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## PRACTITIONER APPLICATION

*Thomas Miller, executive director—southern region, Children's Hospital of Wisconsin*

The concept of the Health Technology Assessment Program (HTAP) presented in this article should be of great interest to most healthcare executives because it addresses two issues that are almost always diametrically opposed: cost containment that actually promotes positive professional relationships between the medical staff and hospital administration. The concepts of the model presented by the authors, whether implemented in part or in whole, should have practical applications in encouraging aligned decision making between hospitals and physicians.

Many hospitals have had a longstanding "us versus them" attitude when it comes to relationships with their medical staff, and that same attitude is often reciprocated from the medical staff's perspective. However, in an environment of increased competition and dwindling reimbursements, developing and fostering trust between hospitals and physician partners will help ensure organizational longevity. Over the next few years, external financial and operational pressures will place the relationship between a hospital and its medical staff in a crucible. Hospitals must cultivate mutual trust now, or face further division between the administration and physicians.

The sheer size of HTAP, and its need for objective financial projections, make it very resource intensive. However, the committee has demonstrated an ability to make thoughtful, impartial, high-stakes decisions that have a direct positive impact on the hospital's bottom line, and, more important, because the committee

is physician-led, its decisions are respected by the entire medical staff. This is clear because no physicians have challenged an HTAP decision in an appeal. The underlying element of HTAP's success is the hospital trusting its physician leaders to make decisions that add value to the organization, and the medical staff trusting the committee to evaluate technology proposals in a greater context.

UCSF's HTAP is a considerably advanced committee, and replicating an identical model in every healthcare organization would not be advantageous. Barriers to implementation would likely be up-front costs or a highly fragmented medical staff, but steps can be taken by any organization to create an environment of trust and alignment. For instance, committees like HTAP must be led by physician leaders who are excellent care providers and have a strong understanding of the business of healthcare. This type of physician leader is almost always created, not found, and every hospital should make the effort to identify, educate, and retain their top physician talent. Endeavors like HTAP become increasingly easy to initiate when home-grown physician leaders are willing to champion the cause.

This article should serve as a reminder for all healthcare leaders to take a long, hard look at their relationship with their medical staff and identify steps that can be taken to bring the relationship into alignment with their organization. Doing so, while a challenging undertaking, will pay dividends in the next few years as decisions become more difficult to make and the stakes become larger. Alignment like that of UCSF is rare, but developing and engaging physician leaders now will provide healthcare executives an additional, and valuable, tool to help navigate an uncertain future.

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# Safety Issues Related to the Electronic Medical Record (EMR): Synthesis of the Literature from the Last Decade, 2000–2009

*Linda Harrington, PhD, vice president for advancing nursing practice, Baylor Health Care System, Dallas, Texas; Donald Kennerly MD, PhD, vice president of patient safety and chief patient safety officer, Baylor Health Care System; and Constance Johnson, PhD, assistant professor, Duke University, Durham, North Carolina*

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## EXECUTIVE SUMMARY

Healthcare is a complex industry burdened by numerous and complicated clinical and administrative transactions that require many behavioral changes by patients, clinicians, and provider organizations. While healthcare information technology (HIT) is intended to relieve some of the burden by reducing errors, several aspects of systems such as the electronic medical record (EMR) may actually increase the incidence of certain types of errors or produce new safety risks that result in harm. Healthcare leaders must appreciate the complexity surrounding EMRs and understand the safety issues in order to mandate sound EMR design, development, implementation, and use. This article seeks to inform executives, clinicians, and technology professionals what has been learned through published research on the safety of HIT systems during the last decade, focusing on computerized physician order entry (CPOE), clinical decision support systems (CDSS), and bar-coded medication administration (BCMA).

For more information on the concepts in this article, please contact Dr. Harrington at [linda.harrington@gmail.com](mailto:linda.harrington@gmail.com).

