Medication Safety and the Electronic Health Record

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University of Texas Southwestern Medical Center
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This is to acknowledge the Dr. Croft has disclosed no financial interests or other relationships with commercial concerns related directly to this program. Dr. Croft will not be discussing off-label uses in her presentation.

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Learning Objectives:

1. Understand the scope and impact of adverse drug events and medication errors.
2. To be aware of how HITECH and Meaningful Use have impacted implementation of the EHR in healthcare systems
3. To increase awareness of the importance of the socio-technical system in healthcare and to appreciate some facets of the human computer interface
4. Be able to describe some of the unintended consequences of implementing EHR tools intended to improve medication safety
5. To understand how some future technologies such as health information integration and exchange may help further our efforts at improving medication safety

Preventable adverse drug events are a major safety problem for both ambulatory and in-hospital patients.[1,2,3] Health information technology (HIT), and more specifically electronic health records (EHR's) have been proposed as a way to limit human error and keep patients safe. Despite a campaign to improve patient safety that has lasted over 20 years, the rates at which adverse drug events (ADE's) occur is no better than it was in 1998.[4] Ample research exists about how HIT can improve patient safety, but it is not always implemented effectively.

The scope of the problem

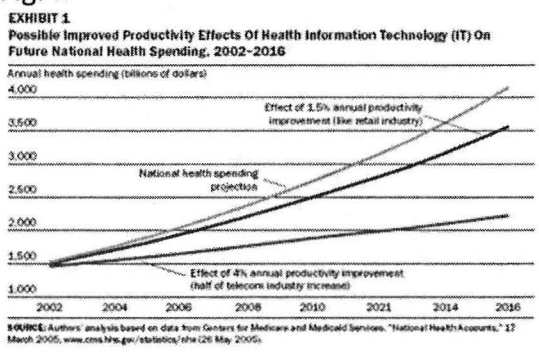
Approximately 1.5 million adverse drug events occur annually among ambulatory patients, and result in tens of thousands of hospital admissions[5,6] ADE's account for 0.6% of all ED visits (6.7% of visits that require hospitalization).[7] Even among inpatients at "highly computerized" hospitals, adverse drug events (ADE's) occurred at a rate of 52 events per 100 admissions and an incidence density of 70 events per 1000 patient-days. One quarter of all hospitalizations had at least 1 ADE and medication errors contributed 27% of the total events.[8]

The hope of Health Information Technology (HIT)

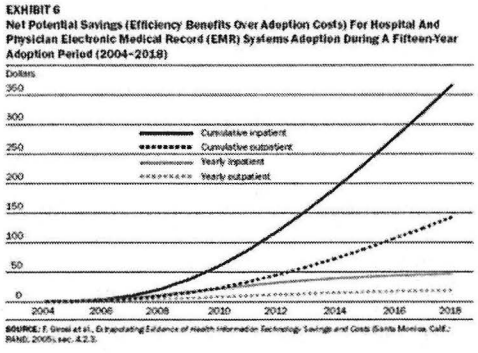
The Institute of Medicine published a report in 2000 entitled, "To Err is Human: Building a Safer Health System ", with the goal of making the healthcare system safer by encouraging an emphasis on changing systems. In to Err is Human, the IOM notes that for optimum use, technology must be a team member, broadening the array of stakeholders to include the technology sector, and motivating hospitals to adopt new, safer practices.[9] Enthusiasm about the use of HIT to achieve the aims set forth in the IOM report (while saving money in the process) is substantial. Hillestad et al used the financial impact of information technology on other industries to project the potential costs and savings in healthcare, and concluded that effective EHR implementation and networking could eventually save more than $810 billion annually by improving health care efficiency and safety.[10] (Fig. 1) Furthermore, HIT-enabled prevention and management of chronic disease could eventually double those savings while increasing health and other social benefit.

While Hillestad studied the use of HIT within a system, Walker et al studied the potential impact of a system that could exchange health information across systems. They estimated that a system able to coordinate exchange of information between providers (hospitals and medical group practices) and other agencies (e.g., laboratories, radiology centers, pharmacies, payers, public health departments, and other providers) could yield a net value of $77.8 billion per year once fully implemented.[11] (Fig 1) Feasibility studies of such programs showed positive results as long as the focus is on an appropriately narrow set of data.[12] Interoperability is recognized as an important component of the EHR by the National Quality Forum, who suggest policies around privacy and other barriers be removed so that important patient information can be shared across multiple sites of care.[13]

Fig. 1



Hillestad R et al. Health Aff 2005;24:1103-1117



Hillestad R et al. Health Aff 2005;24:1103-1117

Such is the general enthusiasm for the use of HIT to improve safety and quality while cutting costs that in 2009 the America Recovery and Reinvestment Act (ARRA) Health Information Technology for Economic and clinical health (HITECH) legislation spurred rapid implementation of HIT by promising financial incentives for providers who adopt electronic health records (EHR's) and demonstrate their ability to improve quality, safety and effectiveness of care. The program stipulates that, to qualify for these "Meaningful Use" payments, providers must use an EHR that includes the elements considered most important in terms of improving patient safety: support of information exchange, computerized physician order entry (CPOE) with clinical decision support (CDS) and other automated processes. Examples of required elements pertinent to medication safety are outlined in Table 1.

