

# Quality and Safety Implications of Emergency Department Information Systems

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The Health Information Technology for Economic and Clinical Health Act of 2009 and the Centers for Medicare & Medicaid Services “meaningful use” incentive programs, in tandem with the boundless additional requirements for detailed reporting of quality metrics, have galvanized hospital efforts to implement hospital-based electronic health records. As such, emergency department information systems (EDISs) are an important and unique component of most hospitals’ electronic health records. System functionality varies greatly and affects physician decisionmaking, clinician workflow, communication, and, ultimately, the overall quality of care and patient safety. This article is a joint effort by members of the Quality Improvement and Patient Safety Section and the Informatics Section of the American College of Emergency Physicians. The aim of this effort is to examine the benefits and potential threats to quality and patient safety that could result from the choice of a particular EDIS, its implementation and optimization, and the hospital’s or physician group’s approach to continuous improvement of the EDIS. Specifically, we explored the following areas of potential EDIS safety concerns: communication failure, wrong order–wrong patient errors, poor data display, and alert fatigue. Case studies are presented that illustrate the potential harm that could befall patients from an inferior EDIS product or suboptimal execution of such a product in the clinical environment. The authors have developed 7 recommendations to improve patient safety with respect to the deployment of EDISs. These include ensuring that emergency providers actively participate in selection of the EDIS product, in the design of processes related to EDIS implementation and optimization, and in the monitoring of the system’s ongoing success or failure. Our recommendations apply to emergency departments using any type of EDIS: custom-developed systems, best-of-breed vendor systems, or enterprise systems. [Ann Emerg Med. 2013;xx:xxx.]

0196-0644/\$-see front matter

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<http://dx.doi.org/10.1016/j.annemergmed.2013.05.019>

## INTRODUCTION

The release of the 2 Institute of Medicine (IOM) reports, *To Err is Human* in 1999 and *Crossing the Quality Chasm* in 2001, focused local quality improvement and national policy efforts on reducing medical errors and improving patient safety.<sup>1,2</sup> One of the major interventions aimed at reducing medical errors was the development and use of electronic health records systems, also referred to as emergency department information systems (EDISs) when focused on the emergency department (ED).<sup>3-6</sup> The most significant legislation in this area was the Health Information Technology for Economic and Clinical Health Act of 2009, which was part of the American Recovery and Reinvestment Act and encouraged hospitals to implement such electronic records by 2011. It also promised financial penalties by 2015 for hospitals that fail to comply. In addition, the Centers for Medicare & Medicaid Services “meaningful use” incentive programs, coupled with additional requirements for detailed reporting of quality metrics, have catalyzed hospital efforts to implement hospital-based electronic health records.

EDISs are an important and unique component of this greater movement toward improving quality and outcomes with electronic health records. There is a wide variety of electronic systems with various functionality available for use by EDs throughout the country. Variation in EDIS functionality affects physician decisionmaking, clinician workflow, communication, and, ultimately, the overall quality of care and patient safety in a particularly challenging clinical environment (eg, high volume, time sensitive). However, the technology is constantly evolving and vendors are adapting to meet new demands by clinicians, health care administrators, and government, and as such, active engagement by front-line clinicians in improving these products is critical.

Recently, studies have emerged in the literature examining the benefits and unintended consequences of these systems.<sup>7-12</sup> The unique characteristics of EDs, including rapid turnover, frequent transitions of care, constant interruptions,<sup>13</sup> large variation in patient volumes, and unfamiliar patients, make the ED environment particularly error prone. These factors and

others must be carefully considered when an EDIS is selected and implemented.

This article is the product of a joint committee composed of members of the Quality Improvement and Patient Safety Section and the Informatics Section of the American College of Emergency Physicians with expertise in safety, computer design heuristics, or both. Members collaborated to conduct a literature search and to explore, from the perspective of the emergency physician, the benefits and potential threats to patient safety that may result from EDIS choice, implementation, and approaches to continuous quality improvement. Specifically, we focus on the need for emergency providers to participate actively in decisions about EDIS selection, in processes related to system implementation, and in the institution of local committees to monitor the ongoing success and failure of these systems.<sup>14-16</sup> EDIS systems should be flexible enough to be modified at the individual user level while having a sufficient uniformity to encourage a best-practice approach to patient care among all users. No system is perfect, and adoption of an EDIS and the transition between different systems is difficult. Nevertheless, there are many ways to optimize implementation. In addition, many seemingly nonideal systems can be improved to conform to local environments.<sup>9</sup>