**W**hile hospital electronic medical records (EMR) are intended to reduce medical errors, several aspects of the EMR may actually increase the incidence of certain types of errors or produce new safety risks that result in harm (Ammenwerth and Shaw 2004; Bates et al. 2001; Horsky, Zhang, and Patel 2005; Koppel et al. 2005). Threats to patient safety can be introduced during any phase of the EMR lifecycle, such as planning, design, development, testing, implementation, operations, and maintenance. Within each of these processes, technology, people, and the work environment can individually or collectively generate errors (Ash, Berg, and Coiera 2004).

The EMR is a very complicated technology, consisting of millions of lines of code typically authored by multiple programmers (Ash, Berg, and Coiera 2004). More important than its technical reliability is that many functions may be designed by people who do not know or fully appreciate the complex interaction of the human-computer interface and the consequences of designs that may, in hindsight, have impaired patient safety. As far back as 1995, the Food and Drug Administration acknowledged that insufficient design and testing of software-driven products could result in errors, increased healthcare costs, and patient harm (Burlington 1996).

End users can serve as sources to identify safety issues during multiple processes. While end users are sometimes consulted in design or design-enhancement processes, many end users lack knowledge of standardized dictionaries, design principles, human-computer interaction, and the impact of

poor design on work and patient safety. During operation of the EMR, multiple end users can introduce errors into the EMR through multiple points of data entry (Hogan and Wagner 1997).

The EMR and the end user come together in a work environment that is also very complex (Ash, Berg, and Coiera 2004). Healthcare work environments are characterized by excessive noise, high workloads, complex tasks that require rapid user responses to information, multitasking, and serious consequences when errors occur (Salvemini 1998). Tasks carried out by healthcare professionals in these environments are often context-dependent, nonlinear, interrupted, and dependent on clear and timely communication (Horsky, Zhang, and Patel 2005). The convergence of the complexities of the EMR and the need for changes in associated work flow create a large socio-technical system where new behaviors emerge, some leading to unintended consequences that cause harm (Ash, Berg, and Coiera 2004).

Healthcare leaders must appreciate the complexity surrounding EMRs and understand the safety issues in order to mandate sound EMR design, development, implementation, and use. This article seeks to highlight what has been learned through research on the safety of these systems from 2000 to 2009. Three aspects of the EMR were selected for examination. These include computerized physician order entry (CPOE), clinical decision support systems (CDSS), and bar-coded medication administration (BCMA). The intended purpose is to prevent errors through effective design, development, and

implementation and, as a result, reduce safety risks. However, all new systems generate unintended adverse consequences to patient safety that may relate to design or implementation problems. What follows is what has been learned related to beneficial effectiveness and unintended consequences associated with three major functions of the EMR.

## BACKGROUND

In 2000, the Institute of Medicine's (IOM) Committee on Quality of Health Care in America released a seminal report titled *To Err is Human: Building a Safer Health System* that estimated that more than a million injuries and nearly 100,000 deaths each year in the United States are attributable to medical errors. In this report, the authors differentiated between active and latent errors. Active errors occur on the front line where the effects of these errors are felt almost immediately. Latent errors result from system failures and tend to be removed from the direct control of frontline people (Reason 1990). Latent errors include things such as poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organizations that create an environment that may fail to prevent or even may promote a human failure that may result in patient risk of injury. The IOM report asserted that latent errors, such as those hidden in complex health information technology applications, pose the greatest threat to safety in a complex system because they are difficult for end users to see and can lead to multiple types of active errors.

A second IOM report, *Crossing the Quality Chasm*, identified challenges

associated with use of information technology in healthcare to improve quality of care (Committee on Quality of Health Care in America 2001). The authors called healthcare the most complex sector of the economy because of numerous and complicated transactions that require many behavioral changes by patients, clinicians, and provider organizations. Underinvestment in clinical information systems by provider organizations is compounded by difficulties in demonstrating the benefit of clinical information systems. Healthcare providers are also challenged in securely maintaining patient health information and creating an infrastructure that enables exchange of data and information across diverse settings.

Another landmark article described anecdotal evidence that while electronic medical records and associated clinical information systems can reduce errors, they can also cause errors (Bates et al. 2001). Examples provided included the wrong selection from two medications similarly spelled appearing in close proximity on the computer screen and physicians writing orders in the wrong electronic record. The authors recommended that adverse consequences resulting from the use of information technology be continuously monitored, measured, and evaluated.

