Electronic Health Records and Patient Safety

Co-occurrence of early EHR implementation with patient safety practices in primary care settings

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Summary

Background: The role of electronic health records (EHR) in enhancing patient safety, while substantiated in many studies, is still debated.

Objective: This paper examines early EHR adopters in primary care to understand the extent to which EHR implementation is associated with the workflows, policies and practices that promote patient safety, as compared to practices with paper records. Early adoption is defined as those who were using EHR prior to implementation of the Meaningful Use program.

Methods: We utilized the Physician Practice Patient Safety Assessment (PPPSA) to compare primary care practices with fully implemented EHR to those utilizing paper records. The PPPSA measures the extent of adoption of patient safety practices in the domains: medication management, handoffs and transition, personnel qualifications and competencies, practice management and culture, and patient communication.

Results: Data from 209 primary care practices responding between 2006–2010 were included in the analysis: 117 practices used paper medical records and 92 used an EHR. Results showed that, within all domains, EHR settings showed significantly higher rates of having workflows, policies and practices that promote patient safety than paper record settings. While these results were expected in the area of medication management, EHR use was also associated with adoption of patient safety practices in areas in which the researchers had no a priori expectations of association.

Conclusions: Sociotechnical models of EHR use point to complex interactions between technology and other aspects of the environment related to human resources, workflow, policy, culture, among others. This study identifies that among primary care practices in the national PPPSA database, having an EHR was strongly empirically associated with the workflow, policy, communication and cultural practices recommended for safe patient care in ambulatory settings.

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The 1999 IOM report *To Err is Human* presented evidence that errors and adverse events occur widely in health care [1]. It was widely expected that adoption of Electronic Health Records (EHRs) would substantially ameliorate threats to patient safety. More recently, models posit that the effect of EHRs on patient safety is mediated by multiple interacting factors [2, 3]. Specifically the Interactive Sociotechnical Analysis (ISTA) framework calls attention to the effects of EHR design, technical infrastructure, and the work environment (workflows, policies, procedures) [2]. Our study contributes to the debate about the effect of EHR on patient safety through an examination of the empirical relationship between EHR adoption and mediating aspects of work environment. Specifically the study utilized a national survey to compare practices with and without an EHR according to the following patient safety work environment domains: medications, handoffs and transitions, personnel qualifications and competencies, practice management and culture, and patient education and communication. We limited the study to pre-meaningful use (MU) era adopters in order to control for aspects of the adoption environment that may be related to monetary incentives. In other words we wanted to look at adoption that was motivated by anticipated intrinsic value of EHR.

1. Background

Much of the patient safety research has focused on inpatient care, but there are significant safety concerns in ambulatory care as well [4, 5]. While hospital care can be more technologically complex, ambulatory care involves challenges with information exchange across multiple settings and inherent risks when patients are expected to assume an administrative role in coordinating their own care [6, 7]. Ambulatory patient safety risks also affect a much larger population, as there are 300 times more patients seen in ambulatory settings than admitted to hospitals [8].

In 2011, the American Medical Association's (AMA) Center for Patient Safety released a report summarizing ambulatory safety research from the decade following the IOM report. In this report, "Research in Ambulatory Patient Safety 2000–2010: A 10-Year Review," the AMA outlined six primary areas of potential harm to patients in the ambulatory setting: medication errors (such as prescriptions for incorrect drugs or incorrect dosages), diagnostic errors (such as missed, delayed, and wrong diagnoses), laboratory errors (such as switched or lost specimens and delays in communicating test results or following up with patients), clinical knowledge errors (such as clinical tasks errors, misdiagnosis, and errors in treatment decisions), communication errors (such as delays in transferring information, language barriers, and low health literacy), and administrative errors (such as failure to protect patient information and errors with scheduling and management of patient records) [8, 9]. Among ambulatory settings, assessing patient safety in primary care is critical. For example, laboratories, imaging facilities and other diagnostic services are generally separate from the primary care practice, and communication of results to primary care practitioners and patients is subject to many sources of failure [6, 15, 16]. The same holds true for referrals and transitions of care that occur frequently in primary care.

When well-designed EHRs are properly implemented and effectively used, they offer the potential to address many of these areas of concern, particularly those related to medication safety, diagnostic errors, and communication issues. Computerized physician order entry (CPOE) has been shown to reduce medication-related errors [12]. Research suggests that proper implementation of interoperable health information technology (HIT) systems can enhance patient safety by establishing more effective communication methods [12]. EHRs can also enhance patient safety by detecting missed diagnoses, producing diagnostic error alerts to prevent misdiagnosis, and assisting the practitioner in gathering and synthesizing patient information [17].