### EDIS POTENTIAL BENEFITS

Quality and safety in health care can be achieved, in part, by reducing variability in practice and performing each step in clinical care with high reliability. EDISs are intended to decrease practice variability and improve system reliability by ensuring legible communication, facilitated retrieval of past information (eg, physician notes, diagnostic studies), and access to computerized physician order entry to aid in clinical decision support.<sup>6,8,17-19</sup> Computerized physician order entry can help identify medication interactions and medication/allergy contraindications. In addition, it allows creation of order sets that help guide patient management with use of “best practices.” With computerized physician order entry, best practice alerts can be created to help provide critical information to providers, such as reminding providers of a clinical protocol (eg, suggesting a specific antibiotic) or facilitating retrieval of less commonly used information (eg, factor replacement dosing per indication for hemophiliac patients). More advanced EDISs help make medical references easily accessible, assist with important calculations, monitor for potential adverse events (eg, ordering of intravenous contrast for patients with an elevated creatinine level or ordering of a computed tomography study for patients with a pending pregnancy test). EDISs can provide the potential to share medical information across different health systems. They also may help with early identification of epidemics (eg, pooling of patient symptoms across systems) and assist with population management in an era of increasing shared accountability and quality reporting mandates. The perceived advantages of electronic health records, including EDISs, are so significant<sup>10,11</sup> that Congress allocated nearly \$30 billion to

build incentive for their universal adoption through the American Recovery and Reinvestment Act.

### EDIS POTENTIAL PITFALLS

Despite their many benefits, electronic health records, such as EDISs, may also lead to medical errors and cause patient safety and quality concerns.<sup>12,20</sup> A recent report released by the IOM, *Health IT and Patient Safety: Building Safe Systems for Better Care*, states that “[p]oorly designed, implemented, or applied, health IT [information technology] can create new hazards in the already complex delivery of health care . . . . As health IT products have become more intimately involved in the delivery of care, the potential for health IT-induced medical error, harm, or death has increased significantly.” Authors cited dosing errors, delay in detection of fatal illnesses, and delaying treatment because of poor human-computer interactions or loss of data as health IT-induced harm that can result in serious injury and death.<sup>21</sup>

Similarly, a new report from the National Institute of Standards and Technology, “A Human Factors Guide to Enhance EHR Usability of Critical User Interaction When Supporting Pediatric Patient Care,” focuses on the issue of critical user interactions. The authors define “critical user interactions” as interactions between a user—such as a physician, nurse, pharmacist, caregiver, or patient—and the electronic health record that can potentially lead to errors, workarounds, or adverse events that are associated with patient harm. The authors go on to state that “[i]n safety-critical environments (eg, hospitals, emergency departments, etc), the importance of well-designed, usable interfaces is increased precisely because of the potential for catastrophic outcomes.”<sup>22</sup>

The electronic health records that are marketed and sold to hospitals and providers are all certified for use by the Certification Commission for Health Information Technology, but this certification process is not focused on system safety issues. In fact, there is currently no mechanism in place to systematically allow, let alone encourage, users to provide feedback about ongoing safety issues or concerns with electronic health records, such as EDISs. In fact, some vendors prohibit users from sharing hazards even in the academic literature.<sup>23-25</sup> Although almost every aspect of health care develops under close regulatory oversight (eg, pharmaceuticals, medical devices), the exploding electronic records industry is comparatively unregulated. Furthermore, EDIS-related errors are often attributed to user experience level and training, but they may not prevent human factors errors that result from poor design of such products. In fact, a growing body of evidence suggests that many errors may be the result of poor design rather than user errors.<sup>26,27</sup> In general, these failures of design can be attributed to simple usability issues, as well as workflow mismatches. Usability is concerned with violation of common interface design heuristic rules, such as presenting consistent models of function or using legible fonts. Workflow mismatches are more related to the match (or lack thereof) between providers’ models of work and the designers’ models inscribed into the EDIS

system. For example, forcing a provider to enter the number of capsules to be dispensed before entering the number of capsules per dose, number of doses per day, and duration of days in the course (counter to a prescriber's normal thought process) may result in increased errors. In another example, a study of the usability of computerized physician order entry in primary care called for the development of a more consistent and intuitive interface to reduce the risk of drugs being prescribed with incorrect dosages.<sup>28</sup>