By 2007 sufficient evidence in the literature prompted Weiner and colleagues to coin the term "e-iatrogenesis" to denote patient harm resulting at least in part from health information technology. The authors referred to e-iatrogenesis as the most critical unintended consequence of health information technologies and said they

coined the term to draw attention this critical issue. An e-iatrogenic event may involve errors of commission or omission and can be associated with any aspect of a health information system such as the EMR, CPOE, or CDSS.

E-iatrogenic errors fall into technical, human-machine interface, or organizational domains and may represent an electronic version of a "traditional" error, such as a medication error, or new errors never seen before, such as a CDSS recommendation for a wrong diagnosis.

Also in 2007, Palmieri, Peterson, and Ford coined the term "technological iatrogenesis" to describe errors caused by the addition of technological innovations into complex healthcare systems. The authors acknowledged the contribution of health information technology to make healthcare delivery safer and the new varieties of iatrogenic errors stemming from this technology. They also advocated for the use of risk management solutions such as failure mode effect and root cause analyses. Additionally, the authors encouraged healthcare leaders to avoid quick fixes to issues surrounding technology, such as a focus on human error, and move to a broader system perspective.

By 2008 The Joint Commission released a sentinel event alert titled "Safely Implementing Health Information and Converging Technologies" focusing on technology-related adverse events and encouraging healthcare providers to be alert to the associated safety risks and preventable adverse events. The Joint Commission cited Weiner and colleagues (2007) stating that unintended adverse events typically arise from two areas, human-machine inter-

faces and organization or system design. Recommendations in the sentinel event alert were to design technology to be safe and to use technology safely.

## METHODS

A comprehensive review of the literature was conducted using CINAHL, PubMed, and MEDLINE databases to identify relevant research published between and including the years of 2000 and 2009. Other databases were added when the original searches yielded fewer than 20 articles. These additional databases included Academic Search Premier, Academic OneFile, Business Source Complete, JSTOR, and Google Scholar. Manual searches of reference lists in published articles on safety issues in the EMR were also conducted.

Search terms included "safety," "errors," "electronic medical record," "electronic health record," "clinical decision support," "computerized physician order entry," and "bar-coded/barcode/barcoding medication administration." Additional terms were identified during the search and included terms such as "unintended consequences," "e-iatrogenesis," "work flow," "work processes," "workarounds," and "computerized provider order entry."

Inclusion criteria were predetermined to be (1) English language publications; (2) research studies identifying errors related to EMR, including CPOE, CDSS, and BCMA; and (3) the hospital setting. Titles and abstracts identified in the database and reference list search meeting these inclusion criteria were initially screened to exclude those clearly not meeting the inclusion criteria. Publications focused solely on the

surveillance or prevention of errors or in settings outside of the hospital were excluded. Similarly, studies published only as abstracts with insufficient information were also excluded.

A spreadsheet was created that contained key elements to be extracted from the publications. Extracted data included author(s), title, journal, publication year, sample, design/methods, findings, conclusions, types of errors, and causes of errors. Data from the published studies meeting the inclusion criteria were then abstracted and entered into the spreadsheet.

## RESULTS

### Summary of Search Findings

A total of 24 studies matching the inclusion criteria were identified through a comprehensive search of databases and references lists as previously described. These studies are outlined in an exhibit on [www.ache.org/pubs/jhmsub.cfm](http://www.ache.org/pubs/jhmsub.cfm).

### Analysis of Literature Review Findings

As can be seen in the online exhibit, studies were found in 13 different journals. Thirty-three percent of the research was presented through the journal or conference proceedings of the American Medical Informatics Association (AMIA). Five studies (21 percent) were published in the *Journal of the American Medical Informatics Association* and three (12 percent) in the *AMIA Annual Symposium Proceedings*. Few studies were published in clinical journals alerting clinicians to the possibilities of system-induced errors. No publications on EMR-related errors were found in healthcare management journals thereby educating manage-

ment about the potential issues. Lastly, few articles on safety issues related to the EMR were found in safety or quality journals in the last decade.

