

Estimating impacts on safety caused by the introduction of electronic medical records in primary care

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ABSTRACT

Context Primary care is a highly complex environment in which multiple safety problems have been identified. Each primary care practice can be viewed as a complex adaptive system with its own unique characteristics. The introduction of an electronic medical record (EMR) into such a system represents a significant perturbation that can have multiple unpredictable effects. From a safety standpoint this can mean reduction in some vulnerabilities and increase in others, as well as the introduction of new vulnerabilities that did not exist under the old system.
Objective To estimate the impacts of a new EMR on various aspects of practice function using a Failure Modes and Effects Analysis (FMEA) approach based on the concept of hazard adapted from safety engineering.
Setting/participants Academic rural primary care practice with 32 staff.
Design At baseline, a survey instrument (Perceived Hazard Questionnaire) was used to elicit staff (physicians, nurses and administrative) perceptions of frequency and severity of multiple different primary care errors in 12 different domains in the practice. For each error, a Hazard score was calculated based on the product of frequency and severity. The Hazard scores thus derived were used to prioritise the safety problems within the practice. One year later, after partial implementation of an EMR, the survey was repeated.
Main outcome measures Comparison is made between priorities identified by physicians, nursing and administrative staff before and after EMR implementation.
Results At baseline, a high concordance between priorities identified by physicians, nursing and administrative staff was recorded. This concordance halved after partial implementation of the EMR. The staff perceived decreased hazard in nurse–physician and physician–chart interactions but hazard increased in the already high-hazard domains of physician–patient interaction in the assessment stage and nurse–chart interactions, apart from three other domains.
Conclusions This FMEA-like approach identified changes in practice hazards apparently related to EMR implementation. This in turn can help in targeting pre-existing and new vulnerabilities in primary care practices.

Keywords: complex adaptive system, culture of safety, EMR, error, FMEA, hazard, practice-based FMEA, primary care, safety, team

Introduction

A large and comprehensive 2004 profile of the quality of health care in various communities across the United States (US) reveals once again a huge chasm between the existing capabilities of and the actual quality of care delivered to patients and citizens by the healthcare industry.[1] This gap appears to be consistently wide across the whole nation.

There are formidable and compelling pressures from the US Federal Government, professional bodies and accreditation authorities to make very rapid and significant improvements in the quality of care in both outpatient and inpatient settings. Whilst most work to date has focused on inpatient settings, some estimates suggest that outpatient settings are at least as important with up to 200 000 avoidable deaths per year.[2,3] Primary care physicians, who provide the vast majority of medical care, are struggling to provide the quality of care that they are trained (over a long period) to provide. They are working harder under the pressures of increasing overheads, competing demands and decreasing rewards in an unpredictable environment (especially related to health insurance and malpractice) that causes instabilities in their efforts to improve and maintain quality.[4]

Quality is defined by the Institute of Medicine (IOM) as having three overlapping domains: safety of patients and practitioners, practice consistent with current domain knowledge and patient-centred care (customisation).[5] Various strategies that can be adopted to improve patient safety in health care can usefully be categorised as:

1 punitive action directed against individuals
2 counselling and retraining staff and patients
3 process redesign
4 technical and technological system enhancements
5 cultural changes aimed at safety.[6]

These strategies have been arranged above in the ascending order of their effectiveness and sustainability. As can be seen, the second most effective strategy is that of technical and technological system enhancements. This includes the use of computers and information technology such as electronic medical records (EMR).

Introduction of relational databases in the form of EMR has received considerable attention and support because of their current and potential effectiveness in (a) improving health care quality, including safety, customisation and practice consistent with current knowledge, particularly in relation to the implementation of decision support, (b) reducing practice expenses, and (c) increasing revenues by improving office efficiency and accuracy of billing as well as customer satisfaction. This strategy also has potential to contribute to the formation of a culture of safety.

