Roadmap for Provision of Safer Healthcare Information Systems: Preventing e-Iatrogenesis
Roadmap for Provision of Safer Healthcare Information Systems: Preventing e-Iatrogenesis

Prepared for
Institute of Medicine

Prepared by
Oregon Health & Science University
Department of Medical Informatics and Clinical Epidemiology, School of Medicine

Authors:
Joan Ash, PhD, MLS, MBA
Charles M. Kilo, MD, MPH
Michael Shapiro, MA, MS
Joseph Wasserman, BA
Carmit McMullen, PhD*
William Hersh, MD

*Kaiser Permanente Center for Health Research, Portland, OR, USA

Contributors:
Dean F. Sittig, PhD, UT-Memorial Hermann Center for Healthcare Quality & Safety, University of Texas School of Biomedical Informatics at Houston, Texas, USA; Adam Wright, PhD, Harvard Medical School, Boston, MA, USA; David Dorr, MD, MPH, Deborah J. Cohen, PhD, Vishnu Mohan, MD, James McCormack, MT (ASCP), Arwen Bunce, MA, Oregon Health & Science University, School of Medicine, Portland, OR, USA

Corresponding Author:
Charles M. Kilo, MD, MPH
Chief Medical Office
Oregon Health & Science University
3181 SW Sam Jackson Park Road, CR9-6
Portland, OR 97239
c: 503-494-6020
f: 503-494-8020
e: kilo@ohsu.edu
Summary of “Roadmap for Provision of Safer Healthcare Information Systems: Preventing e-Iatrogenesis”

Summary of Background and Methods

e-Iatrogenesis, defined as “patient harm caused at least in part by the application of health information technology,” (Weiner et al., 2007, p. 387) is of increasing concern as more and more hospitals are implementing health information systems (HIS). This report assesses how HIS can be designed, developed, implemented, monitored, and maintained to maximize safety. We specifically focus on hospital electronic health records (EHRs), clinical decision support (CDS), and computerized provider order entry (CPOE) systems. This white paper is intended to provide background for an Institute of Medicine (IOM) report on how the use of health information technology affects the safety of patient care by answering the following IOM-posed questions:

1. What are the risks of healthcare information systems that arise from workflow and related issues?
2. How have organizations acted to implement healthcare information systems safely?
3. What are the impacts of customization on safety?
4. What is the industry approach to managing change and customization?

A recent literature review by Harrington et al. has summarized the EHR safety literature, so we first reviewed all papers cited in their report (2011). Of their 43 references, we identified 37 that were relevant to the scope of this report. We analyzed the bibliographies of these selected papers and performed a reverse bibliography search on the articles deemed most relevant and published since 2000. In total, we identified over 100 sources relevant to the scope of this report. We then targeted topics for which published evidence was lacking and conducted several interviews with experts to help fill the knowledge gaps.

Summary of Results

What are the risks of healthcare information systems that arise from workflow and related issues?

We found seven publications (Chou and Hicks, 2008; Joint Commission, 2008; Magrabi et al., 2010; Myers et al., 2011; Santell et al., 2009; Walsh et al., 2006; Zhan et al., 2006) presenting results of assessments of e-Iatrogenic risk. All are studies of large databases of reported errors and they consistently indicate low levels of HIS-related risk, under 1% of all errors. All point to the need for human diligence when using HIS. Specifically, they indicate that HIS-related errors are due to inadequate staffing levels, lack of user experience, mislabeled barcodes on medications, human distraction, inaccurate data entry, system downtime, and missing data.

How have organizations acted to implement healthcare information systems safely?

Prior to implementation, healthcare organizations can mitigate risk. There is a large literature base devoted to the risks inherent in commercial EHR systems, and also warnings about their impact on workflow. Organizations have acted in a variety of ways to implement systems safely.
Many publications offer guidance to hospitals about assessing workflow, selecting systems for purchase, conducting simulation tests, training, and other mechanisms for ensuring safe HIS implementation. Numerous publications exist to guide the implementation process itself, but there are also several pointing to the risks of rapid implementation without appropriate preparation. Finally, after implementation, continuous monitoring and improvement can mitigate safety risks.

**What are the impacts of customization on safety?**

The literature indicates that customization of the EHR to fit local situations seems to be necessary for many reasons, but there is scant research on how much customization or what form of customization is needed to optimize EHR use and what the risks are from either too much or too little customization. The content of clinical decision support likewise needs adaptation, especially to avoid alert fatigue. Any customization must be done with care so that system upgrades can be accommodated.

**What is the industry approach to managing change and customization?**

The current industry approach is fragmented; a report sponsored by the Agency for Healthcare Research and Quality describes a wide variety of vendor practices related specifically to usability of systems (McDonnell et al., 2010). Because purchasers must usually customize systems to fit local workflows and regulations, HIS safety depends on a combination of industry and local diligence.

**Summary of Recommendations**

Although current evidence is limited, the presence of HIS appears to contribute to less than 1% of total errors in health care settings. However, indirect effects from disruption of workflow are difficult to measure. Further investigation into these issues is needed as soon as possible so that solid evidence can inform the bolus of HIS implementations in hospitals resulting from meaningful use regulations. In addition, expert consensus-based recommendations would be highly useful.
Roadmap for Provision of Safer Healthcare Information Systems: Preventing e-Iatrogenesis

I. Introduction

E-Iatrogenesis, defined as “patient harm caused at least in part by the application of health information technology,” (Weiner et al., 2007, p. 387) is of increasing concern as more and more hospitals are implementing health information systems (HIS). This report assesses how HIS can be designed, developed, implemented, monitored, and maintained to maximize their safety. We specifically focus on hospital electronic health records (EHRs), clinical decision support (CDS), and computerized provider order entry (CPOE) systems.

We consider safety from the perspective of HIS vendors, users (e.g., hospitals), and regulators focusing on eight dimensions of HIS safety: hardware/software; clinical content; human computer interaction; people; workflow and communication; internal organizational features; external rules and regulations; and measurement and metrics (Sittig and Singh, 2009, 2010). Recommendations on how to maximize the safety of HIS have been generated based on a review of available published evidence on HIS-assisted care on patient safety and consultation with experts.

“HIS-assisted care” refers to health services that incorporate HIS for the purpose of improving the processes and outcomes of care. HIS-assisted care includes care supported by and involving electronic health records (EHRs), CDS, CPOE, health information exchange, patient engagement technologies, bar-coding, and other health information technologies used in clinical care. Technologies that do not require a human intermediary, such as devices to monitor the vital signs of patients, are not included in this definition.

In this manuscript, we focus on the literature about HIS safety, defining safety as the avoidance of harm and injury during the process of medical care. We do not focus on quality, which is the provision of optimal care.

Please see Appendix A for a glossary of terms used throughout this report.

Specifically, the purpose of this report is to answer the following questions as requested by the Institute of Medicine:

1. What are the risks of healthcare information systems that arise from workflow and related issues?
2. How have organizations acted to implement healthcare information systems safely?
3. What are the impacts of customization on safety?
4. What is the industry approach to managing change and customization?

II. Background

Electronic tools such as health information systems can help improve quality, safety and efficiency in healthcare delivery (Chaudhry et al., 2006). This is a commonly held belief, and good data support the assertion depending on the specific electronic tool or system of interest and the outcome being studied.

HIS can assist in improving clinical outcomes, patient safety, and efficiency by automating, standardizing, and simplifying processes. Electronic tools can assist healthcare professionals in performing common tasks, creating legible medical records, organizing and using data, accessing and sharing of data, and more.

Historical Context

The history of HIS development tells the stories of those who seek improvements in quality, safety, and efficiency. Efforts to improve care through electronic tools date back to the earliest days in the development of electronics. For instance, the electrocardiogram was developed by Einthoven and others in the early 1900s (Jenkins, 1996).

Efforts to develop electronic records started in the 1960s when computing was in its infancy. The goal was to standardize the way the medical history, physical exam, clinical data, and the resulting impression and plan were organized and recorded. The result was the “SOAP” note as characterized by pioneer physician Larry Weed. The SOAP note is the recording, in sequence, of Subjective information such as patient history, Objective data such as physical exam and laboratory findings, Assessment of the patient given this information, and the Plan for care such as therapeutic procedures, medications, or additional diagnostics.

Weed realized that data needed to be organized to improve its use in patient care – the SOAP note record structure accomplished this and remains in use today in both paper and electronic formats (Feinstein, 1986; Hurst, 1971; Schoenbaum and Barnett, 1992; Weed, 1986).

Computers have been used in a wide variety of healthcare clinical processes since the 1970s. For instance, while physicians may not have been using computers to place orders, ward clerks, pharmacists, and others have been entering orders, related communications, and other data into computers in varying ways for many years. Laboratory and radiology report systems have been computerized for decades: information from such systems has been available in the clinical environment via computer terminals since the 1970s and 1980s.

Both computing and programming have advanced dramatically over the past two decades as we have evolved rapidly from large mainframe computers to much more distributed and pervasive devices. Many vendors have entered the EHR marketplace with a wide variety of products and capabilities.
The first EHRs were designed in the late 1960s and implemented in the early 1970s. The few institutions that deployed EHRs over the ensuing three decades were focused on the quality and efficiency of care. The EHR represents a convergence of information technology on the front-end of care—with the physicians, nurses, and other clinicians—and it combines the automation of charting, ordering, decision support, and other functions. EHRs connect these front-end functions with back-end systems such as those in the pharmacy, the laboratory, radiology, administration and data management areas.