Exhibit 1 illustrates a temporal trend of articles related to EMR safety issues in CPOE, CDSS, and BCMA during the last decade. While the adoption of EMRs by hospitals is increasing steadily, the published research involving the safety of the EMR seems to have peaked in 2005, and only three papers per year have been published for the last four years (see Exhibit 2).

The design of the 24 studies is also worth noting. There was one randomized controlled trial, one interventional study, one quantitative and qualitative study, two qualitative studies, and three case studies. The remaining 16 studies used descriptive or comparison designs.

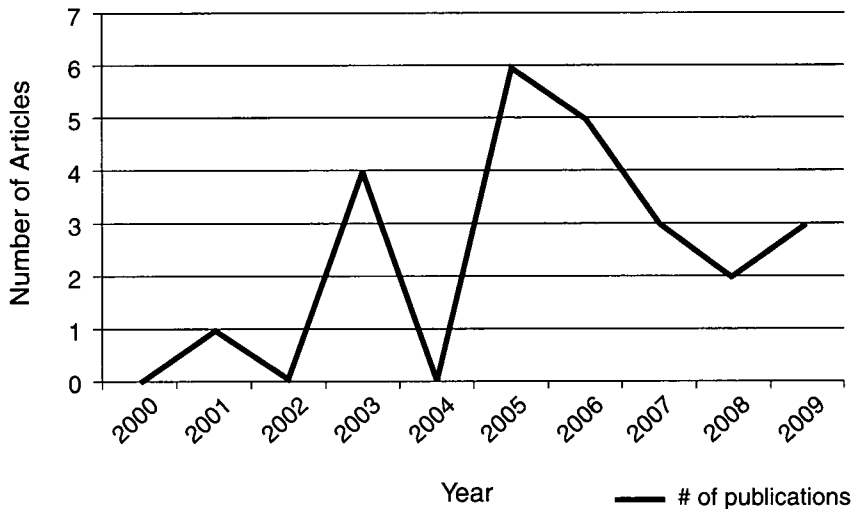
Exhibit 2 illustrates differences related to the focus of published research on errors related to CPOE, CDSS, and BCMA during the last decade. The dominance of articles related to CPOE is notable in 71 percent of the publications, followed by clinical decision support systems (17 percent) and bar-coded medication administration (12 percent).

By extracting information from the online exhibit, patterns related to the three areas of focus can be identified (Exhibit 3). These patterns are grouped as process, people, technology, organization, and environment related.

Exhibit 4 presents a picture of EMR-related safety issues reported in the research literature from 2000 to 2009, one that should be compelling to healthcare leaders, clinicians, and technology professionals. Thirty-five safety

**EXHIBIT 1**

**EMR Safety Articles Published over the Last Decade, 2000–2009**



issues were reported in the literature on BCMA, 16 on CDSS, and 83 on CPOE. The larger number reported for CPOE is a result of the significantly larger number of studies evaluating CPOE as demonstrated earlier in Exhibit 3. These findings indicate that the promise of the EMR to reduce errors in healthcare must be tempered by the need to identify, evaluate, and improve safety issues resulting from the EMR.