In a recent analysis of data collected by the American Academy of Family Physicians (AAFP), Valdes *et al* found that only 1297 (23.5%) of the 5517 respondents, from a total mailing list of 35 554, reported using an EMR. As many as 264 different EMR software programs are currently used with only 0.4% using the same EMR software. This reflects the fact that the primary healthcare industry in the US is in the very early phases of adoption of this strategy.

Primary care is a highly complex environment in which multiple safety problems have been identified. Each primary care practice should be viewed as a *complex adaptive system* (CAS) with its own unique characteristics.[8–15] The introduction of an EMR into such a system represents a significant perturbation that can have multiple unpredictable effects. From a safety standpoint this can mean reduction in some vulnerabilities and increase in others, as well as the introduction of new vulnerabilities that did not exist under the old system. The transition period, from start to full implementation of an EMR, that is, partial implementation, can present a particular challenge to safety.

For a complex practice system to make the transition successfully it must be adaptive. The authors propose the following three steps to achieving adaptation:

1 Generation of information about the vulnerabilities in the system (or sub-system). This places attention on system failures instead of individual failures. Dissemination of this information internally to all team members is essential to aid learning about the vulnerabilities. The US National Patient Safety Foundation has identified this as the hallmark of a safety culture.[16]
2 Pooling of diverse resources (including all members of the healthcare team, patients and families, as well as financial, organisational and material resources) to generate options to respond to these vulnerabilities and to cope with unpredictable external and internal pressures.
3 Creation of good teams with qualities of *mutual trust, respect, collaboration and co-operation, and with a shared vision of quality and mission of patient care* to perform steps 1 and 2 well and keep the prevailing anxieties in check.[12–15] These qualities and vision become '*central attractors*' in a complex adaptive system. These attractors are the forces that produce, over a period of time, order (pattern) in disorder (chaos/unpredictability).

The most commonly used method for estimating vulnerabilities in health care is to collect and count errors through voluntary reporting systems (often referred to as 'incident reports').[17] These are fraught with difficulty due to under-reporting (according to

the IOM report, only 5% of known errors are typically reported), and then there are unknown errors and abuse (such as reports filed and counter-filed as a means of retaliation against colleagues).[5] Bates *et al* describe difficulties involved in defining and quantifying errors. They report that even direct observational studies, which are highly labour-intensive, often miss errors.

Furthermore, error reporting generally does not promote steps 2 and 3 above. Instead it tends to be associated with blame and shame and frequently results in antagonism between team members, undermining mutual respect, trust and co-operation.

An alternative approach that is prospective, rather than retrospective, and permits involvement of all team members to identify and prioritise safety and quality problems, is Failure Modes and Effects Analysis (FMEA). This has been widely used in other high-risk industries and has been advocated by the IOM as a means of analysing a system to identify its weaknesses ('Failure Modes'), possible consequences of failure ('Effects') and to prioritise areas for improvement.[5] The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has required since 2002 that all accredited hospitals perform proactive risk assessment each year following a series of steps that are based on FMEA.[19,20]

The authors have adapted the FMEA approach to provide a rapid measurement tool for assessing the effects of safety-motivated interventions.[10,21] It is a Practice-based Failure Modes and Effects Analysis (P-FMEA) type of proactive methodology that can be tailored for individual practices and is highly adaptable. It is based on Hazard concepts adapted from safety science and engineering. It aids formation of self-empowered practice teams with a common 'good enough' vision to help the unique complex systems adapt and thrive, taking advantage of site-specific 'central attractors' of trust, mutual respect and collaboration. This methodology succeeds in generating considerable enthusiasm and support from all the workers in the practice. It is thought to be superior to alternative methods of measurement and can also be used to supplement and complement them.