Safety did not become a formal objective until medical errors and patient safety became defined through research done by Leape, Bates, and others in the 1990s, culminating in the IOM’s report *To Error Is Human: Building a Safer Health System* (1999).

**Defining and Studying HIS Safety**

After the IOM report *To Err Is Human* (1999) was published, the focus on patient safety sharpened quickly and this led to research on HIS safety impacts. Because patient safety is easily confused with quality of care, a clear definition of patient safety is important to research that seeks to discern the impact of HIS.

The Agency for Healthcare Research and Quality (AHRQ) defines patient safety as “freedom from accidental or preventable injuries produced by medical care” (AHRQ, 2011). This is distinct from quality of care, which is defined as the provision of optimal care (Donabedian, 1988). For example, a surgery may go well (quality), but the patient develops a hospital-acquired infection due to poor handwashing (safety). A nurse practitioner may know the appropriate medication and dose to order (quality), but the design of the CPOE system may unintentionally lead to the wrong medication being ordered (safety).

There are ample reasons for studying the HIS effect on patient safety. First, HIS are becoming pervasive, leading to substantial changes in processes of care. While they may improve safety in some areas, they can create novel safety risks in other areas, some easy to detect and some difficult. Ash et al. (2004) explored this using qualitative methods to investigate HIS implementation. They identified instances in HIS usage that foster errors rather than reduce their likelihood. Errors fell into two main categories: those in the process of entering and retrieving information and those in the communication and coordination process that HIS are supposed to support.

Second, HIS products exist in a broad number of categories such as the core EHR, CPOE, CDS, health information exchanges, patient portals, medical devices with imbedded programming, and much more. Products within each category can also differ substantially in design, user interface, functional capability. This makes product-to-product comparisons difficult given that the study of one product may reveal safety problems unique to that product.

Third, institutional differences can significantly impact HIS safety influenced, for example, by how a product is implemented, used, and monitored.
In summary, HIS research should inform vendors, users, and regulators, guiding product design, implementation, and monitoring to enhance quality and protect against errors. Such research can help to identify common lessons that they can be applied across myriad platforms and products.

III. A Framework for Considering HIS’ Safety Impact

Figure 1 presents a framework for categorizing contributors to HIS-enabled safe care. It incorporates dimensions of HIS safety within the context of three primary constituencies:

- Vendors who design and develop the products and then seek to improve their products through post-market surveillance (user feedback);
- Users, namely hospitals and clinics, that prepare, implement, and continuously monitor and improve HIS use; and
- Regulatory structures organized to assure safe practices across the industry.

Figure 1: A Framework for HIS-Assisted Safe Care (Adapted from Sittig and Singh, 2009, 2010)
The framework we have outlined is a new paradigm for continuously improving the systems and care; it may also serve as a guide for policy makers.

Our framework was adapted from Sittig and Singh’s eight sociotechnical dimensions of HIT safety (2009, 2010):

1. external rules and regulations that impact the organization;
2. measurement and metrics that can assess the safety of HIS;
3. internal organizational attributes such as organizational structure;
4. the workflow and communication practices of the individual organization;
5. people or stakeholders who use or deal with the system;
6. human-computer interactions and interfaces;
7. clinical content, including CDS and patient data within the system; and
8. the hardware and software itself.

We prefer the term health information systems over health information technology because these systems involve much more than the “technology.” Based on Carayon et al.’s Systems Engineering Initiative for Patient Safety (2006), these eight sociotechnical dimensions come from human factors studies that take into account HIS design in addition to human-environment and human-machine interactions. In Figure 1, the dimensions are outlined on the left side and the arrows show how each dimension cuts across the phases of EHR development and use.

From the vendor point of view, the phases include design and development, and post-market surveillance and improvement. Post-market surveillance can mean many things, including soliciting feedback from users. The arrows labeled “structured feedback” denote the optimal collaborative feedback loop necessary for continuous product improvement.

In the clinical setting, the hospital and/or clinic prepares for implementation, proceeds through implementation, and then stabilizes its use, with continuous monitoring and system performance improvement structures in place. As users move through these stages, they provide structured feedback to vendors who work to improve customer use – an active cycle of interaction between vendor and user.

Both vendor and user function within a regulatory environment necessary to assure adequate product design and appropriate use. Different agencies participate in these regulatory activities, from the Food and Drug Administration that oversees medical devices to accrediting bodies that oversee product use.

This framework includes the broad and complex milieu within which these systems operate. The systems impact the organizations, vendors, and care and vice versa in an ongoing and iterative cycle. The model assisted us with generating answers to the IOM’s four questions (above).
Question 1 about risk involved a vertical look through all eight dimensions; question 2 about implementation was answered by focusing on the hospital-oriented lifecycle on the right of the diagram; question 3 about customization also primarily involved the right side; and question 4 about the industry approach involved a focus on the left side, the vendor-oriented lifecycle.

IV. Literature Review Methods

Identification of References
Because Harrington et al. recently reviewed the EHR safety literature, we first reviewed all papers cited in their report (2011). Of the 43 references in Harrington’s paper, we identified 37 that were relevant to the scope of this report. From these initial references, we identified gaps in our literature review by sorting our findings into categories based on relevant actor (vendor, user, and regulator), stage (design and development, implementation, and continuous monitoring and improvement), and sociotechnical dimensions as outlined in Figure 1.

To fill these gaps, we analyzed the bibliographies of our collected resources and performed a reverse bibliography search using Scopus on the articles we deemed most relevant that were published since 2007. In total, we identified over 100 sources relevant to the scope of this report. All citations were imported into EndNote X1 citation manager. In addition to familiarizing ourselves with these publications, we drew on several experts in the field of medical informatics for additional information.

Synthesizing the Literature
Our strategy to synthesize the literature consisted of three parts: (1) writing a bibliographic annotation about the relevance of each reference to this report, (2) categorizing each reference according to the eight sociotechnical dimensions and organizational model, and (3) using a modified ground theory approach (Glaser and Strauss, 1967) to distill the collected body of literature into a number of key themes and takeaway messages in response to each of IOM’s four research questions. All annotations and categorizations were imported into EndNote X1 to compile a complete annotated bibliography. Two reviewers read each source to annotate and categorize each one. All annotations and categorizations were agreed on by three reviewers. Key themes and takeaway messages were arrived at by consensus and iterative review of our annotated bibliography. Next, we address each question with supporting literature and recommendations for future research.
V. Answers to IOM Questions

Answer to Question 1: What are the risks of healthcare information systems that arise from workflow and related issues?

To identify risk levels, it was first necessary to investigate sources of risk. Table 1 outlines a lengthy list of safety issues identified in the Harrington et al. paper; we have reorganized it for clarity. What this list shows is that the literature about CDS and CPOE in hospitals is rich with details about HIS safety issues, but the issues cover an extremely broad spectrum of concerns. Nearly every issue is related to workflow, however.

Table 1: CDS / CPOE – Considerations for Safety (adapted from Harrington et al., 2001)

<table>
<thead>
<tr>
<th>People related</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inexperience</td>
</tr>
<tr>
<td>Clinical knowledge deficit</td>
</tr>
<tr>
<td>Clinical judgment gaps</td>
</tr>
<tr>
<td>Perceived accuracy</td>
</tr>
<tr>
<td>Knowledge gaps of CDSS safety issues</td>
</tr>
<tr>
<td>Transfer of responsibility to CDSS</td>
</tr>
<tr>
<td>Data overload/increased cognitive load</td>
</tr>
<tr>
<td>Typing errors</td>
</tr>
<tr>
<td>Alert fatigue</td>
</tr>
<tr>
<td>Erroneous alert overriding</td>
</tr>
<tr>
<td>Overdependence on technology</td>
</tr>
<tr>
<td>False expectations of clinical decision support</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Organization related</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes in the power structure</td>
</tr>
<tr>
<td>Cultural changes</td>
</tr>
<tr>
<td>Interruptions</td>
</tr>
<tr>
<td>Insufficient staffing/clinical and IT</td>
</tr>
<tr>
<td>Heavy workloads</td>
</tr>
<tr>
<td>Failure to educate on what the CPOE can and cannot do</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Technology related</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential points of failure – human</td>
</tr>
<tr>
<td>Misidentification of patient because of poor CPOE display</td>
</tr>
<tr>
<td>Failure to differentiate look-alike patient names</td>
</tr>
<tr>
<td>Keypad entry error</td>
</tr>
<tr>
<td>Conflicting orders</td>
</tr>
<tr>
<td>Duplicate orders</td>
</tr>
<tr>
<td>Wrong selection of order set</td>
</tr>
<tr>
<td>Wrong selection from a pick list</td>
</tr>
<tr>
<td>Selection of incorrect dosing frequency</td>
</tr>
<tr>
<td>Selection of inappropriate dosage for required route</td>
</tr>
<tr>
<td>Delay/failure in discontinuing medications because of difficulty in seeing entire list of current medications</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Potential points of failure – system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conflicting orders (also human)</td>
</tr>
<tr>
<td>Duplicate orders (also human)</td>
</tr>
<tr>
<td>Failure to differentiate look-alike patient names (also human)</td>
</tr>
<tr>
<td>Inability to select individualized dose ranges</td>
</tr>
</tbody>
</table>
Incorrect guidance for medication dosing
Lack of patient-specific clinical decision support
Inaccurate program logic
Inaccurate clinical decision support
Failure to suggest prophylactic therapy
Failure to suggest medication monitoring
Lack of maximum daily dose alert

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

**Information presentation (HCI issues)**
Difficulty discerning patient’s medications because of multiple screen displays
Dense pick lists
Delay/failure in discontinuing medications because of difficulty in seeing entire list of current medications

**Interface breakdown – between paper and EHR**
Discrepancy between verbal order and electronic form in CPOE
Requirement to cancel current medication prior to modifying current medication
Failure to cancel procedure-related medications if procedure postponed or cancelled
Default drug times causing first and second doses to be administered too closely together
Missing data resulting in inaccurate recommendation

**System downtime or performance issues**
Loss of data during system crashes
Delays in medications during downtime
Increased time required to input orders/slowed system response during peak use
Loss of connectivity

**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
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

**Environment related**
Distractions

**Other challenges and potential problems**
Default stop orders
Cancellation of all medications for surgery
Challenges with variable dosage regimens
Impermissible antibiotic diluents
Post hoc timing of allergy information
Improper data placement
Low alert specificity
Unclear alert information
Timed logout disruption
Unable to input orders prior to patient admission
Poor coordination in deploying test, train, and production versions
Loss of information during care transitions
Ongoing system changes

**Workflow-related Safety**

The term workflow in healthcare and HIS refers to an ordered set of tasks performed by one or more individuals to complete a given procedure. E-prescribing is an example of a discrete workflow – there is an ordered set of steps or tasks that lead to the completion of a desired action – the sending of a prescription.