**DISCUSSION**

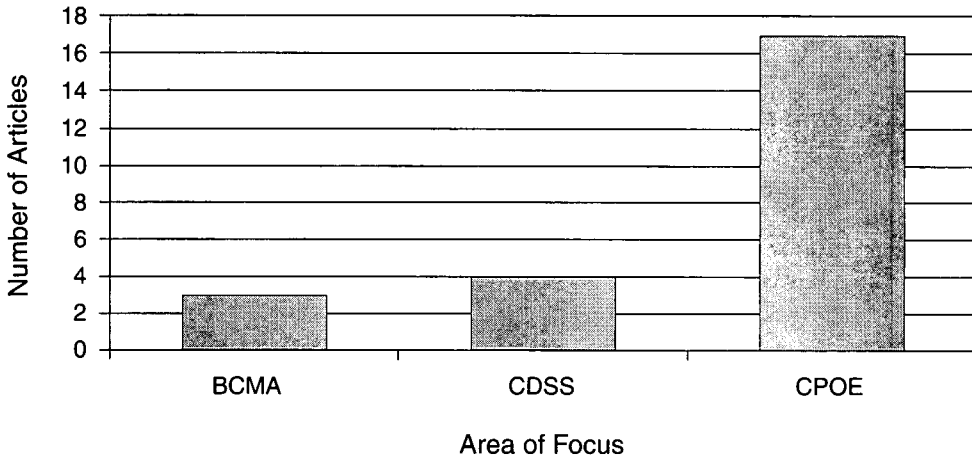
CPOE has been touted as reducing errors in patient care, in large part by eliminating illegible orders and transcription errors. However, CPOE can actually increase the number of adverse events (Berger and Kichak 2004). Research studies in the last decade demonstrated safety issues with CPOE ranging from communication to medication errors to mortality and other unintended consequences (Dykstra

2003; King et al. 2003; Han et al. 2005; Campbell et al. 2006).

Researchers also found that CPOE can increase the coordination load among clinicians resulting in new opportunities for new sources of error (Cheng et al. 2003). For example, nurses may be unaware of new patient orders when physicians enter new orders remotely using CPOE. Prior to CPOE, nurses would see physicians making rounds, talk with them, and thus know when to expect orders. Using a descriptive design, Cheng and colleagues (2003) observed clinicians in an intensive care unit following implementation of CPOE. They concluded that the increased coordination load and the resulting new sources of errors were related to the assumption by designers that physician ordering is a linear process.

Ash and colleagues (2007) studied the extent and importance of



**EXHIBIT 2****EMR Aspects Studied in Published Articles over the Last Decade, 2000–2009**

unintended consequences related to CPOE in 176 hospitals drawn from 448 acute care hospitals listed in the HIMSS Analytics Database, plus 113 US Veterans Affairs Hospitals. Using telephone interviews, the researchers found that unintended consequences of CPOE considered most important by subjects included new work or more work, work flow, system demands, communication, emotions, and dependence on the technology. They found no correlation between the types of unintended consequences and number of years using CPOE.

CDSS is intended to support the real-time clinical decisions of healthcare professionals in providing optimal patient care. CDSS is thought to be the key differentiator between paper-based and electronic documentation by providing necessary data and/or algorithm-based alerts or reminders to clinicians during their daily work. Tsai, Fridsma,

and Gatti (2003) discovered that CDSS can be reduced in its usefulness when incorrect information is provided. Some healthcare professionals may trust the computer more than is warranted, resulting in errors in decisions.

Similarly, the effectiveness of CDSS is reduced when clinicians are subjected to alerts or other information perceived to lack benefit. Van der Sijs and colleagues (2009) studied the alert overrides for time-dependent drug–drug interactions (TDDI). The researchers found that incorrect overrides of TDDI alerts were an important cause of medication administration errors. Overrides were found to be a result of alert fatigue along with low alert specificity and unclear alert information content.

Garg et al. (2005) published a systematic review of randomized and nonrandomized controlled trials to assess the effects of CDSS and to identify study characteristics predicting benefits.

**EXHIBIT 3**

**Types of EMR-Related Safety Issues**

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**BCMA**

*People related*

Knowledge gaps of BCMA  
 False sense of security in BCMA  
 Knowledge gaps of BCMA safety issues

Incorrect dose dispensed  
 Stocking errors  
 Storage errors  
 Organization related  
 Insufficient staffing

*Process related*

Changes in clinical communication patterns  
 Weakening human vigilance  
 Failure to scan bar code  
 Wrong bar code wristband on patient  
 Scanning steps omitted  
 Scanning steps performed out of sequence  
 Unauthorized scanning steps  
 Patient situation interferes with scanning  
 Insufficient monitoring of patient  
 Mislabeling of medication with wrong bar code  
 Medication not administered as documented  
 Overriding of error warning  
 Clinician exceeds preset medication administration time  
 Drug not in formulary  
 Different drug formulation  
 Incorrect medication dispensed