In a study that aimed to identify the types of unintended consequences associated with implementation of computerized physician order entry systems, researchers found new kinds of errors, including these: juxtaposition errors, in which users select an item next to the intended choice, such as a wrong patient being selected; desensitization to alerts or alert overload; confusing order option presentations; and system design issues related to poor data organization and display.<sup>29</sup> Furthermore, some electronic health records are not designed with mechanisms to help providers notice and recover from user errors.<sup>30</sup>

Electronic health records, including EDISs, should be designed to match common properties of human perception and decisionmaking, as well as task- and user-specific properties of work. The following clinical scenarios will further illustrate how EDIS design can have a profound influence on patient safety.

## CLINICAL SCENARIOS

This section will provide fictitious yet realistic clinical scenarios related to 4 common pitfalls of EDIS use in EDs: communication failure, poor data display, wrong order/wrong patient errors, and alert fatigue. We hope these examples will provide greater insight into the unintended consequences of implementation of any given EDIS; they are not product specific.

### Communication Failure

The loud moaning draws you into room 10, where you find a patient rocking back and forth, holding his right flank. "He says it is his kidney stones," informs the nurse. After a cursory examination, you ask the nurse to give him 1 mg of hydromorphone to ease his obvious discomfort. You then receive an urgent request to reevaluate a critical patient. Finally, you sit down at a computer station to chart and enter orders for the patient with a presumed kidney stone. Half an hour later, you check in on the patient and he is difficult to arouse. "How many milligrams of hydromorphone did the patient get?" you inquire. The nurse tells you 3 doses of 1 mg each. "How did that happen?" "Well, you remember you asked me to give 1 mg of hydromorphone while we spoke in the room, then you ordered another 1 mg in computerized physician order entry with an as needed order for a third."

Does an EDIS promote or hinder communication? Some of the communication benefits of an EDIS include elimination of

illegible handwriting and nonstandard abbreviations, chart accessibility from multiple sites simultaneously, use of visual cues and signals to flag the next steps in care,<sup>31,32</sup> efficient transfer of information (eg, incorporating laboratory results and patient demographics), and recording accountability (eg, staff who have acknowledged or carried out an order).

However, EDIS do not replace human interaction and face-to-face communication in providing a shared higher-level understanding of a situation.<sup>33</sup> Although communication errors may certainly occur with paper-based charting systems, new forms of communication failure can be introduced if users are not sensitive to the limitations and pitfalls of an overreliance on the EDIS. Some of the barriers to effective communication within current EDIS include the following:

- Data entry options are limited, generally requiring a computer and keyboard, which are not always readily available.
- EDISs are inadequately sensitive to different preferences for location and timing of data input, which may lead to dangerous workarounds to an existing suboptimal process, such as use of handwritten items that are later transcribed into a computerized physician order entry.
- An overreliance on the EDIS as a primary source of communication can degrade the quality of communication, leaving providers with the dangerous task of decoding generic messages, eg, EDIS macros (ie, scripted text) with variable applicability to individual patient encounters.
- EDISs are not yet adept at providing a meaningful summary of a patient's course.

Implementing structured communication strategies (eg, assigning responsibility for who enters verbal orders into the electronic record), in addition to conducting simulation training before live computerized physician order entry, may help avert common errors associated with EDISs and ensure safe, appropriate transfer of information among providers.

### Poor Data Display

It's 10:30 PM, admitted patients have been stacking up in the ED since the day before, and there is no relief in sight from the crowding. You have 27 patients in your section of the ED, and more than half have results pending from various imaging and laboratory studies. You are waiting for a few critical laboratory values on your sickest patients, and you are scrolling through the "Results" section on the new EDIS.

You try to review laboratory results for many of your patients quickly and click a button to "accept all" results, which enters the results into individual patient charts. In doing so, you miss an elevated troponin level for a patient who was admitted for a cardiac evaluation. Fortunately, the laboratory calls a short while later, alerting you to the laboratory value, and you are able to notify the admitting team of the patient's change in status to a non-ST segment elevation myocardial infarction. A repeated evaluation and ECG show evolving ST changes, prompting the cardiology team to take the patient to the catheterization laboratory directly from the ED.