The P-FMEA approach is based on a Perceived Hazard Questionnaire (PHQ). This questionnaire is based and structured on a visual model of the entities and their interactions.[22] The survey focuses on 12 of the key entities and interactions shown in Figure 1 and dedicates a page to each. Each page has a list of failure modes that can occur in that specific part of the practice. The lists were developed by review of the literature and consultation with practice leaders and can be customised to incorporate special circumstances for any given practice if desired. The survey contains a total of over 130 failure modes; respondents are invited and encouraged to supplement this list and comment upon it. Instead of asking each staff member about their own personal error experiences, it asks each staff member about their perception of the whole practice.[10,21] This approach takes advantage of practice-based experiential knowledge and, like the highly acclaimed Aviation Safety Reporting System, has three important attributes of (a) safety (immunity to blame and punishment), (b) simplicity and convenience, and (c) worthiness and value (provides feedback

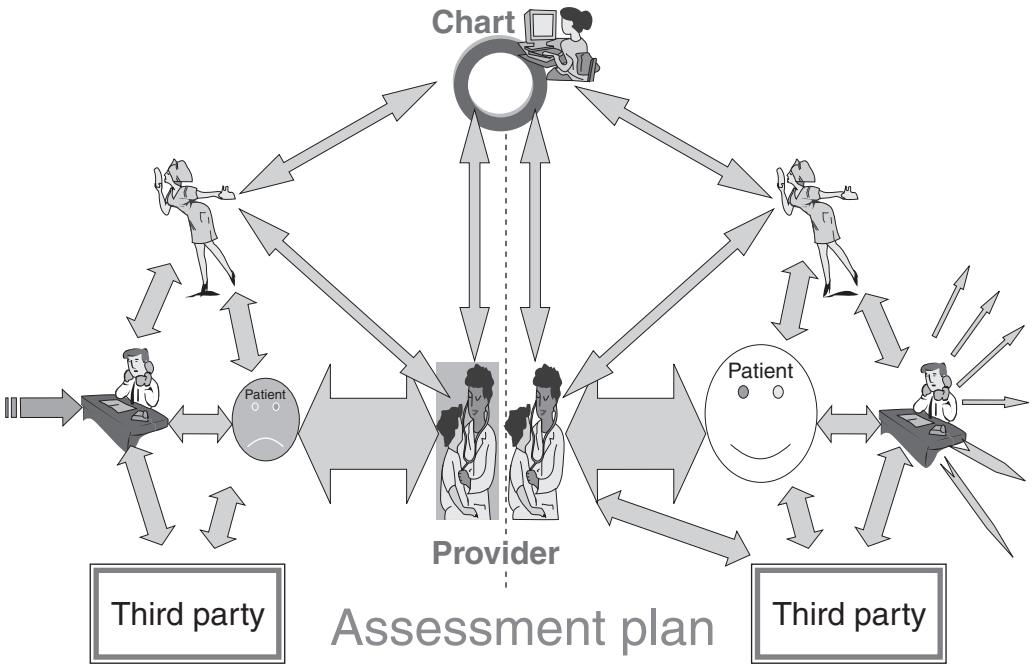

Figure 1 Visual model of the practice micro-system

and is a tool for development of improvement strategies and enhancement of staff self-esteem).

Objective

The main objective of this study was to estimate the impact of an EMR on various aspects of practice function using the P-FMEA type approach, concentrating first on the transitory period leading to full implementation. It is in the nature of implementations such as this that they cannot be instantly implemented in practice. Assessment of their influence at various stages of implementation is necessary to understand as fully as possible the implications of these perturbations in the practice.

Methods

At baseline, the instrument was used to elicit, anonymously and confidentially, physicians', nurses' and administrative staff perceptions of frequency and severity of multiple different primary care errors in the 12 different domains in the practice. For each error, a Hazard score was calculated based on the product of frequency and severity. Table 1 shows the Hazard rating matrix used.

One year later, after *partial* implementation of an EMR, the survey was repeated. Comparison was made between priorities identified by the whole practice team as well as by physicians versus nursing versus administrative staff. At the time of the repeat survey the EMR was being used for scheduling and prescribing of medication only. Paper charts were in use for progress notes, labs, X-rays and other documents. Physicians generally carried a laptop computer and the paper chart into the exam room for each patient.