Table 1

Meaningful Use Core Objectives

Requirement	Eligible Professionals
CPOE for medication orders	More than 30 percent of all patients seen during reporting period with medication orders have at least one order placed using CPOE
Drug-drug, drug-allergy checking	Capabilities enabled for all CPOE
Maintain up-to-date problem/ diagnosis list	More than 80 percent of patients have at least one entry as structured data
Generate and transmit e-Rx	More than 40% permissible Rx transmitted electronically using an EHR
Maintain active medication list	More than 80% of patients seen have at least one entry as structured data
Maintain active allergy list	More than 80% of patients seen have at least one entry as structured data
Implement capability to exchange key clinical information among patient-authorized entities	Perform at least one test of capability to exchange key clinical information
Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance with that rule.	Implement one clinical decision support rule

Meaningful Use and Quality

What evidence do we have the HIT and specifically the Meaningful Use requirements will improve quality and safety, and result in cost savings? Amarasingham's cross-sectional study of urban hospitals in Texas revealed that greater automation of hospital information was associated with reduced rates of inpatient mortality, complications, costs, and length of stay. For all medical conditions studied, there was an inverse relationship between automation of notes and fatal hospitalizations. Likewise, higher levels of decision support correlated with a lower complication rates, and the greater automation of test results, order entry and decision support, the lower the cost of the hospitalization.[14] Notably, they used a tool called the Clinical Information Technology Assessment Tool (CITAT) to assess how physicians interacted with the information system and did not just assess whether technologies were present or absent. This is especially important because the best information technology application in the world is of no value if it is not clinically used. To derive benefit, what is important is not the application itself but the interaction between the technology and its routine use in actual clinical care.[15-17]

The Brigham and Women's Hospital in Boston had a cumulative net savings of $16.7M when they implemented a computerized physician order entry (CPOE) system between 1993 and 2002. The CPOE system elements that resulted in the greatest cumulative savings were renal dosing guidance, nursing time utilization, specific drug guidance, and adverse drug event prevention.[18] At Gunderson Lutheran Health Care system in Wisconsin, CPOE resulted in a decrease in lab tests, radiology examinations and transcription costs per hospitalization. Near misses per 1000 hospital days increased and the percentage of medication events that were medication errors

decreased from 66.5% to 55.2%, all of which suggest that the implementation of an inpatient EHR with CPOE can result in rapid improvement both in measures of cost of care and safety.[19]

Readiness for "Meaningful Use"

Current data indicate that while most of the large industrialized nations embrace the ideas stipulated in the HITEC legislation, most do not yet have a compliant system in place. Despite almost universal adoption of EHR's in UK, Netherlands, Australia, and New Zealand (and significant use by Germany) fewer than 10% of the hospitals in any single country had the key components of an EHR, and the early efforts have had varying degrees of active clinical data exchange.[20] (Table 2)

Table 2

Comparison of rates of electronic medical record use							
	Australia	Canada	Germany	Netherlands	New Zealand	United Kingdom	United States
Primary care							
HER (%)	79–90	20–23	42–90	95–98	92–98	89–99	24–28
CPOE (%)	75–81	5–11	59	85a	90	>90	9

Jha AK et al, Int J Med Inform, 77 (2008) 484-845

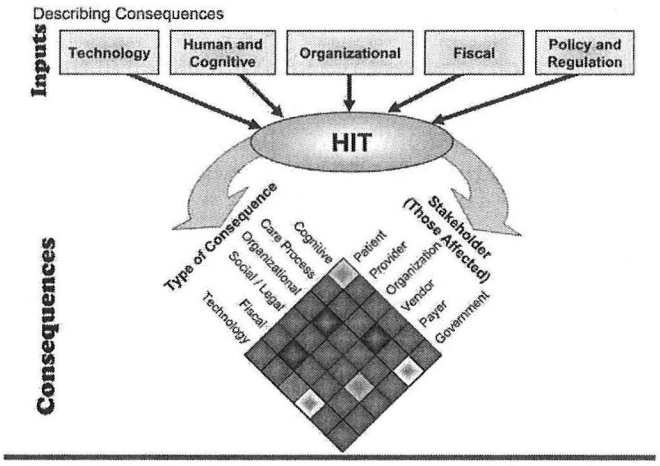
The US and Canada were well behind the other industrialized nations in the study above, with only 10-30% of ambulatory providers using EHR consistently. A separate study of U.S. hospitals using EHR revealed that only 1.5% of U.S. hospitals had a comprehensive electronic-records system (i.e., present in all clinical units), and an additional 7.6% had a basic system (i.e., present in at least one clinical unit). CPOE for medications had been implemented in only 17% of hospitals. Larger hospitals, those located in urban areas, and teaching hospitals were more likely to have electronic-records systems. The primary barriers to implementation were capital requirements and high maintenance costs, although hospitals with electronic-records systems were less likely to cite these barriers than hospitals without such systems.[21] Approximately 72% of hospitals had adopted three or fewer of the key applications as of 2009, meaning most U.S. hospitals lack the technological pre-conditions for achieving Meaningful Use incentives.[22]

The rush to adopt new technology

The American Medical Informatics Association (AMIA) devoted a 2009 meeting to consideration of unanticipated consequences of the rapid implementation of HIT, addressing both hardware and software systems that are implemented and the constraints they impose.[23] When complex new technology is introduced into an already complex social system, unanticipated consequences can occur that unintentionally result in patient harm. To understand the risks inherent in the use of HIT in general, and rapid implementation in particular, it is necessary to take a broader look at the systems being asked to merge, and the sociological ramifications of the interactions. (Figure 2)

Figure 2

Input–output model of unintended consequences.



Bloomrosen M et al. JAMIA 2011;18:82-90

Understanding socio-technical systems

Peter Drucker described the modern hospital as "altogether the most complex human organization ever devised".[24] The clinical workplace is a system in which technologies, people, and organizational routines are interdependent and dynamically interact. Organizations are simultaneously social (consisting of people, values, norms, culture) and technical (require tools, equipment, procedures, technology, and facilities to function). These two facets of a healthcare organization are deeply interdependent and interrelated, creating a new integrated system that can be called a socio-technical system. Good program design and implementation is therefore not a uniquely technical problem, but one in which both technological and social needs must be met.[25] Experts agree that the first step in the introduction of new technology is organizational change. The technical infrastructure, without the social support, is bound to fail. This has significant implications for the adaptation of meaningful use technology – before it can be used effectively, social systems must be prepared to receive it.[26]

Professionalism is at the heart of risk management in complex, dangerous work such as medicine, aviation, and military operations. Professionalism is closely connected to expertise and is therefore closely connected to the ability to prevent and mitigate errors. Holtman pointed out two paradoxes in this connection. First, professionalism can increase, rather than reduce, the risk of errors and accidents by promoting practitioners' tendency to break procedural rules. This is because professional expertise tends to favor adaptation to local circumstances over standardized approaches to problem solving. Second, professionalism can create blind spots within organizations, blocking the flow of critical information about unsafe conditions. This is because professional groups develop unique subcultures, specialized language, and communication habits that tend to separate them from other professional groups, even when those groups work within the same organization. This paradox can run counter to the necessary engagement of users when optimizing HER implementation.[27]