The automation of workflows to improve quality, safety, and efficiency is a major promise of HIS, and there is reasonable evidence that quality and safety are generally improved, although the effect on efficiency is less clear. For example, Donyai et al. (2007) assessed hospital medication errors pre and post implementation of an electronic prescribing system (e.g., workflow) in Britain. Their study demonstrated a reduction in both prescribing errors and the need for clinical interventions by pharmacists.

**Standardization**

Complex workflows would seem to benefit from standardization, in that it simplifies complex tasks, ensures appropriate sequencing of tasks within the workflow, and defines specific key choices if they exist in the workflow. However, no study examines best practices for such standardization.

**Customization**

Some EHRs allow a high degree of workflow customization. Even in those that do, some organizations adopt a standardized approach (as opposed to customization) in order to achieve desired quality and safety objectives. Some organizations allow extensive customization of workflows, believing that it is more clinician-friendly.

Workflow design is also influenced by local factors such as state laws and regulations, medical specialties using the system, and potentially complex relationships within the health system such as the inclusion of multiple hospitals and linkages to ambulatory care.

The ability to customize an EHR has advantages and disadvantages. Customization is done to tailor a product’s workflow to the specific needs of the organization and to different situations and types of clinicians. Customization also creates task variability and system complexity, thereby increasing opportunities for errors and safety problems. Complexity expands if organizations strive to please more and more users via customization. Since products differ in
design and then are further differentiated by unique organizational customization, workflow customization makes studying the safety impact of HIS challenging.

For example, Cheng et al. (2003) conducted an observational study of the healthcare team in an intensive care unit after CPOE implementation, finding that policies designed to increase flexibility and safety led to an increased “coordination load” on the healthcare team, and created opportunities for new sources of error. Cheng and colleagues hypothesize that CPOE system design may assume that execution of medication ordering to delivery is a linear process whereas their observations demonstrated the non-linear complex nature of this process. How much of this increased coordination load is amenable to standardization is difficult to estimate.

No studies specifically examine customization and the level of risk caused by customization.

**Human-Computer Interface**

Many studies address various aspects of the human-computer interface design. While interfaces vary substantially, it is possible to draw some generalizations. For example, Horsky et al. (2005a) used case study analysis of potassium chloride dosing errors (e.g., an ordering workflow) to assess failures in the human-CPOE system interface. Horsky and colleagues’ human factors analysis revealed design features that converged to increase error risk in hospital CPOE medication ordering process: confusing on-screen laboratory results review, system usability difficulties, user training problems, and suboptimal clinical system safeguards. Based on this analysis, the authors provided the following general recommendations for the human-EHR-CPOE interface design:

- Screens for ordering continuous IV fluid drips and drips of limited volume need to be clearly distinct, so that the ordering of each is unambiguous.
- Screens that list active medication orders also should list IV drip orders.
- Laboratory results review screen needs to clearly indicate when the most recent results are not from the current day.
- Add an alert that would inform users when the patient already has another active order for the same medication.
- Add an alert informing users ordering a medication that requires laboratory monitoring (i.e., drug or metabolite level) when that lab has not been performed within a prescribed period of time.
- Design ordering screens to create consistency in ordering screen workflow.
- CPOE training should include procedural knowledge (how to use the CPOE system) as well as conceptual understanding and safe entry strategies using real working cases with various levels of problem difficulty.

While this list is not complete in terms of addressing all aspects of workflow design, one gets a sense of the type of detail that will be necessary if standards are to be created around best practices. Vendors can use such information to improve future product releases and users can benefit from such recommendations to alter their use of existing systems.
Singh et al. (2010) suggest 10 strategies to improve the management of HIS safety hazards stemming from a mismatch between information systems and workflow. Taken collectively, however, these and other recommendations have not been consolidated into an agreed-upon set of industry standards, and no process in currently in place to develop or adopt such standards. A key part of the challenge is lack of a common framework to discuss discrete HIS issues such as design and use with safety in mind.

**Recommendations for HIS and Workflow**

Vendors must by necessity design systems flexible enough to fit the non-standardized workflows that exist across healthcare. Based on current studies, it is impossible to estimate the impact on safety of standardization within institutions and across institutions. In general, standardization to the extent possible, while being respectful of truly unique needs of some users, is a good thing and can lead to greater safety. We recommend that cross-site research studies about standardization be conducted.

Greater standardization at the level of design would allow vendors to focus their efforts, yet flexibility is often necessary to comply with a variety of regional regulatory differences. Vendors should work to understand methods of standardization and safe customization and should test and understand workflow nuances to be mindful of the impact on safety and overall system performance.

Likewise, users should conduct careful workflow analyses and understand the positive and negative impacts of standardization and customization within their organizations. They should study and publish the different impacts of ways of standardization and variations in customization so that the lessons can be shared with others. Such analyses can lead to improved workflow and increasingly better workflow-HIS fit.

Finally, informatics researchers should study fundamental workflow issues across sites so that a body of knowledge develops over time that can inform both industry and users about optimal workflow-information system fit.

**Assessing the Risk of e-Iatrogenesis**

A number of studies about HIS-induced errors have analyzed data from the U.S. Pharmacopeia’s MEDMARX database. Since 1998, the USP has gathered, reviewed, and coded voluntary reports of medication errors from hospitals and related health systems. A study by Chuo and Hicks (2008) analyzed 343 NICU medication errors associated with computer entry or CPOE and found that of 298 computer entry errors, 21 ended in harm; of 45 CPOE errors, 3 ended in harm. This represents less than 1% of all NICU errors. Most of the CPOE-related errors were due to inadequate staffing, lack of experience, and workload, so the authors caution that during the first six months of the implementation period when these problems are likely at their worst, human diligence is especially needed. They describe a number of training strategies that could motivate HIS users to be more diligent, especially when entering any information into the computer, including medication orders.
Another CPOE pediatric medication error study, published by Walsh et al. (2006), analyzed 104 errors detected during 352 randomly selected pediatric admissions to a teaching hospital. Of these, seven serious errors were computer related. The authors concluded that “serious pediatric computer-related errors are uncommon (3.6 errors per 1000 patient-days)” (Walsh et al. 2006, p. 1872).

In another study based on MEDMARX data, Zhan et al. (2006) found that of the 7,029 CPOE-related medication errors reported in 2003, 0.1% resulted in adverse events. The greatest contributing factor to these particular ADEs was user distraction in eight out of 10 cases.

Santell et al. (2009), in another MEDMARX study of nonprescriber computer medication errors, found likewise that harm is low but that most errors came from inpatient pharmacy input of data.

The Joint Commission’s (TJC) Sentinel Event Alert (2008) cites the USP MEDMARX (MEDMARX data reports) data for computer-related harmful errors for 2006, which includes 176,409 medical errors in all. Of this total, fewer than 1% of those that resulted in harm were related to CPOE, and fewer than 1% were related to computer entry other than CPOE. Mislabeled barcodes on medications resulted in the highest percent of harmful errors.

Of the 344 instances of unintended consequences analyzed by Campbell et al. (2006), only 6.9% were new kinds of errors caused by or related to CPOE. In a national interview survey of all U.S. hospitals that reported having CPOE, Ash et al. (2007b) asked respondents to rate the level of importance of eight types of unintended consequences related to CPOE. Only two types ranked low in importance and one of those was “new kinds of errors.” Interviewees explained that the errors are generally minor and are caught by staff, so they were not highly concerned.

Another patient safety incident reporting system, the Advance Incident Management System (AIMS), is used internationally and goes beyond medication error reporting. A recently published study (Magrabi et al., 2010) analyzes AIMS reports of patient safety incidents caused by computer use in hospitals in one Australian state where hospitals routinely use HIT. The authors found that 0.2% of all incidents reported were computer related. Of these, a very small number had consequences.

Myers et al. (2011) analyzed data reported to the FDA pertaining to clinical-information-system-related adverse events. The data are stored in three different databases and all reports are about medical devices. The researchers identified reports that were not only about devices but also included some aspect of clinical information systems. They then read the reports to identify the cause of the problems. They found 120 unique reports of clinical information system/device errors out of 1.4 million total reports about device errors and found that information system errors were generally caused by data displayed for the wrong patient, system downtime, and missing or incorrect data.