Setting

An academic rural primary care practice in western New York State with 32 staff. Table 2 summarises the characteristics of this practice.

Table 2 Characteristics of the practice

Practice type	Residency practice site
Visits per year	23 000
Physicians	6
Nursing staff	10
Administrative staff	16
Total practice staff	32
Respondents	30

Results

Table 3 shows the average score of the top five hazardous items for each of the 12 different domains in the practice (Figure 1). Some improvement in safety was found only in the domains of physician–chart interaction, nurse–physician interaction and patient in the planning phase. In the domains of nurse, nurse–chart interaction, patient assessment, physician–patient interaction in the assessment phase as well as physician–patient interaction in the planning phase, safety was adversely affected. This effect was very significant in the first four. It is interesting to note that the physician–patient interaction suffered more in the assessment phase than in the planning phase. The perturbation effects are illustrated in Figure 2. The rest of the (four) domains do not appear to have been affected.

Table 1 Hazard matrix. Calculation of hazard: $h=p\times s$

Severity (s)	Probability (P)			
	Remote	Uncommon	Occasional	Frequent
Minimal (=1%)	0.01	0.02	0.24	1
Mild (=5%)	0.03	0.10	1.20	5
Moderate (=20%)	0.10	0.40	4.80	20
Severe (=100%)	0.50	2	24	100

Table 3 Comparison of areas of practice in terms of the *average* of the top five hazard items within each area: before and after partial implementation

Domain of practice	T1: Before	T2: After
Reception	16.31	16.50
Nurse	8.19	14.69
Nurse–patient interaction	9.45	9.53
Nurse–chart interaction	18.73	28.26
Patient: assessment	14.10	22.80
Physician: assessment	6.46	6.51
Physician–patient interaction: assessment	7.26	13.44
Physician–chart interaction	17.72	14.82
Nurse–physician interaction	9.92	6.99
Physician: plan	11.14	11.01
Physician–patient interaction: plan	4.92	7.12
Patient: plan	12.91	10.92