Poor data display is a serious problem with many of today's EDISs. Most vendor products simply list the results in tabular or text format, not taking into consideration the graphic way clinicians have traditionally recorded their results (eg, the stick format). The need to scroll through long tables or lists of results makes it incredibly easy to miss abnormal results. Although abnormal results are often bolded, red, or underlined, it is still difficult to quickly home in on important abnormal results (eg, positive D-dimer result) among other, less significant abnormal results (eg, slightly elevated chloride level). This is especially true when simple human computer interaction design heuristics, which have existed for more than 20 years, are inadequately implemented by some vendors.<sup>34</sup>

Even with the best designs in place, EDISs change the way we cognitively process data. For example, the cognitive task of transcribing results, though less efficient, forced clinicians to process the information they were reviewing more thoroughly. Now, the ability to quickly scroll through a screen that displays results in tabular format makes it easier to miss critical results. Some EDISs require that the user "acknowledge" that the results were viewed by clicking a box or performing some other function on the screen, yet other systems simply post the results and keep a log file of which users actually viewed the results. Because results are no longer manually transcribed, it is possible that less cognitive processing of values leads to potentially harmful oversights.

In some instances, the existence of software/hardware incompatibility issues requires the user to scroll in 2 directions on the screen to see important information such as reference ranges. This is sometimes due to poor software design, poor specification of the hardware requirements for the software, or refusal of the purchaser of the software to upgrade certain hardware to the vendor's specifications (eg, a wide-format monitor).

Display of an icon, or different color or font of critical laboratory values, is at least a start in attempting to improve data display. Separating these from the noise of normal laboratory values or abnormal values of less significance might also be beneficial. In addition, verbal communication requirements for critical laboratory values provide a useful redundancy feature in preventing errors such as that depicted in the above scenario.

### **Wrong Order–Wrong Patient Error**

It is a typical busy evening in your community ED, and you are caring for several patients and have just left the room of an agitated 34-year-old woman who is withdrawing from alcohol. You go to your computer, open the patient tracker, and intend to order 2 mg of intravenous lorazepam for the patient. While in the process of preparing to enter the order, you are interrupted to "sign" an ECG of a 65-year-old man with chest pain who has just arrived by ambulance. You are concerned about a possible ST-segment elevation myocardial infarction, so you hurriedly enter the order for lorazepam and proceed to go to the room of the chest pain patient. The lorazepam order is

inadvertently entered on another patient, an 80-year-old with congestive heart failure, who is also one of your current patients and whose name is listed on the EDIS tracker. The patient has a near respiratory arrest and needs to be intubated.

This is a case example of a grouping of adverse events that can be categorized as wrong order–wrong patient errors, which may pose significantly more risk for EDIS users. Although these errors can occur with paper-based systems, an alarming number of clinicians are anecdotally reporting a substantial increase in the incidence of wrong order–wrong patient errors while using the computerized physician order entry components of information systems. There are few consistent data on how commonly these errors occur, and few studies are actually focused on collecting evidence of these errors.<sup>35</sup> These errors can occur in several ways: ordering a medication or diagnostic intervention for an unintended patient, ordering the incorrect medication (look alike/sound alike) or test for an intended patient, or reviewing data or medical information (laboratory, history, radiographic studies) for an unintended patient.

Possible contributing factors that can lead to wrong patient errors may include lack of clarity on which patient name is highlighted or selected from a tracking list, lack prominence of the patient name and other identifiers on the current work/order page, inadequate means of distinguishing duplicate names on a tracking board (Jones and Jones), and overreliance on redundancy or alert mechanisms. One cohort of ED patients particularly vulnerable to this problem is the unidentified patients: those coming in as cardiac arrest, unresponsive, or trauma patients. Most EDs have a standard but often not distinguishable way of labeling these patients' records in the EDIS (eg, XXX unique identifier), and often because of level of acuity, these patients are cohorted to the same section of an ED, amplifying the potential of wrong order–wrong patient errors occurring. Some systems do prompt the user about whether the order is for the correct patient, but when done routinely, this can lead to alert fatigue and clicking through the warning.

Though described in the Health Information Technology literature under "juxtaposition errors,"<sup>20,36</sup> we believe the descriptive acronym for wrong order–wrong patient error (WOWPE) is more intuitive for wider understanding and adoption because of its less technical nature that emphasizes the effect on patients. Although this is likely to remain a challenging issue, displaying the patient's room number, age, sex, or chief complaint, and even perhaps an image of the patient, in computerized physician order entry might help avoid such errors.