In summary, these publications are the only ones we could find that report quantitative research showing the risk of clinical systems in hospitals and they consistently report low levels of harm. As several of the authors have noted (Chuo and Hicks, 2008; Myers et al., 2011; Santell et al.,
2009; Zhan et al., 2006), the MEDMARX and some of the FDA data are reported on a voluntary basis and few hospitals have clinical information systems, so few of the overall reports relate to HIT. The Magrabi study (2010), however, was conducted on Australian data from hospitals that are computerized. This study is focused on development of a classification for HIT-related events, so it does not offer great detail about the actual events. Results of these existing studies are indicative of a trend: HIT poses little risk of serious adverse events that threaten patient safety.

**Recommendations about the Risk of HIS**

We recommend that reporting mechanisms be put in place because further data about risk levels can be gained by increased reporting about harms. We also recommend that further studies about risk levels be conducted. These should include studies of indirect causes of harm such as workflow disruption. In addition, we recommend investigation of the pros and cons of mandatory reporting of e-Iatrogenic events. Organizations should ensure that the human intermediaries who thus far have been able to intervene to prevent harm from occurring when HIS-related errors (also caused by humans) are maximally and continuously diligent.

**Answer to Question 2: How have organizations acted to implement healthcare information systems safely?**

The literature on hospital implementation is fortunately rich with details and recommendations. Although safety has not been the focus of most papers, it is clear that organizations have developed many strategies for what they consider successful implementation. Literature about what leads up to the implementation process is scant, however. We divide this discussion into preparation, implementation, and continuous monitoring and improvement periods.

**Preparation**

**Vendor Design and Development**

Much that has been published reports expert opinion and not research-based findings. Some reports, for example, have described but not evaluated their attempts to mitigate safety concerns (Goldstein et al., 2001). Nevertheless, there is consensus that human-computer interface issues can and do generate errors and patient safety risks (Ash et al., 2004; Bates et al., 2001; Borycki and Kushniruk, 2008; Eslami et al., 2006; Horsky et al., 2005b; Karsh et al., 2010; Koppel et al., 2005; Kushniruk et al., 2005; Magrabi et al., 2010; Salvemini, 1998; Walker et al., 2008; Zhan et al., 2006) and that the application of better human factors principles and evaluation would improve safety (Ammenwerth and Shaw, 2005; Borycki and Keay, 2010; Borycki et al., 2010; Karsh et al., 2010; Phansalkar et al., 2010; Singh et al., 2009a; Walker et al., 2008).

Although based on expert opinion, a published consensus statement offering considerations for successful CPOE implementation has been widely used as a checklist for planning. These
include assessment of the motivation for the implementation; vision, leadership, and personnel; cost considerations; integration with workflow and healthcare processes; value to users; project management; the technology itself; training and support; and learning, evaluation, and improvement (Ash et al., 2003).

A commonly found human-computer interface design challenge is that dense pick lists of similar-looking items make it easy to select the wrong entry, whether a patient, order, or medication (Campbell et al., 2006; Donyai et al., 2007; Santell et al., 2009; Walsh et al., 2006; Zhan et al., 2006). Koppel et al. (2005) identify additional risks, including displays that present a fragmented view of a patient’s medications and mistaking a pharmacy inventory screen for dosage guidelines. There has been increasing documentation that clinicians have a tendency to inappropriately rely on default dosing (Donyai et al., 2007; Eslami et al., 2006) or computer interpretations (Tsai et al., 2003).

Borycki and Kushniruk (2008) provide an overview of literature on technology-induced errors and identify several sources of error that arise during the design and development of HIT systems: inadequate specification of requirements; inadequate design; and problematic programming.

There have been some detailed explorations of usability and human factors pertaining to EHRs. One of note is the study by Phansalkar et al. (2010), who contrast a review of human factors principles with a review of CDS alerting, and find that even rudimentary human factors principles concerning false alarms, placement, visibility, prioritization, color, learnability and confusability, textual information, habituation, mental models, and task proximity are not applied in informatics. They conclude with 10 concrete recommendations (Phansalkar et al., 2010, p. 498).

Although Walker et al. (2008) fail to identify consensus in the literature on effective EHR risk-reduction strategies, they present numerous recommendations, including to build EHRs with the specific goal of safety in mind, to use human-factors engineering, and to apply rigorous software safety methods. Additionally, they recommend that EHRs be built to accommodate iterative process improvement. Other research on sources of errors (Koppel et al., 2005; Nebeker et al., 2005) has direct implications for the design of EHRs.

Evaluation and assessment of systems at all stages—including during development and initial implementation—have been strongly recommended (Ammenwerth and Shaw, 2005; Borycki and Keay, 2010; Borycki et al., 2010). Several authors have developed detailed guidelines and frameworks that can assist in evaluating the safety aspects of EHRs (Borycki and Keay, 2010; Borycki and Kushniruk, 2010; Borycki et al., 2010; Carvalho et al., 2009; Kushniruk et al., 2010a, 2010b).

**Recommendations about Vendor Design and Development**

The existing literature suggests a need for vendors to use rigorous software safety methodologies incorporating human factors principles, but standards do not exist despite many lists of
recommendations. We recommend that vendors come together to develop such standards voluntarily or else they could be developed and imposed by regulatory agencies. In addition, recommendations in the AMIA white paper concerning responsibilities of vendors and users should be seriously considered by all parties (Goodman et al., 2011).

Organizations and vendors should work together to ensure the best HIS-organization fit. Testing the use of the system on site prior to purchase should be standard procedure.

Hospital Preparation
The literature outlines a number of strategies hospitals can use to avoid risk. They need to recognize that one characteristic of EHRs that poses a potential safety risk is that EHRs often model clinical workflows in a much more linear and rigid fashion than when these workflows are in practice (Ash et al., 2004; Campbell et al., 2006; Donyai et al., 2007; Horsky et al., 2005b). While designing systems in ways that can handle non-linear workflow flexibly is a challenge for vendors, ensuring that clinicians’ new workflows that incorporate the EHR are safe is a challenge for hospitals.

For example, implementing an EHR can unintentionally create unsafe workflows by causing duplicate orders or bypassing important double-checks on orders (Campbell et al., 2006), or separating functions that lead to duplicate and contradictory orders (Koppel et al., 2005). Donyai et al. (2007) emphasize the importance of being able to easily alter as needed medication frequencies, specify a maximum daily dose, and select a standard dosing schedule for a complex but standardized regimen.

Chuo and Hicks (2008) propose a five-category strategy for evaluating emerging technology embedded in workflows involving medication ordering, dispensing, and administering. The five categories are context (unit needs and workflow), unit attributes (culture and infrastructure, including support), personnel (training, roles, and responsibilities), performance (historical performance of the technology in other sites), and health policy (cost versus safety). Kushniruk et al. (2006) take another approach when they describe using simulations to evaluate how new HIS will alter and interact with workflows. Another aspect of ensuring safe workflows and EHR use is training users on the full range of functions relevant to their work, as well as having clear expectations about who is responsible for what (Chuo and Hicks, 2008; Singh et al., 2010).

Additional preparatory work that promotes safety includes implementing an EHR as part of care-process transformation and broader safety initiatives (Karsh et al., 2010; Walker et al., 2008) with the goal of decreasing errors (Bates et al., 2001). Several publications recommend evaluating systems prior to purchase and before implementation (Borycki and Keay, 2010; Borycki et al., 2009; Carvalho et al., 2009; Kushniruk et al., 2010a; Walker et al., 2008). Borycki and Kushniruk (2008), in their overview of literature on technology-induced errors, identify insufficient beta testing as a potential source of error. Walker et al. (2008) suggest that readily available information on the safety of EHR systems would facilitate the selection and implementation of safer systems. Kushniruk et al. (2010a) argue that more rigorously evaluating
EHRs while attempting to select one will lead the development of not only systems that are a better fit for individual organizations, but safer HIT and healthcare systems.

**Recommendations about Planning and Preparation by Organizations**

Numerous lists of recommendations exist based mostly on observational studies and expert opinion, but these recommendations are not consolidated into a unified, user-friendly guide to planning and preparation. Such consolidated recommendations would be useful.

Vendors and hospitals should work together to ensure that each HIS product will fit the local situation and ensure that the system is used safely. In addition to possible use of scenarios and usability testing on site, organizations should ensure that training is sufficient for all users. As noted in the literature, systems that are implemented as part of a broader healthcare safety context are safer systems.

**The Implementation Process**

Numerous papers have been written that outline success factors for implementation and, of course, each vendor has its own recommendations. The range of recommendations is broad because implementers must evaluate each consideration to determine whether fits their particular organizational context. The quality of the implementation is tightly tied to the preparation process.

Chuo and Hicks (2008) and others have noted that a flawed implementation may actually increase errors. The oft-cited Han (2005) study highlighted an increase in mortality for patients admitted to a children’s hospital following implementation of a CPOE system. They described a number of care processes that were negatively impacted by the introduction of HIS.

Many papers describe the substantial change that occurs when a system goes live; many organizations reduce user caseloads for some period of time to allow users to get used to the new work processes. Rapid implementation without appropriate planning and organizational preparation, such as education and training, increases safety risks (Ash et al., 2003).

**Recommendations about the Implementation Process**

Formal studies and/or a consolidated list of expert-recommended best practices should be developed to guide both preparation and implementation with patient safety in mind. The risks of rapid implementation deserve study as well.