*Technology related*

BCMA system unavailable  
 Patient without bar code wristband  
 Inability to scan bar code  
 Multiple screens required to complete transaction  
 Connectivity failures  
 Battery not charged or fails  
 BCMA equipment failure  
 Information not readily available  
 Computer cart or scanner is too large, heavy, or bulky  
 Bar code scanning procedure slower or more difficult than other methods

*Environment related*

Ambient noise interference  
 Distractions

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**CDSS**

*People related*

False expectations of clinical decision support  
 Perceived accuracy  
 Clinical knowledge deficit  
 Clinical judgment gaps  
 Knowledge gaps of CDSS safety issues  
 Transfer of responsibility to CDSS  
 Data overload  
 Alert fatigue  
 Overdependence on technology

*Technology related*

Lack of patient-specific clinical decision support  
 Drug-drug interactions  
 Rearranging clinician priorities  
 Inaccurate clinical decision support  
 Inaccurate program logic  
 Missing data resulting in inaccurate recommendation  
 Lack of maximum daily dose alert

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**CPOE**

*People related*

Inexperience  
 Clinical knowledge deficit  
 Critical thinking gaps  
 Erroneous alert overriding  
 Increased cognitive load  
 Typing errors  
 Negative emotions  
 Overdependence on technology

*Process related*

Change management  
 More data to manage  
 Changes in clinical communication patterns  
 Increased coordination load among clinicians  
 Execution of orders prior to submission of CPOE

*continued*

EXHIBIT 3 *continued*

*CPOE Process related (continued)*

Execution of orders prior to verification  
 Need for clinician to be at workstation to receive phone orders  
 Requirement for additional verification tasks  
 Changes in work flow  
 Urgency of medical care  
 More work  
 New work  
 Less time with patient due to more time with computer  
 Paper persistence

*Organization related*

Changes in the power structure  
 Cultural changes  
 Interruptions  
 Insufficient clinical staffing  
 Insufficient IT staffing  
 Heavy workloads  
 Failure to educate on what the CPOE can and cannot do

*Environment related*

Distractions

*Technology related*

Multiple required passwords  
 Insufficient interface design  
 Misidentification of patient because of poor CPOE display  
 Fragmented displays  
 Difficulty discerning patient's medications because of multiple screen displays  
 Free text orders  
 Linear nature of CPOE for nonlinear physician ordering  
 Discrepancy between verbal order and electronic form in CPOE  
 Default stop orders  
 Default drug times causing first and second doses to be administered too closely together  
 Difficulty ordering non-formulary medications  
 Requirement to cancel current medication prior to modifying current medication

Delay/failure in discontinuing medications because of difficulty in seeing entire list of current medications  
 Failure to cancel procedure-related medications if procedure postponed or cancelled  
 Impermissible antibiotic diluents  
 Inability to select individualized dose ranges  
 Failure to suggest prophylactic therapy  
 Failure to suggest medication monitoring  
 Failure to flag drug-drug interactions  
 Failure to flag drug-allergy contraindications  
 Failure to flag drug-disease contraindications  
 Failure to alert nurses with new or stat orders  
 Failure to differentiate look-alike drug names  
 False allergy information  
 Post hoc timing of allergy information  
 Conflicting orders  
 Duplicate orders  
 Cancellation of all medications for surgery  
 Challenges with variable dosage regimens  
 Failure to differentiate look-alike patient names  
 Keypad entry error  
 Improper data placement  
 Wrong selection of order set  
 Wrong selection from a pick list  
 Dense pick lists  
 Selection of incorrect dosing frequency  
 Selection of inappropriate dosage for required route  
 Loss of data during system crashes  
 Delays in medications during downtime  
 Low alert specificity  
 Unclear alert information  
 Incorrect guidance for medication dosing  
 Inconvenience of logging in  
 Timed logout disruption  
 Difficulty identifying who is logged in  
 Increased time required to input orders  
 Unable to input orders prior to patient admission  
 Slowed system during peak use  
 Loss of connectivity  
 Ongoing system changes  
 Poor coordination in deploying test, train, and production versions  
 Loss of information during care transitions  
 Timely updating of order sets

The review included 100 studies over six years (1998 through 2004). The researchers concluded that while CDSS has been reported to improve practitioner performance, the effects on patient outcomes are understudied, and findings from the few published studies are inconsistent.