### **Alert Fatigue**

"Warning!" the system proclaims. "There is no weight on file for this patient. You must enter a reason why you wish to proceed with your order of 1,000 mL normal saline solution."

Your nursing home patient is septic with pneumonia. You are trying to order a fluid bolus and start administering antibiotics promptly.

“Warning! The patient has a documented allergy to penicillin. You must enter a reason why you wish to proceed with your order of cefepime.”

You sigh, recalling the very low cross-reactivity between cefepime and penicillin. When you attempt to order vancomycin: “Warning! The patient has an adverse reaction to vancomycin. You must enter a reason why you wish to proceed with your order of vancomycin.” “What’s that?” you think to yourself. “Didn’t we just do this?” You click to get past the pop-up and order the antibiotic anyway. An hour later, a nurse has turned off the vancomycin infusion, asked you to order diphenhydramine, and is filing an incident report about a preventable adverse medication reaction.

Clinical decision support has the potential to improve medical decisionmaking by incorporating evidence-based guidelines and patient characteristics to influence orders at the point of order entry. Although clinical decision support is a compelling idea, in practice it is commonly experienced within the context of a series of alerts and warnings that can range from completely irrelevant to life threatening. The sheer volume of such alerts and warnings can dull the senses, leading to a failure to react to a truly important warning. Research investigating the effect of alert fatigue on clinical decision support and computerized physician order entry has largely focused on patient care outside the ED.

In one study, 250,000 prescription alerts during a 6-month period prevented 402 adverse drug events, 49 of which were judged as serious and 3 as potentially fatal, and likely prevented dozens of hospitalizations and ED visits. However, it took more than 2,700 warnings to prevent 1 serious adverse drug event, more than 90% of alerts were overridden, and just 10% of alerts accounted for the majority of adverse drug event prevention and cost savings.<sup>37</sup> In a follow-up study of drug interactions most likely to be accepted by outpatient clinicians,<sup>38</sup> even “high-severity” alerts were accepted only 25% to 45% of the time, whereas the worst high-severity alerts had a 2% to 8% acceptance rate.<sup>39</sup> Taken together, these led the authors to wonder “whether the juice is worth the squeeze.”

Findings as above ideally would stimulate discussions between emergency providers, hospital pharmacists, and drug interaction database vendors about editing their interactions list to scale back the volume of clinically insignificant alerts, improving the signal-to-noise ratio and preventing alert fatigue. At the very least, clinically insignificant alerts (as defined by the providers and pharmacists who will be receiving them) could be screened out at the EDIS level. Despite the value of such efforts, many are doubtful that legal barriers or risk management concerns can be sufficiently addressed to encourage vendors to participate in such efforts.

However, even useful alerts can have unintended consequences when they disrupt workflow. One study of a drug interaction warning system gave users the option either to speak with a pharmacist or to enter an indication for alerted drugs and acknowledge a personalized warning to proceed.<sup>40</sup> The trial was

discontinued because of excessive delays in medication administration. Thus, improving the signal-to-noise ratio and reducing fatigue for drug alerts is not enough; the interface for alerting users to real dangers must not disrupt workflow or the benefits of clinical decision support will not be realized.

The burden that overalerting places on practitioners has been recognized.<sup>41,42</sup> With the advent of American Recovery and Reinvestment Act’s Meaningful Use incentives (which in stage 2 places additional priority on clinical decision support that is sensitive to patient context) and new usability guidelines from the National Institute of Standards and Technology geared toward improving patient safety, there is room for optimism that improvements to the overalerting problem may be on the horizon.

## RECOMMENDATIONS

In 2011, the IOM released its report titled “Health IT and Patient Safety: Building Safer Systems for Better Care.”<sup>21</sup> The IOM report concluded that “current market forces are not adequately addressing the potential risks associated with use of health IT” and made the following recommendations: “. . . [A]ll stakeholders must coordinate efforts to identify and understand patient safety risks associated with health IT by facilitating the free flow of information, creating a reporting and investigating system for health IT–related deaths, serious injuries, or unsafe conditions, and researching and developing standards and criteria for safe design, implementation, and use of health IT.” Although the recommendations made by the IOM are important, the unique ED environment warrants additional recommendations specific to the EDIS.