However, new concerns have arisen about unintended consequences of EHRs, which may include dosing errors, failure to detect fatal illnesses, and delays in treatment [2, 3, 12, 18]. Several models posit that complex interactions between technical and non-technical factors influence the effects of EHR. Harrison et al. describe how unintended consequences may result from complex and recursive interactions between the following: the design of the EHR, the work environment, the technical and physical infrastructure, and interactions between these elements [2]. Further elaborating the relationships between HIT and safety, Sittig and Singh present eight interacting domains: hardware and software computing infrastructure, clinical content of the HIT, human computer interface, people,

workflow and communication, internal organizational features, external rules and regulations, and measurement and monitoring [3].

While interactions between policies, workflow, people and technology are posited to interact with EHRs, potentially leading to unpredictable outcomes, it is unknown how often EHRs may indeed undermine, rather than support, needed workflows, communications, policies, and other practices. The Physician Practice Patient Safety Assessment (PPPSA) database, described in a previous publication, provides an opportunity to study the empirical association of EHR with the implementation of patient safety practices in six domains: medications, handoffs and transitions, invasive procedures, personnel qualifications and competencies, practice management and culture, and patient education and communication [19, 20, 21, 22]. The research team hypothesized that EHRs enable implementation of some patient safety workflows and practices – particularly in the areas of medication management, handoffs and transitions, and patient communications – and would thus be empirically associated with those workflows and practices.

2. Methods

Data presented in this paper pertain to primary care practices that submitted data to the Medical Group Management Association's PPPSA benchmarking database between 2006 and 2010. This was done in order to focus on early EHR adopters as the research team believed that there would be a difference between practices that adopted EHR before the existence of widespread Meaningful Use incentives compared to practices that adopted later.

Practices were included that clearly identified their level of HIT adoption as "EHR-based" or "paper-based". This classification was determined by responses to: "Describe how the health/medical records system stores information for the majority of patients served by the specific practice/location. If the specific practice/location uses multiple technologies, choose the system used for the majority of your patients' medical records." The 117 practices that answered "Paper medical records/ charts filed in record cabinet" were labeled as "paper-based practices" and the 92 that selected "An EHR that stores patient medical and demographic information in a database accessible by computer terminals or other electronic means…may also incorporate features of a document imaging management system (DIMS)" were classified as "EHR-based practices". Practices that replied "other", or reported using DIMS only, were excluded from the analysis.

The research team was affiliated with a regional extension center (REC) for EHR adoption, and utilized extension center staff – with exposure to a wide range of actual EHR utilization in a variety of settings – to rate each survey item as employing workflows that are:
1) substantially enabled by EHRs,
2) potentially enabled by EHRs but dependent on product and setting, and
3) unrelated to EHRs.

Two REC staff independently classified the items. In case of divergence, the item was discussed with REC and research staff and a consensus classification was assigned. Based on this classification, items in ▶ Table 1 are noted as to whether an empirical association is expected (yes, possible, or no, respectively).

Responses for items within each section ranged on a five-point ordinal scale:
A. Unaware of this issue or aware but there has been no activity to implement this item.
B. This item has been formally discussed and considered, but it has not been implemented.
C. This item has been partially implemented in the practice for some areas, patients, drugs,
D. This item is fully implemented in the practice for some areas, patients, drugs, procedures and/or staff.
E. This item is fully implemented in the practice for all areas, patients, drugs, procedures and/or staff.

The gamma statistic was computed to test for differences between paper-based and EHR-based practices on all survey items, excepting those related to surgery which would not apply to primary care settings. Gamma (γ) is a measure of rank correlation used for cross-tabulated data when both

variables are ordinal. It is estimated by $\gamma=(P-Q)/(P+Q)$. Analysis was performed using IBM SPSS statistics version 21.

3. Results

3.1 Sample

Two-hundred-nine primary care practices responded to the PPPSA during the years 2006–2010. Of these, 117 used a paper medical records system and 92 used an EHR. A strong majority of the practice respondents (70%) were part of a hospital integrated delivery system with almost all (99%) single specialty practices. The number of physician FTEs in these practices was primarily 10 or fewer (96%) and the same held true for non-physician providers. Practices were located across varied populations including non-metropolitan areas of under 50,000 population (27.6%), moderate sized metropolitan areas of 50,000–250,000 (27.6%), larger metropolitan areas of >250,000 to 1,000,000 and very large metropolitan areas of >1,000,000 (14.3%).