**Continuous Monitoring and Improvement**

Campbell et al. (2005) describe the “never-ending demands for system changes” (p. 550) complicated by the need for perpetual retraining, consequently adding an element of instability into the clinical environment and new opportunity for errors.

The road that leads from planning to implementation to fully functional and effective EHR, CPOE, and CDS systems never ends. Rather, the road travels through ongoing cycles of user feedback and improvement, software updates, and system maintenance and repair. The following
sections address common user challenges that are accompanied by opportunities to introduce or prevent errors.

**Monitoring Ease of Entering and Retrieving Information**

Getting accurate information into and out of the EHR or the CPOE system is a basic tenet of error avoidance and patient safety. However, the literature tells us that the occurrence of errors is not only a fundamental aspect of such systems but that they happen frequently. A paper on computer-related safety incidents in Australia found that more than 50% of these events could be categorized as being either information input or information output problems (Magrabi et al., 2010).

Chuo and Hicks (2008) found in their analysis of the MEDMARX medication error-reporting database that clinicians made errors both in the faulty entry of information and through flawed use of the CPOE system. They determined that computer-entry errors were most evident (61.8%) in transcribing or documenting medications, whereas three-quarters of the CPOE errors involved prescribing. Examining what contributed to entry errors, they found the factors were diverse and none was predominant. However, CPOE mistakes were strongly associated with distraction and staff inexperience.

In their study of the MEDMARX database, Santell et al. (2009) found a large contribution of reported errors generated by non-prescribers, with the major portion of these originating in the inpatient pharmacies. The incidence of patient harm was low, and the causes of error were mostly attributable to deficits in human performance. The authors concluded that these errors could be reduced through feedback and training as well as by further refinement of the HCI to improve drug information presentation. It should be noted that during the years for which errors were collected (2001-2005) many hospitals were still employing a combination of paper-based and computerized systems to process medication orders, which may correlate with the high incidence of transcription and documentation errors. Similar results for medication errors, in the post-implementation stage of CPOE, were reported by Spencer et al. (2005) in their study conducted at the University of North Carolina at Chapel Hill utilizing a different error reporting database. At UNC, the errors arose predominantly in the pharmacy order processing activity.

Hogan and Wagner’s study (1997) examined data accuracy in computer-based patient records, and categorized data according to the two measures of correctness (proportion of observations that are correct) and completeness (proportion of observations captured in the system). Shaw (2006) and others have also written about the measures of correctness and completeness. In her editorial comparing banking to the EHR, Shaw makes the point that clinical decision support systems “depend on very high-quality data being present in the record” (2006, p. 81) This raises the question of whether having accurate patient information stored in the wrong place is worse than no information at all. Having the correct data, but entering them into an inappropriate field within the EHR, may create comparable potential for harm. Considering the example of entering patient information in a free-text field, Campbell et al. note that some clinicians “don’t
understand that the free text allergy information cannot be used by the decision support system” (2007, p. 96).

Attending specifically to the outputs of HIS, Santell et al. (2009) state that many of the CPOE errors they identified were essentially the result of users being unable to correctly read the information being provided. Examples of suboptimal data presentation facilitating mistakes include juxtaposition errors (Ash et al., 2004) where proximity of two pieces of information on the screen increases the likelihood of a wrong selection. Campbell et al. (2006) offer a litany of problematic data displays, including inappropriate text entries and confusing order option presentations. Salvemini’s paper (1998) points out that errors may occur when users are required to differentiate pieces of information that appear very similar, such as in a lengthy listing of medication dosing options.

**Recommendations about the Entry and Retrieval of Information**

We urgently need more research about the number and types of HIS-caused errors and harm. This will likely require error reporting of some type to a centralized source. A study is need to determine the most efficient manner for doing this with the fewest negative impact on vendors and their customers. Continuous improvement of systems and safety requires such feedback.

**Monitoring Persistence of Paper and Impact of Hybrid Systems**

The potential for introducing errors in entering and retrieving data from HIS can be compounded by those implementations where part of the care process record remains on paper, or, due to interoperability failures, data must be extracted from one system and re-entered into another. Dykstra et al. (2009) explain that paper records sometimes persist to fill gaps between systems as hospitals move incrementally toward computerization. They further describe paper as functioning as a “portable database” or a “repository of information a patient will take home with them” (p. 160). The complete elimination of paper, therefore, is not desirable. Campbell et al. reported that, during ethnographic observation, they “typically saw nurses manually transcribing allergy, blood type, and medication information from the CPOE system” (2006, p. 551). Each transfer of data between paper and computer, in either direction, becomes a fresh opportunity for diminished correctness or reduced completeness. The Magrabi et al. paper (2010) supports this view, reporting that problems in transferring information accounted for 20% of all reported safety incidents.

**Recommendations about Persistent Paper**

It is unclear how much paper may be needed to ensure the safety of HIS. Studies about this, and about the dangers of hybrid paper-electronic systems, are recommended. Also recommended are studies about the accuracy of data and the need for monitoring and even regulation of data quality.

**Monitoring Workarounds**

Negative reactions to the introduction of new technologies have prompted some clinicians to develop workarounds so that they can do their work in a timely manner. For example, Campbell
et al. relate that if “busy clinicians cannot find the correct data location, they tend to enter data where it might fit,” (2006, p. 552) making that data harder to find and thereby potentially unavailable to other clinicians. In their paper reporting on the effects of CPOE in an ICU, Cheng et al. (2003) detail adaptations employed by clinicians that circumvented some of the built-in safety features of the new technology.

Recommendations about Monitoring Workarounds
Studies of workarounds are an excellent way to learn about system problems, yet very few have been conducted and reported in the literature. More such studies are needed.

Monitoring Overdependence on Technology
The converse to HIS resistance described by Campbell et al. (2006) goes beyond acceptance to overdependence. Thus, when a system inevitably goes down or is taken down for maintenance, going back to paper becomes an unexpected ordeal. The dual hazard in such circumstances is trying to function in now less familiar territory and the challenge of capturing and faithfully transferring information into the EHR, once systems are again up and running. Campbell et al. (2007) also describe users who have the misperception that if data are in the computer they must be accurate and complete. This leads to overdependence and at times to misguided trust. Further research on how and when the highly trained clinician cedes authority to the computer could be enlightening.

Recommendations about Overdependence on the Technology
As more systems are implemented in hospitals around the country, more opportunities will arise for safety hazards when systems go down or are otherwise unavailable. Research about the best ways for organizations to plan for and deal with these eventualities is needed.

Monitoring in General
Sittig and Classen (2010) have proposed a framework for monitoring and evaluating the safety of EHRs. We previously mentioned research utilizing the MEDMARX and other error reporting databases, and such reporting of safety events or potential hazards is a foundation of their framework. They also advocate for on-site accreditation of EHRs after deployment, with oversight provided at local, state and national levels.

Recommendations about Measurement
The appropriate and most efficient measures and mechanisms for reporting must be researched and planned. Ongoing surveillance of the safety of HIS at a national level, similar to that for drugs, may be needed, but the nature of that surveillance must be carefully investigated over the next few years.

Recommendations for the Continuous Monitoring and Improvement Period
Although most papers about HIS seem to focus on this stage, much more research is needed. It is clear that measures and reporting of HIS errors should be investigated and regulatory decisions made that are based on research. Research on the value of certain metrics is urgently needed.
These should focus on all stages, including structure (e.g., do you have drug-drug-interaction checking?), process (how often do these alerts fire?), and outcome (how many adverse drug events are prevented?). Without measurement and reporting, systems are not likely to improve. Continuous improvement of systems can also be expedited by open dialogue between vendors and users. Users should feel free to report safety problems to the vendor, and the vendors should be transparent about their response. If the mindset within the broad sociotechnical context that includes vendors, customers, and regulation is for continuous improvement and never-ending diligence, the safety of systems can eventually be maximized.

**Answer to Question 3: What are the impacts of customization on safety?**

**Customization of the EHR**

EHR customization seems to be taken for granted in the literature. No papers specifically address or compare customization efforts. Papers describing the need to fit HIS to workflows, and vice versa, acknowledge that EHR systems cannot be accepted out of the box. Ash et al. (2007b) and Campbell et al. (2006) indicate that, of all unintended consequences of CPOE, those related to a mismatch between the EHR and workflow rank next-to-most common.

Borycki et al. (2010) suggest using clinical simulations so that a system can be tested either prior to purchase to see how well it fits local practices or after purchase to test for safety purposes. Horsky and Zhang (2005b) outline considerations for design primarily for pre-implementation that would help a system best fit an organization. Karsh et al. (2010) clearly state that the notion that “one size fits all” is a fallacy.

Clinical roles, clinical situations, clinical environments, and institutions all differ to some extent. Kushniruk at al. (2010a) offer suggestions for assessing systems before purchase and for testing their continued usability as they go through the customization process. The systematic review by Shamilyan et al. (2008) indicates that specialized units, presumably with heavily customized EHR processes, perform better in terms of fewer medical errors, although this might also be due to specialized CDS. Walker et al. (2008) focus on human factors engineering, which again implies that people and processes need to fit well and comfortably together in HIS. The paper describes the early locally developed EHRs fitting their organizations well and gaining success in adoption and outcomes because they were completely customized for the local situation.

In summary, customization of the EHR to fit local situations seems to be necessary for many reasons, but there is scant research on how much customization or what form of customization is needed for either quality or safety.

**Recommendations about Customization of the EHR**

Both vendors and users would benefit from deeper investigation into the balance between standardization and customization, including the methods to use both to promote quality and
safety. Again, a clear framework for understanding HIS customization would provide researchers with a roadmap for their investigations.