Unintended consequences

The study of unintended consequences is not a new one. In 1936 Robert K Merton listed possible causes as: ignorance, error, overriding of long-term interest by immediate interest, basic values that require or prohibit action and self-defeating prophecy. [28] In 2000 the Robert Wood Johnson (RWJ) Health Policy Fellowships Program and the IOM conducted a workshop on the subject of unintended consequences of health programs

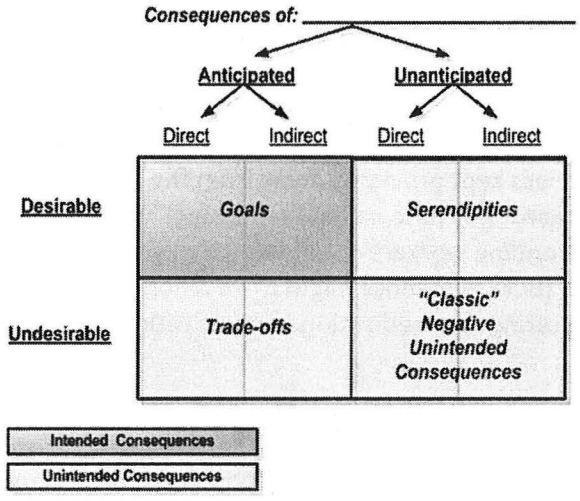
and policies, and acknowledged that adaption of HIT can result in unintended consequences. Government entities responsible for Meaningful Use payments are also aware of this possibility, and in 2010 issued a request for proposals addressing unanticipated consequences of HIT adoption.

The unintended consequences of integrating HIT into the socio-technical environment of healthcare organizations (workflows, culture, social interactions and technologies) are well described.[29-31] It is critical to consider the impact of technology on care processes, workflow and safety 'human factors'.[32] If not carefully planned and integrated HIT can create new work, complicate work flow or slow clinicians down. Learning new processes takes time and energy causing strain on demanding work schedules. This can cause uncertainty, frustration and resentment, all of which impact the worker's ability to execute complex cognitive tasks.[30] Failure to fix technology when it becomes counterproductive is especially insidious because unsolved problems engender dangerous workarounds.[16,33] Inconsistent upgrades or integration create opportunities for safety to be compromised. Multiple networks can results in poor interoperability and increased costs.[8,16,33-35]

In addition to un*intended* consequences (in which there is a lack of purposeful causation), there can also occur un*anticipated* consequences (implying a inability to forecast what eventually occurred).[30,36] If a consequence is undesirable but anticipated it can be addressed and managed. If not anticipated, problems can arise. (Figure 3) For example, drug interaction alerts intentionally interrupt a clinician's workflow because, although the alert might annoy the physician, it will mitigate error. The unanticipated consequence may be that the MD ignores all the alerts or refuses to use the system.[37,38]

Figure 3

Relationships across and among consequences.



Bloomrosen M et al. JAMIA 2011;18:82-90

Human Factors

Unintended consequences can occur in any complex system, but the risk is even greater when human beings are part of a process. The overall safety and effectiveness of technology in health care ultimately depend on its human users, ideally all working in close concert with properly designed and installed electronic systems.[39] A safe technology or device must also be operated safely within a safe workflow process.[40] Cognitive science and human-computer integration are crucially important in understanding the technology-related adverse events, which can spring from any component of a comprehensive technology system, and may involve errors of either

commission or omission. Most commonly, these events stem from human-machine interfaces or organization/system design.[41]

Cognitive research shows that the use of information systems by physicians changes as a function of their background, developmental level, and expertise. Standardization, although necessary, has its limitations because each user brings to the table a different set of thought processes, behavioral habits, and mental capabilities. Cognitive science and the emerging field of human-computer integration (HCI) help designers understand the needs of the end user in health care and how they differ from solutions applied in non-analogous fields. Patel et al report that exposure to HER's tightly structured format has been shown to be associated with changes in physicians' information gathering (more efficient) and reasoning strategies (hypothesis driven) compared to their use of paper records (slow and data driven).[42]

Human factors engineering is a discipline that studies human strengths and limitations in the design of interactive systems that involve people, tools and technology and work environments to ensure safety, effectiveness and ease of use. Activities are broken down into their component tasks, and take into account such elements as physical demands, skill demands, mental workload, team dynamics, work environment (e.g., lighting, noise, distractions) and device design required to complete the task optimally. The focus is how systems work in actual practice with real, fallible humans at the controls and attempts to design such complex systems in ways that optimize safety and minimize the risk for error.[43,44] For example, designers need to understand the environment in which their technology will be used: how task flow may vary based on context, how often users are interrupted and deviate from a linear completion strategy, the uncertainties inherent in complex decision-making, and the crucial role of clear and speedy communication in collaborative assessment and treatment.

Some common tools and techniques used in human factors engineering include:

1. Usability testing: systems and equipment are tested under real world conditions to identify unintended consequences (e.g., introduction of computerized physician order entry (CPOE) increases mortality in an ICU because an unnecessarily cumbersome order process kept providers away from the bedside) One benefit of usability testing is the identification of workarounds (also called "satisficing"[45], in which policies or procedures are consistently bypassed by frontline workers to get work done efficiently. For example, a faulty Barcode Medication Administration (BCMA) scanner might drive a nurse to give an urgent medication without scanning and manually entering the medication administration later, circumventing the safety strategy.[46]

2. Forcing functions: a design strategy that prevents an unintended or undesirable action from being performed or allows the action only if another specific action is performed first. For example, an alert will fire at each attempt to prescribe ampicillin to a patient with a documented penicillin allergy. The alert requires cancelling the order.

3. Standardization: equipment and processes should be standardized whenever possible in order to increase reliability, information flow and to minimize cross-training needs. Checklists are a good example as they ensure safety steps are performed in sequence to optimize safety.

4. Resiliency: a system should be designed to detect and mitigate unexpected events. An ideal system will not only preclude error, but should also be resilient enough to anticipate and adapt to changing conditions, and then recover and protect the process (patient). The concept of resiliency grew out of study of high-reliability organizations and complex adaptive systems.