3.2. Data Overview

►Table 1 presents a comparison of responses from practices utilizing electronic vs. paper records across five patient safety domains that are relevant for primary care. Overall, primary care practices that were early EHR adopters were more likely to adopt a series of patient safety practices. In fact, of all items included in the study, there were no items in which paper-based practices out-performed practices using an EHR. There were some areas in which no substantive or statistically significant differences were present.

3.3 Medication Safety

Of 16 medication-related patient safety practices, all but three (medication information for non-English speakers, warfarin tracking system, and pregnancy testing teratogen prescribing) had statistically significant and positive relationship to full EHR adoption.

3.4 Handoffs and Transitions

The differences between EHR and paper-based practices were statistically significant for six out of 11 safety practices related to hand-offs and transitions. Tracking consultations and imaging test results, as well as communicating about medications during transition care were associated with EHR use, but were not statistically significant. The following differences were statistically significant in favor of EHR sites: tracking of laboratory tests, communicating test results to patients, and having a process to learn and record new information from outside the practice. EHR impact on cross-setting communication was dependent on interoperability and data exchange. ►Table 2 presents additional data from the PPPSA showing that manual processes for consult tracking, lab ordering, and results tracking were widespread even in EHR-based settings.

3.5 Personnel/Qualifications/Competency

Items in this section of the survey related to education of practice staff, competency assessment, and orientation of new practitioners and staff. Although these items do not have a clear connection to EHR use, all differences between practices were statistically significant.

3.6 Practice Management/Culture

Twenty-two questions were asked in the domain of overarching management practices that indicate a culture of safety. Consistent with other results, practices with EHR outperformed those on paper across most items – 13 of which were statistically significant. As with other areas of the survey, there

were no a-priori expectations for EHR-based practices to outperform paper-based practices on items such as: patients instructed in proper use of devices, or patients encouraged to share safety concerns. There was a strong emphasis on staff and patient safety in the EHR-based practices. In contrast, in an area where differences might have been expected – essential patient information recorded on a separate intake form in such a way that it is clearly evident and easily accessible – compliance was equally high (nearly 96% adoption) in both types of settings while compliance was low in both settings on using current literature on adverse events for practice improvement.

3.7 Patient Education and Communication

Differences between EHR and paper-based practices were statistically significant in seven of the 13 items. Seventy-nine percent of practices with EHR also provide translation services for individuals for whom English is a second language or who have a hearing impairment – compared to 63% of practices without (p=0.001). Early EHR adopters did not report a statistically significantly higher level of identification of patients with chronic disease and providing special education and monitoring services.

4. Discussion

This paper took advantage of a large national dataset to investigate the empirical association between early EHR adoption and implementation of workflows, policies, and practices that promote patient safety. Our findings confirm that among the primary care settings studied, EHR adoption was associated with adoption of numerous patient safety practices, including those beyond the expected relationship to an EHR. It appears that these early adopters were specifically adopting EHR as part of a larger strategy: an overall emphasis on patient safety. Since sociotechnical models posit that the ultimate effect of EHR on safe patient care is mediated in part through complex interactions with workflow, policies, and other aspects of the environment, it is good news that the empirical association between EHR use and patient safety workflows and policies was found to be strongly positive. It is unknown whether later adopters of EHR – motivated in part by MU financial incentives and penalties [23] – are adopting EHR along with patient safety workflows.

As expected the most consistent differences between EHR and paper-based settings were in the areas of medication documentation and decision support. However, in some areas where a computer might be expected to offer the most advances over paper – such as in chronic disease management – significant differences were absent. This could be attributed to the fact that registry functions, preventive care reminders, integrated search, and other functions are more recent advances in EHR software.

This paper reports the empirical association of EHR use with a broad range of patient safety practices but does not address causation. It is possible that other underlying factors, such as being part of a hospital system that is more heavily resourced, are related to both EHR and broad patient safety practice adoption. Moreover, safe patient care can be offered with or without EHR, as very high responses on a number of items indicate. Finally, an important limitation is that the PPPSA is based on survey data rather than objective verification of having the patient safety workflows, policies and practices in place.

Overall, however, these data support expectations that EHR adoption enhances patient safety generally. On nearly all items, practices with an EHR scored higher. This is particularly noteworthy in relation to patient communications, an area that some posit to suffer when an EHR is adopted.