**Customization of Content**

Published research related to content is primarily focused on the problem of alert fatigue that comes with CDS. Bates (2010), commenting on Strom et al. (2010), emphasizes the urgent need for better evidence about which drug-drug interactions are important. He further argues that “the strength of the alert should be related to the severity and importance of the interaction” (p. 1584). Customization of content in the CDS and specifically limiting drug-drug alerts may help avoid desensitization.

Van der Sijs et al. (2009) studied the impact of alerts on preventing time-dependent drug-drug interactions. Despite the presence of these alerts, a high percentage of these combinations were being incorrectly prescribed, suggesting that the alerts were either not read or else they were misinterpreted or handled incorrectly. The authors suggested specially trained nurses to correct the orders for time dependency during drug administration in order to work around the apparent limitations of the HIS to protect patients.

**Recommendations for Customization of Content**

Safety is likely to be enhanced by refining the specificity and accuracy of alerts in the CDS. Studies are needed about the extent and impact of alert fatigue. While users have some control over this in some EHRs, much of it is controlled by vendors, and no standards exist to give industry guidance on this topic. The development of such standards would be useful.

**Answer to Question 4: What is the industry approach to managing change and customization?**

There are no studies on this topic in the literature, but an AHRQ report describing vendor practices related to usability (McDonnell et al., 2010) and testimony before the Office of the National Coordinator in Health Information Technology (ONC HIT) Advisory Committee’s Adoption/Certification Work Group (U.S. Department of Health and Human Services, 2010) during a hearing on HIS safety provide useful information. In addition, we polled several informatics faculty members who consult with companies and healthcare organizations to gather more information about how vendors manage change in the form of response to customer feedback.

The AHRQ publication (McDonnell et al., 2010) summarizes vendor interviews and expert panel deliberations culminating in recommendations about product usability. The AHRQ authors polled EHR vendors of varying sizes selling to different market segments (ambulatory and hospital, large and small) to solicit best practices use in system design and deployment, usability testing throughout the product lifecycle, and post-implementation monitoring to ensure safe use.
The AHRQ report demonstrates that vendors use a wide array of usability practices, but formal usability engineering processes are rare. Best practices for EHR usability are not readily available, so general industry best practices guidelines for software design and usability are often used informally. The authors report that views on customer customization “varied dramatically,” but they provide no specifics. Vendors also use a variety of processes for addressing patient safety issues after implementation. They collect but do not share information about safety incidents. They do not collaborate with one another on usability because product usability is a competitive differentiator. When asked, they supported the idea of an independent body generating voluntary EHR usability standards.

Vendor testimony from the ONC HIT safety hearing corroborates the AHRQ report of existing practices and includes information from the Electronic Health Records Association’s (EHRA) patient safety work group (U.S. Department of Health and Human Services, 2010). Vendors seem to have dedicated quality assurance personnel in place, although quality assurance in software development tends to refer to ensuring that programming bugs are corrected rather than ensuring usability. When customers report potential safety problems, vendors appear to have escalation processes for handling them. In addition, the EHRA reports that each vendor has processes for notifying customers when safety risks arise (U.S. Department of Health and Human Services, 2010).

The only mention of customization occurs in the testimony, which indicates that customization by customers, which the vendors call local configuration, is a safety risk. Mapping of vocabularies, for example, needs to be carefully tested.

In our interviews, experts described how vendors respond to requests or changes. If a customer discovers a serious system problem, the vendor assigns it a high priority. Other user recommendations are considered by vendors based on their usefulness to a high number of customers, ease of implementation, and their safety implications. Vendors issue patches and small improvements as often as monthly and, like all vendor releases, customers determine if or when they are implemented. Like other software, customers can modify it, and they must track their modifications.

**Recommendations for Change Management**

We recommend the development of standards for usability testing during product design and development that include the incorporation of human factors engineering analysis and other best practices gleaned from other industries. Whether these standards are voluntary or not is beyond the scope of this paper.

**The Legal Situation**

Few papers address legal issues related to EHR safety, and none are based on empirical research. They discuss legal risk and anecdotes without providing specific risk data.
Bates et al. (2001) note that fear of lawsuits has impeded commercial development and customer sharing of CDS content. Koppel and Kreda (2009) describe contracts between EHR vendors and users that include clauses to ensure that the vendor is held harmless and/or that prevent customers from communicating with each other when problems arise with the product. However, the AHRQ report on usability notes that “no vendors reported placing specific contractual restrictions on disclosures by system users of patient safety incidents that were potentially related to their products” (McDonnell et al., 2010, p. 2).

To delve deeper into the realities of vendor-purchaser obligations and liability, the American Medical Informatics Association appointed a task force to study the topic (Goodman et al., 2011). The task force recommended further study about best practice guidelines for continued post-implementation evaluation, the role of regulation, hazard reporting and tool development, responsibilities of different stakeholders, and indemnification. It concluded that the responsibility for HIS safety is an ethical issue and should be shared between vendors and customers. Task force members did not reach consensus about the need for HIS regulation, although the majority did favor it.

In several papers published in the legal literature, Hoffman and Podgurski (2008, 2009, 2011) outline a number of legal issues focusing mostly on privacy or personal health records, but not safety. The EHR liability risks they describe include the possibility of new kinds of malpractice claims such as claims against clinicians who misuse EHRs and as a result cause patient harm. They discuss risk related to information overload, reliance on others’ diagnosis and treatment decisions promulgated through health information exchanges (HIE), input errors, clinical decision support, and “product defects.” They claim that the presence of federal regulations would diminish liability risks for clinicians and hospitals.

Sittig and Singh (2011) echo many of these legal risks. There could be risks to clinicians who accept information through HIEs or who ignore HIE data. Clinicians can experience information overload and miss critical information. Monitoring of clinician behavior through EHR tracking could put them at increased risk for liability. There are many documentation-related risks, such as copy and paste features and misuse of templates. Not following CDS recommendations, or blindly following them, involves risk as well. In addition, the EHR itself could generate problems because of usability and reliability (downtime).

Recommendations about the Legal Situation
We concur with the AMIA task force recommendations that include development of best practice guidelines for continuous HIS evaluation, hazard reporting and tool development, and shared responsibility between the vendors of systems and the organizations that implement them.

The Regulatory Debate
Health information technology is not heavily regulated compared to other high hazard industries. Reporting of adverse events and investigation into their causes is primarily in the hands of TJC and at times CMS, but neither has existing standards specific to EHRs. Palmieri et al. (2008)
note that HIS risk could be addressed by hospital risk management processes that are already in place, including failure mode effect analysis and root cause analysis and they suggest an increased focus by TJC on these issues.

TJC called attention to the risks of health information and converging technologies (e.g., the interrelationship between medical devices and HIT) in a 2008 Sentinel Event Alert, noting that any existing TJC standard could “potentially be tied to technology” (2008, p. 2). Although facilities accreditation by TJC is voluntary, over 17,000 organizations in the United States participate (U.S. Department of Health and Human Services, 2010).

The Food and Drug Administration (FDA) regulates medical devices and, although health information technology falls under this designation, the FDA has thus far chosen not to regulate HIS (U.S. Department of Health and Human Services, 2010). The FDA does regulate devices that provide data to the EHR, however. The FDA reasoning to date has been that EHR usage involves human intermediaries who are providing their expertise for patient care. If the device feeds information directly to the EHR, there is no opportunity for human intervention, so for safety purposes the FDA closely regulates these devices before they are marketed.

There is some post-market surveillance, although Lenzer and Brownlee (2010) cite examples of the weaknesses in the oversight process. In 1997, a consortium of information-technology-related organizations published a set of recommendations for regulation of clinical software systems that categorized risk levels and recommended local oversight rather than FDA regulation (Miller and Gardner, 1997a, 1997b). “FDA regulation should exempt most clinical software systems and focus on those systems posing highest clinical risk, with limited opportunities for competent human intervention” (Miller and Gardner, 1997a, p. 442).

Recommendations about Regulation
There needs to be careful study of the impact of regulation on both vendors and users and a plan for phasing in possible regulations. In the meantime, local oversight, such as that recommended by Miller and Gardner (1997a, 1997b), should be encouraged.

VI. EHR Safety in the Ambulatory Setting

Although the focus of our literature review was inpatient EHRs, we will briefly review the literature on ambulatory EHRs since many hospital organizations deploy both inpatient and outpatient systems. While there has been a significant focus on patient safety and HIS use in the inpatient setting, the ambulatory setting has been less well studied. This may reflect the fact that hospital settings have a longer history of using health information technology in the care delivery process; hospitals exist in an environment that promotes a culture of safety (i.e., longstanding accrediting organizations oversee, publicly report, and influence safety in this setting); hospitals have the capacity (i.e., dedicated and trained staff) to evaluate and improve safety; and the field
of studying safety and continuous quality improvement is more mature and advanced in the inpatient setting.

The adoption of HIS, such as EHRs, by ambulatory care has accelerated substantially and is widely recommended as a means to promote quality and safety. (Bodenheimer and Grumbach, 2003; Institute of Medicine, 2000, 2001; Martin et al., 2004). Opportunities exist to lower rates of missing clinical information, foster better decision support and adherence to guidelines, reduce medication errors (Smith et al., 2005), and improve the monitoring and coordination of patient care (Burton et al., 2004). The current literature, however, provides limited evidence of the effects of the ambulatory EHR on patient safety. Recent review articles have found few studies demonstrating improvements in patient care from EHR use, pointing to a gap between current usage and the promise of this technology (Crosson et al., 2007; Delpierre et al., 2004; Garg et al., 2005; Meigs et al., 2003; Montori et al., 2002; O'Connor et al., 2005; Sequist et al., 2005).