5. Work Environment: system design must take into account that health care environments are often characterized by excessive noise, high workloads, multi-tasking, and execution complex tasks that require rapid responses to information.[47]

When complex systems are rapidly integrated into systems sensitive to human factors, unintended consequences for patient safety can occur. The data on safety issues related to EHR use are not robust. A recent review characterizing the literature on safety issues related to EHR use revealed that research from 2000-2009 was published in only 13 journals, very few of which were journals read by clinicians or devoted to healthcare management, quality or safety. Fully one third of the research was presented through the journal or conference proceedings of the American Medical Informatics Association. The modal publication date was 2005, despite the steadily increasing use of EHR in hospitals, and the study design were rarely randomized controlled clinical trials. More often studies were descriptive or comparison designs.[48]

HIT and medication safety

The great promise of adopting EHR's and other HIT is a dramatic increase in patient safety and quality of care. Unfortunately, for a variety of reasons, adverse events and errors of both commission and omission continue to occur despite the use of the many tools designed to prevent them, including EHR's, CPOE, BCMA or Clinical Decision Support (CDS) tools. A critical unintended consequence of HIT is what Weiner et al. have called "e-iatrogenesis", a term used to describe patient harm resulting at least in part from HIT. Errors can be technical, human-machine interface related, or organizational.[41] "Technological iatrogenesis" describes errors caused by addition of technological innovations into complex healthcare systems.[49]

There is inadequate data about the incidence of adverse drug events caused by HIT. Technology related adverse events with medications can involve any element of the EHR: CPOE, automated dispensing cabinets (ADCs), EHRs, CDS, or BCMA. In 2007, 83% of hospitals had ADCs, 43% had EHR, 24% used BCMA, and only 18% had implemented CPOE.[50,51] The US Pharmacopeia MEDMARX database review of 176,049 medication error records for 2006 show that only 1.25% resulted in harm. Twenty five percent of those errors (43,372) involved some aspect of computer technology as at least one cause of the error. Causes include mislabeled barcodes, unclear or confusing computer screen displays, CPOE, overrides of barcode warnings.

There are published estimates of the error rates for each step in the medication management process as well as the likelihood that an error will be intercepted.[52] Table 3 lists IT systems that target improvements in the execution of each step.[53] Even the best systems have room for improvement. Although the provider-oriented EHR in the Veteran's Healthcare Administration (VHA) is considered a model for patient safety, a large number of ADE's were detected by prospective manual electronic chart review that had been missed by the EHR and what was considered a sophisticated ADE detection scheme.[54]

Table 3
Steps, Error Rates, and IT Systems in Medication Management

Stage	Error rate, %	Intercept rate, %	True error rate, %	Relevant IT systems
Prescription	39	48	22	CPOE with decision support Electronic medication reconciliation
Transcription	12	33	11	Automated transcription
Dispensing	11	34	10	Robots, automated dispensing cabinets
Administration	38	2	51	Bar-coding, electronic medication administration

Agrawal A. Br J Clin Pharmacol 2009 67:6; 681–686

CPOE and CDS

Research into unintended consequences of HIT adoption has focused largely on CPOE systems, rather than BCMA or CDS, because the resulting errors in medications and procedures are easy to connect directly to patient harm.[55] (Bates 2005) Overall, CPOE systems are effective in reducing medication error rates, and the cultural and workflow changes that accompany adoption of CPOE have not been shown to adversely affect acuity-adjusted length of stay or total cost. Electronic prescribing (E-RX) is a component of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Electronic transmission of prescription data from physicians' offices to a pharmacy nearly halved the risk of dispensing errors compared with generating the prescription with outpatient CPOE and printing it and giving it to the patient.[56] Reductions in transcription errors, medication turn-around times, and improvements in timely reporting of results supports the view that CPOE and eMAR provide a good return on investment.[57]

Despite the elimination of illegible orders and transcription errors, CPOE can actually increase the number of adverse events.[58] Koppel et al studied users of a single CPOE system in a large academic medical center and identified 24 different types of failures of which users were aware; roughly half the participants said these faults occurred from several times per week to daily.[16]

Adoption of CPOE can redistribute work in unexpected ways. (Table 4) By increasing the coordination load on clinicians, CPOE in turn increases opportunity for error. Telephone interviews of CPOE users in almost 300 hospitals found the unintended consequences of CPOE considered most important by subjects were new work or more work, work flow, system demands, communication, emotions and dependence on the technology.[36] Socially, physicians may resent the need to enter orders into a computer. They also report feeling a loss of professional autonomy when CPOE systems prevent them from ordering tests or medications they prefer, force them to comply with guidelines they don't endorse, or limit their flexibility through structured rather than free-text clinical documentation and communication.[39,59,60]

Table 4
Unintended Consequences of CPOE and Their Frequencies of Occurrence

Unintended Consequence	*Frequency (%) n = 324*
More/new work for clinicians	19.8
Workflow issues	17.6
Never ending system demands	14.8
Paper persistence	10.8
Changes in communication patterns and practices	10.1
Emotions	7.7
New kinds of errors	7.1
Changes in the power structure	6.8
Overdependence on technology	5.2
Total	100

Campbell. JAMIA. 2006;13:547-556.