5. Conclusions

Sociotechnical models of EHR use point to complex interactions between technology and other aspects of the environment related to human resources, workflow, policy, and culture, among others. This study identifies that among primary care practices in the national PPPSA database, having an EHR was strongly empirically associated with the workflow, policy, communication and cultural

practices recommended for safe patient care in ambulatory settings. This association held across domains measured: medication safety, handoffs and transitions, practice management and culture and patient education and communication. The consistent and strong empirical association of EHR use with adoption of other safety practices suggests that early adopters were using the EHR as part of a broader strategy to provide safe care.

Clinical Relevance Statement

The PPPSA is a tool designed specifically to measure patient safety activities and to serve as a directional instrument for ambulatory care practices interested in adopting extensive safety practices across all aspects of care-provision. When practices implement EHR, thought should be given as to how the EHR will perform as a tool to support patient safety practices, and what additional workflows and resources may be necessary to maximize the usefulness of EHR to promote safety.

Conflict of Interest

Clare Tanner, Joanne Pohl, and Joanne White have no financial or personal relationships with people or organizations that would influence or bias the objectivity of the study. David Gans and Radhika Nath do not report any conflicts of interest.

Human Subjects Protections

This study was conducted solely with de-identified archival data. No human subjects were involved that would make the study subject to the provisions of 45 CFR 46.

Table 1 Patient safety practice adoption by primary care settings with and without EHR, years 2006–2010, n=209.

Expected relationship to EHR	Items	% Fully implemented n=209*		Sig.**
		Paper n=117	EHR n=92	
Medications (16 items)				
Yes	Patients receive up-to-date medication list at each visit	10.3%	44.6%	0.000
Yes	E-prescribing system in place	17.9%	94.6%	0.000
Yes	Documentation system (manual or electronic) for all prescribed medications and renewals	57.3%	91.3%	0.000
Yes	All prescribing practice staff have access to drug information and CDS for medications	88.0%	96.7%	0.001
Possible	Detailed records/log on all vaccines dispensed	74.8%	90.6%	0.001
Possible	Review of all medications and side effects with documentation at every visit	70.1%	85.9%	0.005
Possible	Complete medication history including over-the-counter medications	82.9%	92.4%	0.016
Possible	List of high-alert drugs relevant to practice that require direct physician-pharmacist contact	37.6%	54.3%	0.020
Possible	Tracking system in place for all patients on warfarin	71.0%	81.6%	0.119
No	Indication for all medications on all prescriptions	19.7%	44.6%	0.000
No	Medications in practice checked regularly for expiration dates	88.9%	98.9%	0.000
No	Detailed labeling of all multi-dose injectable vials	64.9%	83.3%	0.000
No	Detailed labeling of all dispensed medications including samples	57.0%	81.7%	0.000
No	External medications labeled and stored separately	52.1%	71.7%	0.009
No	Up-to-date medication information for non-English speakers	30.8%	43.5%	0.072
No	All child bearing age females required to have pregnancy test before teratogens prescribed	60.7%	60.9%	0.382
Handoffs and Transitions (11 items)				
Yes	Practice tracks all laboratory and pathology testing	68.4%	85.9%	0.013
Possible	Process for learning and recording essential new information about patient from outside practice	63.2%	85.9%	0.001
Possible	Patients have easy access to all laboratory and consult results	70.1%	83.7%	0.006
Possible	All test results are communicated to patient in timely manner (24–48 hours)	72.6%	87.0%	0.010
Possible	Confirm/record patient discharge from hospital/facility	71.8%	81.5%	0.027
Possible	System in place to track critical versus routine laboratory and pathology tests	88.0%	93.5%	0.060
Possible	Practice has process to communicate all medications when patient admitted to hospital/facility	79.5%	87.0%	0.110