The clinical scenarios portrayed above illustrate how patient safety can be affected by implementation of EDISs in the ED. In accordance with these examples and a literature review, 7 recommendations to improve patient safety were developed (Table). These recommendations apply to EDs using any type of EDIS (custom-developed systems, best-of-breed vendor systems, or enterprise-wide systems) and are divided into recommendations for the end user and vendor. These recommendations are based on expert consensus and are not directly evidence based.

*End-User Recommendation 1: A local ED clinician champion should be appointed to maintain a performance improvement process for the EDIS and lead the EDIS performance improvement group.*

The EDIS clinician champion serves as a liaison between ED clinicians, technical staff (vendor or hospital information systems staff), and ED or hospital leadership. This clinician has primary responsibility to ensure safe and efficient EDIS operations and should be included in hospital and medical staff quality committees. Ideally, this clinician will have formal training and experience in emergency medicine and clinical informatics (a newly approved American Board of Medical Specialties medical specialty).

**Table.** Recommendations to improve the safety of ED information systems.

1	A local ED clinician champion should be appointed to maintain a performance improvement process for the EDIS and lead the EDIS performance improvement group.
2	A multidisciplinary EDIS performance improvement group should meet regularly and communicate regularly with ED and hospital leadership.
3	A review process should be in place to monitor ongoing patient safety issues with the EDIS. ED providers and other stakeholders should be encouraged to submit safety concerns for review. In addition, prospective risk assessments should be conducted regularly.
4	EDIS-related patient safety concerns identified by the review process should be addressed in a timely manner by ED providers, the EDIS vendors, and hospital administration. Each of these processes should be performed in full transparency, specifically with openness, communication, and accountability.
5	Lessons learned from performance improvement efforts should be measured and shared publicly, including with other EDs using the same EDIS.
6	EDIS vendors should learn from local patient safety improvements and ensure timely distribution of necessary changes to all installation sites.
7	“Hold harmless” or “learned intermediary” clauses should be removed from vendor software contracts.

*End-User Recommendation 2: A multidisciplinary EDIS performance improvement group should meet regularly and communicate regularly with ED and hospital leadership.*

Most EDs have developed infrastructures to handle clinical care concerns. A similar process must be established for EDIS concerns. A multidisciplinary committee should meet regularly to review EDIS issues that are affecting patient care. Because EDIS shortcomings are frequently due to larger hospital-wide product builds and may involve multiple, complicated software systems, committee membership should include a wide range of key stakeholders from clinical, IT, and leadership areas.

*End-User Recommendation 3: A review process should be in place to monitor ongoing patient safety issues with the EDIS. ED providers and other stakeholders should be encouraged to submit safety concerns for review. In addition, prospective risk assessments should be conducted regularly.*

Ideally, EDIS safety issues should be identified and prevented before they occur. Health care failure mode and effects analysis is one approach to performing a risk analysis on health care processes and detecting threats.

When EDIS safety issues occur in the ED, there should be a reporting process. Several approaches can facilitate reporting: (1) a direct link from the EDIS software to a database; (2) a separate paper or Web-based electronic form; (3) a component of the hospital's existing safety reporting system dedicated to the EDIS; or (4) an information system help desk. ED and hospital leadership should support a hospital-wide culture that encourages safety incident reporting, including EDIS issues.

*End-User Recommendation 4: EDIS-related patient safety concerns identified by the review process should be addressed in a*

*timely manner by ED providers, the EDIS vendors, and hospital administration. Each of these processes should be performed in full transparency, specifically with openness, communication, and accountability.*

After EDIS safety issues are reported, they must be investigated to determine the underlying cause that needs to be addressed (with careful attention to ensure that the solution does not introduce new unintended consequences). Although the underlying issues may be complex and costly to address, they should be appropriately recognized, highlighted, and mitigated. The extent of the redesign that may be required and its timeliness will depend on the severity of the safety issue at hand. After implementation of a change in the EDIS to address a patient safety issue, testing and evaluation should be undertaken to monitor safety outcomes.

*Vendor/End-User Recommendation 1: Lessons learned from performance improvement efforts should be measured and shared publicly, including with other EDs using the same EDIS.<sup>43</sup>*

Many vendors have developed online discussion groups in which users on the same vendor system can share ideas with one another. Vendors should be encouraged to continue this practice and to specifically encourage users to share lessons learned from safety incidents, including near misses. Furthermore, such information sharing can be expanded so that lessons learned with a single vendor at a single site can be shared across vendor systems and with the public and regulatory agencies.