Clinical Decision Support tools and Drug-Drug interaction checking

Although most ADEs are not preventable given what is known today, many types are, and one key cause of those is drug-drug interactions (DDIs). Adverse events can results from either diminished therapeutic effect of toxicity. Clinically important DDIs can often be predicted based on drug properties, route of administration and patient specific factors. DDI used to be performed by pharmacists, but with the development EHRs this task is now performed by physicians as part of CPOE, with pharmacists doing a "double check". How does CDS software that contains drug-drug interaction information augment pharmacists' ability to detect clinically significant interactions? Metzger's study looked at critical DDIs picked up in actual outpatient pharmacy practice using simulated patient scenarios. Only 28% of pharmacies correctly identified eligible DDIs. The median percent correct DDI responses was 89% (47%-100%). A similar study done in inpatient setting using EHRs found that only 52.4% of critical DDIs were detected among hospitals with EHRs and CPOE.[61] Studies indicate these systems may miss some important interactions. Comprehensive system improvements regarding the manner in which pharmacy information systems identify potential DDIs are warranted.[62]

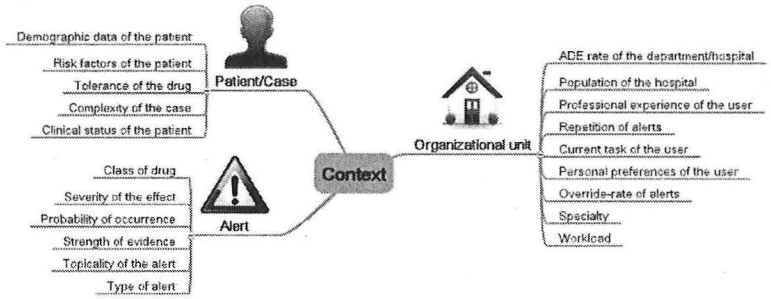
Most drug-drug interaction (DDI) checking is done with EHRs that are linked to CDS supplied by content vendors. The knowledge in these domains requires continuous updating. The databases contain exhaustive information that is difficult to customize for local use, and sometimes forbidden by contractual obligations. Therefore, as implemented currently DDI checking can be burdensome and workflow insensitive. When too many warnings are displayed, productivity issues and workflow interruptions may lead to DDI checking being turned off or dramatically reduced. Too many warnings lead to can lead to "alert fatigue"; in some studies override rates by physicians are as high as 90%.[60] Tiering of DDIs can be helpful in ensuring providers accept the truly important interactions.[63] Intrusive alerts should be used only for the most severe clinical indications where remediation of the prescription is required before completion. Shah et al demonstrated that with careful selection of which interactions are "interruptive", high levels of provider acceptance can be achieved.[38]

A group in the Netherlands performed a retrospective analysis of overridden drug safety alerts through qualitative interviews with physicians and pharmacists. Although the Dutch drug database is already a selected reduction of DDIs mentioned in the literature, the majority of respondents wanted to turn off DDI alerts to reduce alert overload. There were no alerts that all clinicians agreed could be turned off safely. However a

significant positive correlation was found between the most common overridden alerts and the number of MDs who thought those alerts should be turned off. There was no correlation between the seriousness of the alert and the number of respondents agreeing to turn off the alerts. Not surprisingly, interviews revealed wide variation in physicians' drug-related knowledge and routine drug monitoring practices.[64]

Physicians routinely request that drug safety alerts be clear, concise and helpful with ready links to supporting evidence.[65] Over-alerting as well as lack of tailoring of the system to the specific requirements of the user, or the specific details relevant to the patient being prescribed for, will not only frustrate the user but will lead to the impression that of the system generates an excessive amount of false alerts, which will in turn degrade the integrity of the system.[37,66] More recent research has produced context models for prioritizing drug safety alerts. Riedmann et al developed a model containing up to 20 factors grouped into three categories: patient characteristics such as demographics and co-morbidities, user or clinician characteristics and alert characteristics like severity of the effect and the strength of evidence supporting it.[67] (Figure 4)

Figure 4



Riedmann et al. BMC Medical Informatics and Decision Making 2011, 11:35

A CPOE standard was one of the first Leapfrog safety best practices because medication errors are so common, dangerous and costly. The Leapfrog standard has been formally incorporated into the National Quality Forum's CPOE safe practice. The Leapfrog CPOE evaluation focuses on implementation of the CPOE application rather than vendor CPOE applications off the shelf. It uses test patients and a set of test orders to determine the extent to which CPOE in use actually intercepts problematic medication orders, including a focus on critical DDIs. The DDI section test evaluates serious DDIs as defined by a group of content experts. A new version was available in the spring of this year. The improvements increased the total number of DDI pairs and tried to harmonize them with third-party content vendors increasing the focus on only the most severe DDIs. The hope is that the inpatient rate of detection has improved significantly from the 52% reported in 2010 by Metzger.

In a review of 100 studies assessing the effect of CDS systems between 1998 and 2004 Garg and colleagues concluded that although CDS has been reported to improve practitioner performance, the effects on patient outcomes are understudied, and the results of the few published studies are inconsistent.[68] The Office of the National Coordinator (ONC) for Health Care Information Technology Advancing Clinical Decision Support Initiative was undertaken with the intent to promote broad CDS adoption, dissemination and effective use of CDS to facilitate evidence based clinical practice and meaningful use of health IT. It was funded by the HITECH legislation of 2009. The RAND Corporation in partnership with Partners Health care is responsible for leading the 4 tasks of this initiative:

1. Distill best practices for CDS design and implementation
2. Distill best practices and standards for sharing CDS knowledge
3. Produce an online platform for sharing CDS knowledge among vendors and provider organizations
4. Develop a clinically important DDI list and a legal brief about the liability implications of using this list.

5. Develop a process that engages clinical specialties to assess performance gaps that may present as opportunities for CDS interventions in EHRs

The goal is to transform the way health care is practiced by effectively incorporating CDS interventions that foster best practices of care and are streamlined with clinicians' workflow.

Collaboration between the RAND Corporation and Partners Health Care resulted in an expert panel tasked with developing a list of highest severity drug interactions and put them into a severity-scoring index. Their work targets the most serious or "cannot-miss" interactions with the intention of making this information widely available. The ONC list was designed to reduce alert fatigue and describe the most clinically significant high priority DDIs to define a "minimum standard". The most severe level 1 interactions create a hard stop (forcing function) that requires the physician to cancel one of the orders. Moderate severity interactions can be overridden, but require specification of reason for continuing with the drugs. The least severe, level 3 interactions trigger informational alerts that are non-interruptive to the clinician's workflow. Organizations can use this to ensure they have included the most important DDIs. The Leapfrog test should include the interactions that are most important to improving care. Some of these DDIs fall into the "cannot miss" group, but the Leapfrog list is more comprehensive because it includes interactions that may be acceptable in some clinical circumstances, but should generally be avoided. Use of the test may help organizations operationalize their DDI detection system.[5]