Current knowledge about the role of the EHR in the safe delivery of primary care is limited in important ways. First, this research is limited in focus. The majority of research in the ambulatory setting focuses on improving quality not safety. Second, research in the ambulatory setting is limited by the design and setting, with the majority conducted in practices that are part of four large health systems: LDS Hospital/Intermountain Care, Brigham and Women’s Hospital/Partners Health Care, the Regenstrief Institute, and the Veterans Administration (Chaudhry et al., 2006).

Each of these organizations uses in-house-developed EHR systems, has substantial information technology support, is able to exchange health information internally, and in some cases benefits from the presence of a knowledgeable and technically sophisticated physician champion. In addition, practices in these settings also have system-level resources that are able to use EHR data to support proactive, population-based care and to establish metrics to track and measure safety. These resources are often not present in privately owned, community primary care practices where most outpatient care in the United States is delivered (InterStudy, 1997). As a result, studies conducted in these settings offer limited insights into safety within community practices using EHR systems.

The extent to which evidence-based findings from inpatient settings translate to the outpatient environment is unclear. Outpatient care tends to be more fragmented, varying considerably by type of ambulatory setting. In addition, patients have a greater role in healthcare safety in the ambulatory setting than they do in hospitals. These characteristics and others distinguish hospital and ambulatory care, and suggest the need for separate lines of inquiry into the role of HIS in safety in these settings.

Understanding the safety landscape in the primary care arena has been of particular interest to AHRQ, and its initiative to advance ambulatory research on patient safety (AHRQ, 2005) lays an important foundation. The establishment of common ambulatory safety metrics would be a step forward.
**Recommendations about Ambulatory HIS**

We recommend that standard ambulatory safety metrics for HIS be developed. The development of standard safety HIS testing in ambulatory care might be possible and would give guidance to both practitioners and researchers who would help develop, study, and improve both the standards and testing processes. In addition, studies of the safety risks in the ambulatory compared to the inpatient environment are recommended. Also, more research is needed concerning e-Iatrogenesis within independent practices with commercial systems.

**VII. Conclusion**

While there is a substantial literature peripherally related to HIS safety, most studies do not directly address it. The majority of the papers are case studies, observational investigations, retrospective analyses, expert opinions, or commentaries. Prospective comparative investigation on the direct impact of system design and usage on safety is weak. We acknowledge that such studies are complex and costly, arising from the wide array of EHR products and the diversity of hospitals into which they are incorporated. Adding to this complexity is the customization that each institution does to adapt the product to their unique needs and environment. Creating meaningful comparisons in such a complex environment is difficult.

It is important to consider health information systems as opposed to health information technology given that the “systemness” – the multiple components of information management in addition to the technology – is important. The systemness is captured in the eight sociotechnical dimensions and the model we used to evaluate the HIT literature. Because of this, studies of systems improvement should look at active, complex systems over time, as well as at the effects of changing those systems on the desired outcomes. This requires system measurement and monitoring over time during attempts to improve the system. Studies that focus on the EHR as a system component functioning over time are much needed.

The literature is rife with investigational findings about the impact of EHRs, CPOE, and CDS on safety, and in general these systems do improve safety significantly. Yet, they can also introduce safety risks that must be guarded against. The literature is also replete with heterogeneous recommendations about the various aspects of HIS vendor design and development, and user preparation, implementation, and monitoring. This variety was a major challenge as we attempted to answer the questions posed by the IOM. We have therefore proposed a broad sociotechnical model, which can be considered by researchers and policy makers in the future.

Little is known about vendor design and development processes, or about specific processes for updating the products for better performance. The impacts of different organizational preparation methods, standardization, or customization on safety have been understudied. And lastly, the regulatory environment is early in its development with little regulation or investigation of regulation on these products and processes.
With this in mind, we offer the following recommendations:

1. **Develop a standard model**, perhaps based on the framework we have proposed in Figure 1, for understanding the complex dynamics of HIS and socialize this model throughout the user and research community. The community needs a standard model upon which to build knowledge or it risks continuing with fragmented studies that do not efficiently assist in advancing the field. Much greater progress could be made with a standard model and language.

2. Despite weaknesses in the current evidence-base, expert consensus can still be highly useful. We suggest **convening expert panels** to further consider and validate our recommendations, preferably based on an agreed-upon model – such as suggested in Figure 1. Then, expert consensus should be used to further refine a clear set of recommendations built around a common framework. Subsequently, experts should convene with key funders such as ARHQ, ONC, NIH, and IOM to develop research priorities based on this aggregated opinion, create hypotheses for testing, and propose methods for testing those hypotheses. If done within a consistent framework, this testing and refinement of the recommendations will help consolidate existing knowledge.

3. Future investigations should attempt to adhere to **systems-improvement methodologies or to prospective comparative analysis** to the extent possible.

4. **Develop EHR usability testing standards based on best practices.** This could also be an output from the above expert consensus work, although we recommend engaging experts from outside healthcare to assist with incorporating human factors principles in this process.
Appendix A: Glossary of Terms

Adverse drug event (ADE)
An injury resulting from the use of a drug. Under this definition, the term ADE includes harm caused by the drug (adverse drug reactions and overdoses) and harm from the overuse, underuse, or misuse of the drug (including dose reductions and inappropriate discontinuations of drug therapy) (Nebeker et al., 2005).

Alert and alert fatigue
An alert, a form of clinical decision support, is a warning generated by the information system, usually in real time. When clinical provider/physician order entry is used, the clinician receives the warning while entering orders. Alerts can be designed so that the clinician can ignore them, acknowledge receipt, or be required to offer a response (e.g., an explanation if overriding the alert). Alert fatigue is the term used when the clinician receives so many alerts that he or she starts ignoring them, at the risk of missing an important one.

Clinical decision support system (CDS or CDSS)
This term refers to “passive and active referential information as well as computer-based order sets, reminders, alerts, and condition or patient-specific data displays that are accessible at the point of care” (Bates et al., 2003, p. 524).

Computerized provider order entry or computerized physician order entry (CPOE)
The ability of a clinician with ordering authority to enter an order into the information system, usually for medications, laboratory tests, radiology, etc., so that the order can be received in the pharmacy or elsewhere and acted on.

Content customization
The addition or modification of clinical decision support tools such as alerts, order sets, or templates to an HIS so that the tools better fit the local regulations, practices, and workflow of a hospital.

Electronic health record (EHR)
A computer-based patient record usually referring to all clinical systems in hospitals. It does not usually include systems that are strictly financial or business systems. Because it implies an electronic version of the paper record, we prefer the term health information system, which is broader.

e-Iatrogenesis
Patient harm caused at least in part by the use of health information technology or health information systems.
e-Prescribing (electronic prescribing)
The ability of an ordering authority to write prescriptions using a computer and to send them electronically to a pharmacy.

Health information technology
Electronic health records that may include CPOE and CDS. Because it implies that HIT includes only the technology aspects (e.g., hardware and software), we prefer the term health information system.

Health information system (HIS)
Refers broadly to clinical information systems, including hardware, software, and patient data used during patient care.

Commercial systems
Standard health information systems offered for sale by a vendor to many customers, with ongoing technical support and upgrades.

Self-developed systems
Internally or custom-developed systems rather than those purchased from a commercial vendor. Examples include the HELP system at the LDS Hospital, and the LMR (Longitudinal Medical Record) at Partners Healthcare.

Open-source systems
A system that is developed and distributed in a manner that allows any interested organization or individual to view, add to, delete, or modify the application’s source code. When successful, these highly collaborative projects can produce software that is highly usable, reliable, and efficient. Examples include the VA’s Vista and CPRS systems and OpenMRS or OpenEHR.

HIS-assisted care
Health services that incorporate health information systems for the purpose of improving care processes and outcomes. HIS-assisted care includes care supported by and involving electronic health records (EHRs), clinical decision support (CDS), computerized provider order entry (CPOE), health information exchange, patient engagement technologies, bar coding, and other health information technologies used in clinical care.

Human-computer interaction or human-computer interface
Terms used interchangeably to refer to the exchange of information between a computer and user. Usually human-computer interface refers more specifically to screen-design-level interactions where the interaction can include the entire context of the exchange.
Human factors engineering
This is the discipline that strives to identify and address safety problems that arise due to the interaction between people, technology, and work environments.

Implementation
The process of installing, testing, debugging, and refining the health information system. Sometimes this term is used in a strict sense for a short period of time during the rollout of a system.

Personalization
Modification of the EHR look and feel to support individual system users. This might include creation of lists of most frequently ordered medications, changes to the screen layout, font size, or color, and even individualized order sets or clinical reminders, for example.

Quality
A measure of excellence or a state of being free from defects, deficiencies, and significant variations, brought about by the strict and consistent adherence to measurable and verifiable standards to achieve uniformity of output that satisfies specific customer or user requirements. ISO 8402-1986 standard defines quality as "the totality of features and characteristics of a product or service that bears its ability to satisfy stated or implied needs" (BusinessDictionary.com, 2011).

Safety (patient safety)
Freedom from accidental or preventable injuries produced by medical care (AHRQ, 2011). This is distinct from quality of care, which is defined as the provision of optimal care (Donabedian, 1988). Walker (2008) describes a safety incident or hazard as a non-routine event which has the potential to contribute to patient harm.