Many EDIS vendor software contracts currently contain provisions preventing reporting and dissemination of critical safety vulnerabilities and failings to other users, the public, and professional and safety organizations. Eliminating these barriers for sharing observed and potential vulnerabilities must occur to assist regulators in tracking and addressing safety threats. Such accountability is necessary to ensure the safety of patients with the expanding role of electronic health records.

*Vendor Recommendation 2: EDIS vendors should learn from local patient safety improvements and ensure timely distribution of necessary changes to all installation sites.*

When an EDIS patient safety issue requires the vendor to make changes in a product, vendor changes should be prioritized and implemented expeditiously. Furthermore, the underlying issue should be immediately communicated to all sites using the vendor product and the product update should be made available to all sites.

Software updates in health IT can be complex. The communication between products can be version specific, so a call to maintain updated software is a difficult proposition. Incompatible system versions can be as unsafe as software. However, maintaining current product versions is usually the least flawed IT environment.

*Vendor Recommendation 3: “Hold harmless” or “learned intermediary” clauses should be removed from vendor software contracts.*

Many contracts contain language that grants the vendor complete indemnification and shifts liability onto the health care facility and its clinicians through the use of “hold harmless” clauses and the application of the “learned intermediaries” doctrine. Hold harmless clauses state that no matter what role the EDIS system may have played in an adverse event, the vendor has no liability. Vendors may also have additional warranties prohibiting claims against their product. The learned intermediary doctrine implies that the end users (clinicians) are the medical experts and should be able to detect and overcome any fallibility or contributing factor of the product.

The lack of accountability for vendors through hold harmless clauses and the shifting of liability to the clinicians through the learned intermediary doctrine are significant and additional impairments to safety improvement. Electronic health records and EDISs are sufficiently complex that the physician and other users cannot be expected to anticipate unpredictable errors.<sup>44</sup>

## LIMITATIONS

Many of the patient safety concerns raised in this article would benefit from greater illumination if evaluated by experts in human factors engineering. Future efforts should include such nontraditional disciplines, as well as a broader array of key stakeholders (eg, payers, patients). In addition to direct patient safety concerns, EDISs have an immense influence on clinicians’ day-to-day professional satisfaction in their working environment. Similarly, aside from safety and satisfaction, EDISs also have an influence on relevant topics such as the security and confidentiality of patient medical records, including patient access to these records. These areas of investigation were not addressed in the limited scope of this article. The authors recognize that much of the literature on electronic health records may or may not be applicable to EDISs because the workflow in the ED varies from that in the ambulatory or inpatient setting. Nevertheless, the available data and irreversible drive toward EDIS implementation should serve as an alert about the potential harmful effect of EDISs if not optimized thoughtfully and with a constant eye toward improvement and hazard prevention.

## CONCLUSION

Potential pitfalls of EDISs in providing optimal patient care are discussed, highlighted by several clinical scenarios in which EDIS facilitates patient care yet also contributes to hazardous situations. Seven recommendations for EDISs are offered and cover a variety of areas: dedication of sufficient clinician time; structured risk gathering, analysis, improvement, and monitoring; risk transparency from the vendors and the clients; widespread collaboration for risk analysis; and a call for legal responsibility from the vendors. In addition to the 7 recommendations presented here, we also support the recommendations from the IOM report on health IT and patient safety. Together, these documents provide a framework that should be studied by every ED to ensure patient safety with regard to EDISs.

*The authors acknowledge the following individuals for their contributions to the article: Emily Graham, RHIA, Robert Broida, MD, Stacie S. Jones, MPH, Dainsworth Chambers, Terry Fairbanks, MD, MS, Rachel Groman, MPH, and Adam B. Landman, MD, MS.*

*Supervising editor: Robert L. Wears, MD, PhD*

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*Funding and support: By Annals policy, all authors are required to disclose any and all commercial, financial, and other relationships in any way related to the subject of this article as per ICMJE conflict of interest guidelines (see [www.icmje.org](http://www.icmje.org)). The authors have stated that no such relationships exist. This article was supported by an ACEP Section Grant (\$1,825).*

*Publication dates: Received for publication December 22, 2012. Revisions received April 1, 2013, and May 20, 2013. Accepted for publication May 23, 2013.*

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