Clinical decision support systems are intended to support real-time clinical decisions and represent a key difference between electronic and paper documentation.[69] Their utility can be reduced by incorrect information. EHR users can introduce errors through multiple points of data entry.[70] Quality of documentation can be degraded by the feature that multiple parties have access to and edit the same records. The positive consequence is multiple checks of the information, the downside can be shared lists may develop duplicate or even contradictory entries. (EHR becomes like Wikipedia—eg. medication reconciliation and allergies) Some providers trust the computer more than is warranted.[71] Problems arise when users have false expectations regarding data accuracy and processing or have unquestioning trust of automated systems without a thorough understanding of the limitations. When the system goes down, they are unprepared to work in the environment without robust backup systems.[30] Alert and reminder systems involve linear, rigid rules, an approach that is poorly suited for the inherent complexity of medical decision making and not consistent with the way people tend to make decisions based in classical decision making literature on heuristics and biases. The formalization of rules to manage decisions that were previously managed informally sacrifices flexibility leading to loss of resilience with the danger of generating medical error as a consequence.

Organizations need a robust understanding of CDS system prior to successful implementation. Medication-related decision support is probably best introduced into healthcare organizations in two stages, basic and advanced. Basic decision support includes drug-allergy checking, basic dosing guidance, formulary decision support, duplicate therapy checking, and drug-drug interaction checking. Advanced decision support includes dosing support for renal insufficiency and geriatric patients, guidance for medication-related laboratory testing, drug-pregnancy checking, and drug-disease contraindication checking. [72]

Wright et al performed a comparison of front-end Clinical Decision Support tools in commercial and internally developed EHRs to determine which help make care safer, more efficient and more cost effective.[73] Examples of these tools include health maintenance reminders, drug-drug interaction checking, dose adjustment, and order sets.[74] The most commonly implemented tools are the simplest. Work flow support, point of care reminders and relevant information displays were less common. Expert systems like diagnostic decision support, treatment planning, and lab data interpretation were least common. The variability among EHR systems was striking; only 15% of CDS tools were found in all systems. The tools with complete penetration are: default

dose and pick lists, medication order sentences, DDI programs and drug allergy checking. It is important to note that results of this study are based on each system as it was designed, not as it was actually implemented. The gap between system design and how the system is implemented in clinical practices can be substantial.[75]

As Wears and Berg point out in a 2005 JAMA editorial, CPOE and CDS had been characterized by frequent reports of success accompanied by predictions of a great promise; however, in their opinion, the benefits had not been realized. They went on to state: "Behind the cheers and high hopes that dominate conference proceedings, vendor information, and large parts of the scientific literature, the reality is that systems that are in use in multiple locations, that have satisfied users, and that effectively and efficiently contribute to the quality and safety of care are few and far between." They go on to point out that information technology in and of itself cannot do anything, and when the patterns of its use are not tailored to the workers and their environment to yield high-quality care, the technological interventions will not be productive.[26]

Phansalkar et al summarized some 'actionable recommendations' for the design and implementation of future clinical information systems

1. Alert philosophy: This should specify (as a minimum) which categories of problems should be included in the alerting system, and how many priorities there should be for each category of risk. A distinction should be made between alerts related to medications versus those that relate to system errors.
2. Prioritization of alerts: This should probably include three levels: low, medium, and high and should be coded using word, color, shape, position on screen, and other indicators known to influence urgency.
3. Low priority alerts: These should be avoided or classified as 'information only' indicators. Although from a safety point of view more alerts are seen as safer, in practice the reverse is true.
4. Information which is linked in forming a holistic judgment should be linked together perceptually; information which is disparate and needs to be considered separately should be readily differentiable.
5. Information which is contemporaneous should be presented at the same time in the system.
6. Interfaces which are tailored to the user and/or the patient are likely to lead to fewer perceived false alarms, and are likely to be less irritating, and less prone to error.
7. Alerts which require acknowledgement before the user moves on should be kept to a minimum.
8. Auditory alerts might have a very specific role in some circumstances, for example missing patient data, and should be considered for use in combination with visual alerts.
9. The presentation of alert information, and information more generally, should as far as possible match the mental models of the user.
10. The format of alerts should be chosen in order to avoid habituation. Alerts of the same level of severity should be perceived as equally urgent, but different from those of a lower severity or purpose.[37]

BCMA

Barcode Medication Administration (BCMA) usually consists of handheld devices for scanning machine-readable barcodes on both patients and medications. They also interface with electronic medication administration records. Ideally, BCMAs help confirm the five "rights" of medication administration: right patient, drug, dose, route, and time. It interposes a computer based check between the nurse and the patient.

Studies suggest BCMA implementation will result in a positive financial return on investment for the health care organization.[76] In a recent analysis of the cost of Implementation of a bar code-assisted medication-dispensing

system in hospital pharmacies use of the bar-code eMAR substantially reduced the rate of errors in order transcription and in medication administration as well as potential adverse drug events, although it did not eliminate such errors. These data suggest that the bar-code eMAR is an important intervention to improve medication safety.[77]

While BCMAs are reported to reduce medication administration errors--the least likely medication error to be intercepted--these claims have not been clearly demonstrated. Investigators find multiple workarounds that result in errors such as omission of process steps, performing steps out of sequence and unauthorized BCMA process steps.[78] The causes of workarounds are numerous: unreadable medication barcodes (crinkled, smudged, torn, missing, covered by another label); malfunctioning scanners; unreadable or missing, damaged or incorrect patient identification wristbands; non-bar coded medications; failing batteries; uncertain wireless connectivity; and interruptions along with others. The authors found nurses overrode BCMA alerts for 4.2% of patients charted and for 10.3% of medications charted. Possible consequences of the workarounds include wrong administration of medications, wrong doses, wrong times, and wrong formulations.[79] Several authors concluded that BCMA could create new paths for adverse drug events and implementation requires preemptive evaluation and interventions.[80]

Medication Reconciliation

Medication Reconciliation is the process of obtaining and documenting a thorough medication history with attention to comparing current and previous medication use. The literature describes its effect on prescribing outcomes such as medication errors and potential ADEs but not on actual ADEs.[81]