System customization
Changing an existing EHR to better fit a hospital’s context. It can be done at many levels by either the vendor or the hospital. Thus, it can include minor modifications, such as altering screen designs, or major modifications to the source code, which is rare, especially for commercial systems.

Technology-induced errors
“Those sources of error that may arise from: (a) the design and development of a technology, (b) the implementation and customization of a technology, and/or (c) the interactions between the operation of a new technology and the new work processes that arise from a technology’s use” (Borycki and Kushniruk, 2008).
**Unintended consequences**

Unexpected effects or surprises and can be positive or negative, direct or indirect. As applied to the unintended consequences of HIS, the term most often implies negative surprises that result from HIS use of HIS.

**Usability**

The international standard, ISO 9241-11, provides guidance on usability and defines it as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use” (Usability Net, 2011).

**Workflow**

Workflow can be defined as the processes or procedures needed to produce or modify work, products, or the delivery of services (Campbell et al., 2009).
### Appendix B: Table of Selected References

<table>
<thead>
<tr>
<th>Eight Dimensions of HIS Safety</th>
<th>Hardware / Software</th>
<th>Carvalho et al (Carvalho et al., 2009) heuristics for prevention of technology-induced errors during design</th>
<th>Goldstein et al (Goldstein et al., 2001) safety precautions for CDS in design stage</th>
<th>Hogan et al (Hogan and Wagner, 1997) the more sites covered by an EHR, the better</th>
<th>Singh et al (Singh et al., 2009b) screening for cancer at VA: FOBT follow up problem caused by software glitch and lack of monitoring for tech problems</th>
<th>Singh et al (Singh et al., 2010) ten strategies for monitoring—call for user, HCI, and workflow strategies= diligence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Carvahlo et al (Carvalho et al., 2009) heuristics for prevention of technology-induced errors during design</td>
<td>Bates et al (Bates et al., 2001) pharmacy systems fail to produce alerts they should (customize); need to remove legal disincentives of content vendors</td>
<td>Campbell et al (Campbell et al., 2007) on overdependence on technology</td>
<td>Carvalho et al (Carvalho et al., 2009) heuristics for safety evaluation</td>
<td>Chuo et al (Chuo and Hicks, 2008) MEDMARX percent of CPOE errors ending in harm NICU 6.6%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ash et al (Ash et al., 2007a) CDS AMIA paper</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Donyai et al (Donyai et al., 2007) electronic prescribing cause new kinds of errors, but reduce others</td>
<td>Dykstra et al (Dykstra et al., 2009) on paper persistence</td>
<td>Eslami et al (Eslami et al., 2006) default values can cause errors when not patient specific</td>
<td>Eslami et al (Eslami et al., 2006)</td>
<td>Garg et al (Garg et al., 2005) CDS process and outcomes—practitioner performance mostly increases; better with active CDS and local champions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Goldstein et al (Goldstein et al., 2001) some potential ways to counteract potential problems</td>
<td>Goodman et al (Goodman et al., 2011) AMIA board position paper on HIT safety</td>
<td>Hogan and Wagner (Hogan and Wagner, 1997) data accuracy: correctness and completeness</td>
<td>King et al (King et al., 2003) study of paper vs. CPOE—significant decrease in errors but not ADEs</td>
<td>Koppel et al (Koppel et al., 2005) types of hospital CPOE errors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nebeker et al (Nebeker et al., 2005) ADE rates still high after CPOE and BCMA in VA; calls for better CDS more tailored to needs (customization)</td>
<td>Santell et al (Santell et al., 2009) MEDMARX study on nonprescriber computer errors; harm low, inpatient pharmacy usual source</td>
<td>Shulman et al (Shulman et al., 2005) hand vs. computer ICU orders and med errors, CPOE sig lower rate of errors, but major (intercepted) errors only w/ CPOE</td>
<td>Singh et al (Singh et al., 2009a) inconsistencies in prescription information, dangers with free text</td>
<td>Spencer et al (Spencer et al., 2005) effect of CPOE on prescribing errors (more reported, lower rate)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thompson et al (Thompson et al., 2005) CPOE and ICU reporting of med errors, 67% user errors, 20%</td>
<td>Van der Sijs et al (van der Sijs et al., 2009) drug-drug interactions not reduced, low alert specificity, bad CDS (customizations!)</td>
<td>Van Rosse et al (van Rosse et al., 2009) CPOE in pediatric ICU review—decreased risk of med errors</td>
<td>Walsh et al (Walsh et al., 2006) pediatrics med errors—computer related ones are uncommon</td>
<td>Zhan et al (Zhan et al., 2006) MEDMARX study - 0.1% of CPOE related med errors resulted in ADEs, fewer errors reach or harm patients with</td>
</tr>
<tr>
<td>Eight Dimensions of HIS Safety</td>
<td>Human-Computer Interaction</td>
<td>People</td>
<td>Workflow &amp; Communications</td>
<td>Internal Organization</td>
<td>Measurement &amp; Metrics</td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-----------------------------</td>
<td>--------</td>
<td>---------------------------</td>
<td>----------------------</td>
<td>----------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Software, 13% computer malfunction</strong></td>
<td>CPOE than without</td>
<td><strong>Campbell et al</strong> (Campbell et al., 2006) dense pick lists, using wrong data fields, poorly labeled test patients</td>
<td><strong>Gaba</strong> (Gaba, 2000) p. 13 on measurement needs</td>
<td><strong>Ash et al</strong> (Ash et al., 2006) balance of power may shift when CPOE is introduced</td>
<td><strong>Hogan and Wagner</strong> (Hogan and Wagner, 1997) monitoring data accuracy and giving feedback to clinicians helps</td>
<td></td>
</tr>
<tr>
<td><strong>But no reduction in ADEs</strong></td>
<td><strong>Goldstein et al</strong> (Goldstein et al., 2001) some potential ways to counteract potential problems</td>
<td><strong>Carvalho et al</strong> (Carvalho et al., 2009) heuristics for safety evaluation</td>
<td><strong>Campbell et al</strong> (Campbell et al., 2006) CPOE introduces new workflow and communication issues</td>
<td><strong>Chao and Hicks</strong> (Chao and Hicks, 2008) CPOE isn’t to blame as much as communication and coordination</td>
<td><strong>Hogan and Classen</strong> (Hogan and Classen, 2010) monitoring and evaluation</td>
<td></td>
</tr>
<tr>
<td><strong>CPOE than without</strong></td>
<td><strong>Hogan and Wagner</strong> (Hogan and Wagner, 1997) dense pick lists, inappropriate use of default doses</td>
<td><strong>Salvemini</strong> (Salvemini, 1998) calls for HCI work, industrial view not medical</td>
<td><strong>Cheng et al</strong> (Cheng et al., 2003) ICU and CPOE—double checks needed and extra communication efforts</td>
<td><strong>Han et al</strong> (Han et al., 2005) organizational lessons especially governance</td>
<td><strong>Strom et al</strong> (Strom et al., 2010) show you must monitor outcomes of your CDS</td>
<td></td>
</tr>
<tr>
<td><strong>Kushnirik et al</strong> (Kushniruk et al., 2010a) ways to better design; shows errors caused by entry, display visibility, and defaults</td>
<td><strong>Singh et al</strong> (Singh et al., 2010) ten strategies for monitoring—call for user, HCI and workflow strategies= diligence</td>
<td><strong>Ash, Berg, and Coiera</strong> (Ash et al., 2004) organizational challenges similar inside US and internationally</td>
<td><strong>Campbell et al</strong> (Campbell et al., 2006) internal organization needs to lead the way through the never ending demands of HIS change</td>
<td><strong>Chao and Hicks</strong> (Chao and Hicks, 2008) need organizational assessment of needs for each role that touches the order—nurse, pharmacy, physician</td>
<td><strong>Zhan et al</strong> (Zhan et al., 2006) voluntary reporting can’t be used to evaluate individual facilities</td>
<td></td>
</tr>
<tr>
<td><strong>Eight Dimensions of HIS Safety</strong></td>
<td><strong>Donyai et al</strong> (Donyai et al., 2007) dense pick lists, inappropriate use of default doses</td>
<td><strong>Hogan and Wagner</strong> (Hogan and Wagner, 2003) computer interpretations effect clinicians’ interpretations, rightly and wrongly</td>
<td><strong>Sittig and Classen</strong> (Sittig and Classen, 2010) monitoring and evaluation</td>
<td><strong>Staggers and Weir</strong> (Staggers et al., 2008) chapter—reviews all papers on nursing safety, research directions for nursing</td>
<td><strong>Zhan et al</strong> (Zhan et al., 2006) computer interpretation of ECGs, lab setting, subjects influenced by wrong advice</td>
<td></td>
</tr>
<tr>
<td><strong>Horsky et al</strong> (Horsky et al., 2005b) HCI hazards, need for fit, distributed cognition</td>
<td><strong>McDonald</strong> (McDonald, 2006) BCMA—need for human diligence, redundancy, patient identifiers, handoff risks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>External Rules &amp; Regulations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chuo and Hicks (Chuo and Hicks, 2008) MEDMARX study, describes Patient Safety QIs and Patient Safety Organizations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gaba (Gaba, 2000) describes present regulations p. 91, role of Joint Commission</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Koppel and Kreda (Koppel and Kreda, 2009) on hold harmless (customization big issue here)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palmieri et al (Palmieri et al., 2008) summary of Joint Commission role</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walker et al (Walker et al., 2008) seven recommendations for safety</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
References