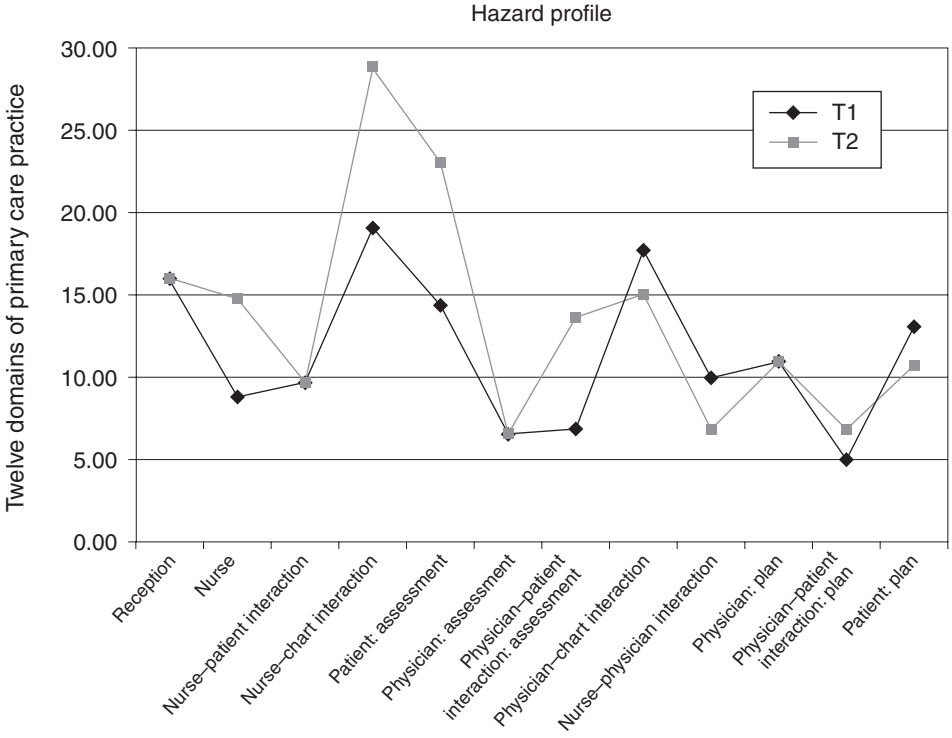

Figure 2 Influence of partial EMR implementation on the practice vulnerabilities

At baseline (T1), there was high concordance between priorities identified by physicians, nursing and administrative staff. After *partial* implementation of the EMR, there was considerable decrease in this concordance. Particularly noticeable is the drop from four to no agreement on the ten top priority hazards between physicians and nurses. The agreement pattern is shown in detail in Table 4. In general the level of agreement was halved.

Table 4 Number of agreements on the top ten priority hazards

Before: T1	After: T2		
	Physicians	Nurses	Admin/ reception
Physicians	[2]	0	1
Nurses	4	[5]	2
Admin/ reception	2	4	[3]

*Numbers above the diagonal (top left to bottom right) of the matrix represent agreements within the practice at Time 2, whereas those below this diagonal represent agreements at Time 1. The numbers in boxes on the diagonal represent agreements between the personnel at the two time points.

Discussion and conclusions

This practice-based FMEA approach identified changes in practice hazards apparently related to EMR implementation. This should help in targeting pre-existing and new vulnerabilities in primary care practices.

It is important to note that the greatest adverse effect due to partial implementation was in the domains which already were perceived to be two of the most hazardous, those of nurse–chart interaction and patient at the assessment stage. This may have been due in part to the transition that was under way, during which time both paper and electronic charts were being used. For example, medications documented in the paper chart are often inaccurate, leading to confusion. Greater vulnerability at the patient assessment domain may be explained by the potential for the physician's interaction with the computer in the examination room to interfere with his/her ability to fully engage the patient during the interview. The greatest reduction in vulnerabilities was in the domains of the physician–chart interaction and patient in the planning phase, followed by physician–nurse interaction. These are thought to be reflections of improved communication and reliability afforded by the EMR. For example, physician–chart interaction improved, perhaps due to greater reliance on the electronic medication list.

It is in the nature of complex adaptive systems that any intervention causes a perturbation that can stabilise, preferably to a better safety state, only after a certain period of time and then only under the influences of the 'central attractors' described earlier. In the absence of these attractors, instabilities and 'devolution' may result. The decrease in concordance between perceptions of the subgroups may be interpreted as a symptom of this. This calls for caution while introducing an intervention such as EMR, especially in the transitory periods (starting from first introduction to its complete implementation). Greater attention needs to be paid to effective team-building and training people (particularly in the new technology) as *members of their practice work teams.* Failure to do so can cause greater hazards to the patients and ultimately the staff, leading to demoralisation and loss of revenue.

Whilst adopting a strategy of introducing EMR (for improving safety through effectiveness, efficiency and timeliness, with accuracy, as well as for increasing revenues) great effort has to be made to ensure that all the components of this strategy are as transparent as possible by making hazards visible so as to facilitate recovery from them.

As stated earlier, the introduction of an EMR into such a practice system represents a significant perturbation that can have multiple unpredictable effects. From a safety standpoint this can mean reduction in some vulnerabilities and increase in others as well as the introduction of new vulnerabilities that did not exist under the old system. These effects need to be monitored as reliably as possible.

The Perceived Hazard Questionnaire has the ability to aid measurement of effects of the intervention. Repeated use over time may provide an effective means of identifying beneficial and detrimental effects and can help to encourage a common shared vision among team members and galvanise their effort to adopt change for the better.

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CONFLICTS OF INTEREST

None.

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