BCMA is intended to ensure safe medication administration. As Koppel and colleagues (2008) point out, BCMA can create workarounds that result in errors. The authors found 15 types of workarounds surrounding omission of process steps, steps performed out of sequence, and unauthorized BCMA process steps.

BCMA is also dependent on the correct performance of other processes. McDonald (2006) describes a case where a patient was mistakenly given the wrong bar-coded identification wristband. A subsequent laboratory test demonstrated severe hyperglycemia and the wrong patient was almost administered what could have been a fatal dose of insulin. Verification of patient identity based solely on an armband is insufficient; it does not guarantee that the armband and the person are the same.

Patterson, Cook, and Render (2002) used a qualitative research design to describe the experience of nurses during implementation of BCMA. Using ethnographic observation the researchers found five negative side effects associated with BCMA implementation:

1. Nurses experienced "automation surprise" by automated removal of medications.
2. Breakdowns occurred in the coordination of care between nurses and physicians.
3. Nurses dropped activities during busy periods to gain efficiencies and reduce workload.
4. Monitored activities such as medication administration were prioritized.
5. There was a decreased ability to deviate from routine linear sequences.

The authors concluded that these side effects of BCMA could create new paths for adverse drug events and require preemptive evaluation and intervention.

Research on safety issues related to the EMR, specifically CPOE, CDSS, and BCMA, has only begun to uncover the unique unintended opportunities for error and harm that derive from clinical information systems deployment. The complexity of these systems, individually and collectively, is notable, as is the effect they have on current practice, work flow, and work environment. While these systems can undoubtedly improve patient care, safety issues left unidentified or unaddressed can undermine their benefits to patient safety. Studies on the benefits of these systems in relation to the potential harm must be considered.

Healthcare leaders must have knowledge of errors resulting from EMRs and access to discussion relative to the accountability for such errors. In 2009, Koppel and Kreda wrote about EMR vendors being liability-free when their products are involved in adverse events. The "hold harmless" contractual and legal device puts liability for technology-induced errors squarely on provider organizations and healthcare professionals referred to as "learned

intermediaries." Under this legal doctrine, physicians, nurses, pharmacists, and other clinicians are held accountable for identifying and correcting any errors generated by software defaults.

## CONCLUSIONS

The pressure on hospitals to implement EMR has never been greater. A large part of the driving force relates to demonstrated and presumed improvements to patient safety. The findings of this review reveal that the literature demonstrates unintended consequences of EMR deployment that must be considered. Several aspects of the EMR can increase the incidence of certain types of errors or produce new safety risks that result in harm. The existence of only 24 published articles during the past decade suggests that greater focus upon the nature and mechanisms of e-iatrogenesis would be beneficial in the near term. The role of healthcare leaders in the safety of EMR cannot be understated. Leaders must be aware that thorough EMR deployment is not a panacea. Effective planning, design, and development are essential to prevent the time, cost, and safety consequences of poorly created and implemented EMRs. Additionally, leaders on the provider side should be involved in the maturation of products; their leadership is essential to realize the potential of these technologies.

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## PRACTITIONER APPLICATION

*David A. Snyder, MD, FACHE, chief quality officer and chief medical informatics officer, Medical College of Georgia Health System, Augusta, Georgia*

**D**r. Harrington and her colleagues have given us a succinct summary of ways that patient injuries still occur despite, or even because of, the use of electronic medical records and their support systems. Certainly, some of the potential sources of injury in electronic systems are purely technical. These are important, and we can't dismiss them. That said, our technical colleagues are adept at fixing them once we as providers and facilitators of care have clearly articulated our concerns.

The more insidious risks of electronic medical records, however, may be found in the nature of the work itself, and in the human factors surrounding the people who do that work. Those of us who have to deal daily with the resource and time

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