The root causes of medication errors that occur on hospital admission are most commonly related to incorrect or incomplete medication histories, variances in patient compliance from what were prescribed and non-comprehensive data systems.[82-85] The MATCH study at Northwestern performed an analysis of medication reconciliation errors and risk factors at hospital admission. Over one-third of the patients in the study had a medication error at admission, the majority being errors originating in their medication histories (almost half were omissions). When these discrepancies went undetected, 52.4% of order errors were rated as potentially requiring increased monitoring or intervention to preclude harm. Presenting a medication list or bottles at admission was beneficial.[86]

Geriatricians at a VA hospital in the Northeast examined the frequencies of medication error and adverse drug events (ADEs) at the time of patient transfer in a system with an electronic health record (EHR) as compared with a system without an EHR. They hypothesized that the frequencies of these events would be lower in the EHR system because of better information exchange across sites of care resulting in improved medication reconciliation. Unfortunately the overall incidence of ADE caused by medication discrepancies was no different with and without an EHR.[87]

Researchers at Vanderbilt studied 120 patients admitted to their ICUs as this population is particularly vulnerable to injury resulting from medication errors because of the severity of illness, need for high risk medications with a narrow therapeutic index and frequent use of intravenous infusions. They found a high incidence of potentially inappropriate medications on the eMARs of patients at transitions in care. The study highlighted the importance of performing an evaluation of medication appropriateness during reconciliation of medications at admission, ICU discharge and hospital discharge. Optimal implementation should involve physicians, pharmacists and the EHR surveillance and clinical decision support.[88]

Accountability for errors resulting from use of EHRs

EHR vendors are currently liability free when their products are involved in adverse events. The so-called "hold harmless" clause is a contractual and legal device putting liability for technology-induced errors on provider organizations and healthcare professionals referred to as "learned intermediaries". A learned intermediary is considered a medical expert whose education and experience enable them to assess the benefits and risks of medications or devices. Decisions made by the intermediary are considered an informed and individualized medical judgment. The HIT vendors then claim that because they are not practitioners and are merely software companies, clinicians are in a much stronger position to identify the errors of faulty software or hardware. Under this legal doctrine, physicians, nurses, pharmacists and other clinician are held accountable for identifying and correcting any errors generated by software defaults.[89]

Initially HIT vendors argued that a hold harmless clause was necessary to prevent stifling innovation in this critical field. Vendors could then retain company confidential knowledge about design, faults, operations and glitches. This non-sharing of software problems is an industry norm but flies in the face of improving patient care. The complexity of implementation of HIT means limited ability to predict scenarios in which software failures could create hazard for patients and liability for the organization. Organizations frequently request customization by vendors to improve the fit between HIT and the workflow of the different practitioners. Such customization could potentially alter data, connectivity or other functionality that creates unanticipated consequences. Obviously, any tool can be misused. Software for HIT is complex and requires significant training for safe use. All the training in the world does not mitigate the potential impact of unskilled users, and vendors do not want liability for the acts of such users.

CDS and Malpractice risk

Part of the ONC project to advance clinical decision support is the evaluation of liability challenges and the barriers they create for adoption. It is intuitive that a good CDS system should attenuate malpractice risk, but in current practical application we have seen this is not the case. One paradoxical result of aggressive use of automated warnings may be to exacerbate malpractice risk for physicians who override alerts or organizations that opt to turn them off. CDS systems create audit reports of physician overrides. Another paradoxical result could be impeded adoption of CDS technologies because of physician and institutional concerns about malpractice risk.[90] Technology vendors are concerned that CDS systems that deliberately neglect to provide warnings for known categories of ADE, no matter how obscure, might create a basis for new products liability claims against vendors. Physicians and health care organizations might be concerned about altering the CDS systems they have in place in order to comply with the optimized DDI list from the ONC.

The AMIA recognized this challenge of ensuring that liability concerns do not derail the clinical value of CDS technology. Some vendors incorporate contract language whereby purchasers of HIT systems, such as hospitals and clinics, must indemnify vendors for malpractice or personal injury claims, even if those events are not caused or fostered by the purchasers. Some vendors require contract clauses that force HIT system purchasers to adopt vendor-defined policies that prevent the disclosure of errors, bugs, design flaws, and other HIT-software-related hazards. To address this issue, the AMIA Board of Directors appointed a Task Force to provide an analysis and insights. Task Force findings and recommendations include: patient safety should trump all other values; corporate concerns about liability and intellectual property ownership may be valid but should not over-ride all other considerations; transparency and a commitment to patient safety should govern vendor contracts; institutions are duty-bound to provide ethics education to purchasers and users, and should commit publicly to standards of corporate conduct; and vendors, system purchasers, and users should encourage and assist in each others' efforts to adopt best practices. Finally, the HIT community should re-examine whether and how regulation of electronic health applications could foster improved care, public health, and patient safety.[91]

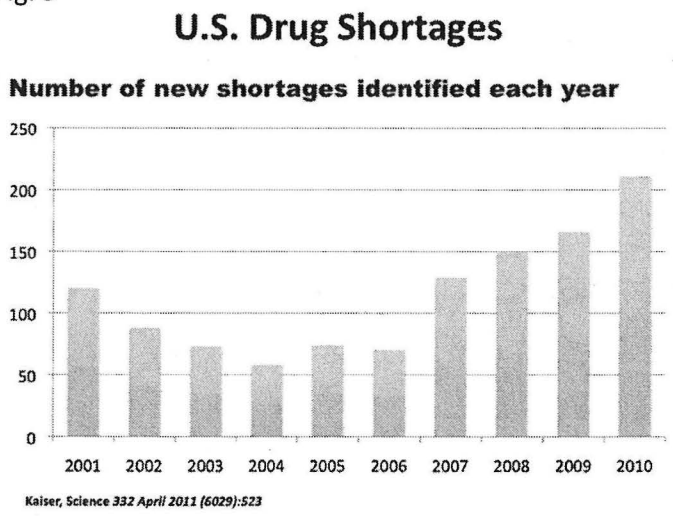
The ONC project to define the DDI list is one step as it will define expert consensus and relieve technology vendors and physicians of some of the onus of deciding on tradeoffs in CDS systems. The Joint Commission, CMS and relevant professional societies could then endorse the approved list. Creation of a legal safe harbor through federal legislation has been proposed. This would mean that physicians managing medications through CS and consensus based DDI list cannot be used as a basis for malpractice liability nor evidence of negligence. Safe harbor could extend to CDS software package and the vendor when they incorporate a consensus-based DDI list.