Table 1 Continued

Expected relationship	Items	% Fully implemented n=209*		Sig.**
Possible	Transfer of patient is clear with new clinician responsibility accepted including patient records	70.9%	72.8%	0.330
Possible	System in place for imaging test tracking	67.5%	77.2%	0.337
Possible	Consultation tracking system in place	57.3%	68.5%	0.480
No	Practice identifies in-office emergent situations with process in place to address them	82.1%	90.2%	0.010
Personnel/Qualifications/Competency (6 items)				
No	Employees educated about new drugs/products by staff/practitioners (not sales representatives)	52.1%	71.7%	0.000
No	System to periodically assess physician competency	65.8%	82.6%	0.000
No	Orientation to policies and procedures for nursing/technical staff	91.5%	100.0%	0.000
No	Orientation to policies and procedures for all new physicians/PAs/NPs	84.6%	92.4%	0.001
No	System to periodically assess nursing/support staff competency	82.1%	87.0%	0.004
No	Practice maintains system for continuing education	70.9%	83.7%	0.018
Practice Management/Culture (20 items)				
Possible	Patients instructed on proper use/maintenance of prescribed devices	80.3%	94.6%	0.001
Possible	Essential patient information clear and easily accessible to appropriate office personnel	95.7%	95.7%	0.318
No	Practice encourages patients to share safety concerns in writing or in surveys	70.9%	87.0%	0.000
No	When errors/near misses occur, open educational efforts used that include all personnel	76.9%	92.4%	0.002
No	All office staff are HIPAA trained	90.6%	97.8%	0.004
No	Practice has protocols for emotional support for all staff involved in adverse events	68.4%	75.0%	0.005
No	Job descriptions for all office staff include requirements to speak up about safety issues	73.5%	85.9%	0.005
No	All practice staff trained to recognize and manage health literacy issues	53.8%	72.8%	0.005
No	Practice provides training to all staff in team communication	69.2%	87.0%	0.005
No	Error reduction principles reviewed at orientation and performance evaluations	65.8%	87.0%	0.006
No	System for reporting potential threats to patient safety/near misses	78.6%	93.5%	0.009
No	Job descriptions for all clinical staff include requirements to speak up about safety issues	74.4%	85.9%	0.013
No	System in place for reporting errors supported by culture of safety and openness	85.5%	94.6%	0.015

Table 1   Continued

Expected relationship	Items	% Fully implemented n=209*		Sig.**
No	Practice uses established tools to monitor staff fatigue/morale	60.7%	75.0%	0.018
No	Safe treatment environment provided	89.7%	98.9%	0.063
No	All patient complaints are documented and reviewed	76.1%	91.3%	0.097
No	Patients are informed of HIPAA	98.3%	100.0%	0.123
No	Measuring device suggested for prescribed oral liquids	78.6%	85.9%	0.206
No	Practice uses current literature on adverse events for practice improvement	58.1%	60.9%	0.493
No	Staff feel comfortable requesting time away	94.9%	96.7%	0.604
Patient Education/Communication (13 items)				
Possible	Practice assists patients in obtaining educational materials/resources on their conditions	78.6%	94.6%	0.021
Possible	Diagnostic/treatment care plans clearly communicated to patient and caregivers	65.0%	87.0%	0.028
Possible	Patients receive critical information (verbal and written) in lay terms about new prescriptions before leaving office	49.6%	63.0%	0.042
Possible	Patients are assessed for financial and physical ability to obtain prescriptions/supplies	65.8%	78.3%	0.062
Possible	Patient life-style information collected and used for care plan	86.3%	93.5%	0.169
Possible	Chronic disease patients identified and monitoring services provided	83.8%	88.0%	0.246
Possible	Process for timely email/phone correspondence with patients and other practitioners	87.2%	93.5%	0.829
No	Patients and caregivers instructed to ask questions regarding medications	70.1%	91.3%	0.000
No	Interpreters are available for LEP/hearing impaired patients	63.2%	79.3%	0.001
No	Patients are routinely asked to repeat back instructions	61.5%	73.9%	0.010
No	Patients' participation sought in decisions regarding their care	94.9%	97.8%	0.039
No	Patients asked to repeat back information and instructions they receive on phone	52.1%	62.0%	0.320
No	Practitioner explains to patients all risks for procedures and testing	85.5%	93.5%	0.454

*Note: "% Fully implemented" includes responses "*fully implemented* in the practice for *some* areas, patients, drugs, procedures and/or staff," and, "*fully implemented* in the practice for *all* areas, patients, drugs, procedures and/or staff."
**Calculated based on estimating gamma (γ).

Table 2   Use of computerized referral and laboratory ordering system by whether the primary care practice had adopted EHR or not, years 2006–2010, n=209.

	Computerized system	Combination manual and computerized	Manual system	NA/other
System to track if consult was requested and consulting physician's report received				
Paper-based	6% (n=7)	22% (n=26)	45% (n=52)	27% (n=31)
EHR-based	10% (n=9)	43% (n=39)	22% (n=20)	25% (n=23)
Clinical lab order entry system				
Paper-based	8% (n=9)	21% (n=25)	70% (n=82)	1% (n=1)
EHR-based	32% (n=29)	54% (n=49)	14% (n=13)	-
Clinical lab results system				
Paper-based	12% (n=14)	39% (n=45)	49% (n=57)	-
EHR-based	30% (n=28)	63% (n=58)	7% (n=6)	-

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