust the sensitivity may enhance use acceptance. We suggest further research to examine the potential unintended consequences from a safety perspective of giving providers individual control.

Because of the varied times of going live with the EHRs, we were not able to analyze pre- and postimplementation DDI pairs making it difficult to say that our low rate of DDI pairs is fully related to the EHR. Yet, with such a low rate of DDI pairs in this sample, and qualitative findings, we believe the EHR played a very important role in this low rate. We also did not verify records for documentation of rationale why a DDI alert might have been overridden. Dosing and drug to disease interaction or monitoring of potential adverse events were also not addressed in this analysis. We cannot say there was sound clinical reasoning for the decisions made with the DDI pairs that did occur, nor can we say the alert was ignored. It would take a study that includes assessing the provider notes, observing providers at the point of care and/or improved EHR decision support recording to get to this level of data. While Stage 1 of Meaningful Use only required that drug–drug checking functionality be turned "on," more current and future stages of Meaningful Use will lead to changes that improve both the software functionality related to DDI checking as well as encourage clinician adoption related to the use of this new functionality. It is likely that these advances in functionality will allow a deeper

understanding of the effect of decision support on provider behavior, patient outcomes, health information exchange, and care coordination. New studies now need to address these issues knowing that the upgraded EHR will allow for this analysis.

Conclusion

Overall, findings from this study indicate an exceptionally low rate of DDI pairs among NP and physician providers in these five safety-net practices after the implementation of the same EHR. We have added to the literature on prescribing and medication safety and the use of an EHR in safety-net settings such as NMHCs and FQHCs. Suggestions for changes to the EHR itself have been recommended, and some of those recommendations have already occurred such as required rationale for overriding a "probable" or "certain" alert.

The significant lack of consistently recorded start and end dates poses a severe limitation on the drug interaction safety functionality in the EHR. Better understanding of factors related to the failure of clinicians to record this information from a usability perspective will be critical to achieving the expected benefits.

Prescribers in this study included physicians and NPs and no differences were found between them or between the FQHC and NMHC settings in the rate of DDI pairs. Training efforts during implementation are often short changed (Nanji et al., 2011), but in the long run these efforts lead to better utilization of the electronic product and may also impact patient safety. This particular study included a strong emphasis on a partnership model throughout implementation and ongoing support that may have impacted the overall use of the EHR and low rate of DDI pairs.

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