Future problems can emerge when patient populations and norms differ from software-embedded rules. Morbidly obese patients may exceed smart pump parameters which will then miscalculate dosages. Errors in inputting critical data such as weight either by estimating versus actually weighing the patient, or use of pounds versus kilograms can create significant consequences.

Drug Shortages

Managing drug shortages adds complexity to our ability to administer drugs safely and effectively. Hospitals and health systems routinely treat patients with acute conditions that often require medically necessary, single-source products. As the number of drug shortages climbs, the challenge to provide seamless, safe and therapeutically equivalent drug therapies (at comparable cost) is a challenge.[92-95] (Figure 5) The operational assessment of drug shortages and their implications are even more complex in the era of the EHR. After a therapeutic assessment of such things as patient prioritization (often aided by opinion from the CDC, NIH and others), risk management and ethical considerations, organizations must communicate their plan. Implementation of the plan must include updating information systems, technology changes like bar codes, inventory system changes, new administration procedures and order sets. Changes in the recommended dose of acetaminophen in combination analgesics, for instance, posed a major implementation burden on IT systems at PHHS given the frequency with which those drugs are incorporated into order sets.

Fig. 5



There are multiple contributors to drug shortages. The majority of raw and bulk material comes from outside the US---primary or sole sources can be compromised by natural disaster, contamination, political upheaval. Manufacturing difficulties can arise from FDA enforcement actions intended to keep drugs safe. In the event their actions involve a medically necessary product, the FDA will help manufacturer return to compliance, qualify additional sites, or permit importation of the product from a foreign manufacturing source where quality controls are met. Voluntary recalls due to manufacturing problems are generally temporary, and limited to

specific lots. Changes in product formulation or manufacturer can cause significant disruption when they affect a very common medication (e.g. the switch from albuterol MDI containing chlorofluorocarbons to MDI containing hydrofluoroalkanes in 2006).

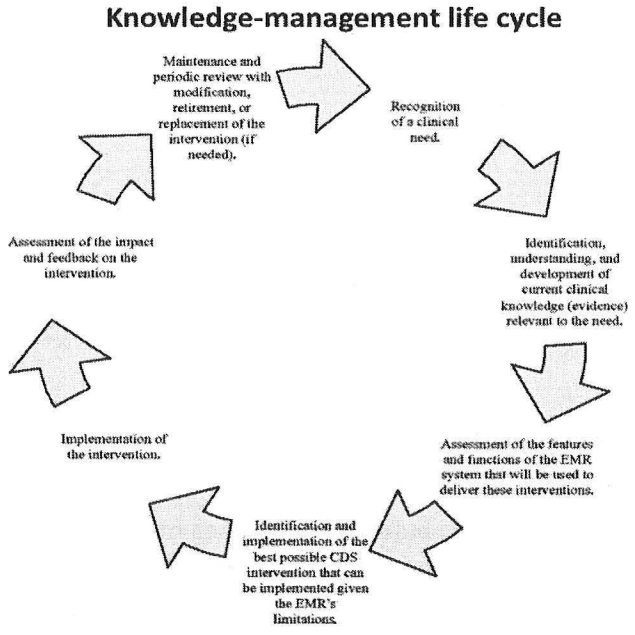
Manufacturers make business decisions, for example production of diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed was discontinued in 2000 by a company with low revenues. Companies don't have to warn the FDA and are under no obligation to make a drug. Even with advance notice, some drugs and vaccines are complex to manufacture and a new supplier cannot be readily identified.

Industry mergers cause narrower focus of product lines or move production to other facilities. Reducing the number of manufacturers also decreases resiliency in the supply chain. Likewise, stockpiling and hoarding before price increases or rumors of shortages can be problematic. Sometimes there are unexpected increases in demand and shifts in clinical practice such as new indication approval, a disease outbreak, publication of new guidelines. In 2006 the CDC recommended annual flu vaccine for children age 6-59 months, but only one product had FDA approved labeling for use in children 6-23 months old.

Governance for CDS and HIT implementation

Effective implementation of CDS requires effective clinical and technical governance structures. Good CDS systems require extremely large knowledge bases of clinical facts that must be engineered or purchased and then kept current as knowledge, clinical guidelines and best practice evolve. Management of the knowledge is an iterative process involving both creation of new content and the continuous review of and revision of existing content. Organizations may rely on existing committees like the Pharmacy and Therapeutics committee or a single person such as the CMIO or in some instances develop new committees and intranet-based content creation, review and approval systems. The AMIA sought to determine the range and variety of governance structures and identify a set of recommended practices. In the absence of such a governance structure, implementation may fail.[73,96]

Fig. 6



Wright A. JAMIA 2011; 18:187-194

The AMIA panel suggests that a critical component of EHR governance and oversight is content management and delineation of a knowledge-management life cycle. (Fig. 6) It provides structure for the assessment of the potential impact of new software on existing clinical information systems: will usability, response time and reliability be changed by adding a new intervention? It is also important to establish clear lines of responsibility and schedules for facilitating updates and ensuring continuity. Organizational committees may need to interact and resolve conflicts fairly and transparently. Iterative system improvements should include a plan to monitor CDS interventions such as rule firing and overrides. User feedback tools should encourage end-user input. The panel did not comment on the cost of CDS governance nor consider the financial implications of different governance approaches, but it is almost certainly significant.[73]

Lorenzi et al describe HIT implementation challenges as focused on the organizational capacity for change and its recognition of the importance of context. Survey results regarding information technology implementations across a wide range of industries suggest that 18% of IT implementations are outright failures, while an additional 53% of IT implementations are challenged by additional problems in the form of cost overruns and delays in project completion. A variety of reports have suggested causes for implementation failures, including lack of user involvement, poor communication, lack of attention to people and organizational issues, and poor project planning. Successful implementations are marked by investment in high-quality training, extensive support, and managers who can respond flexibly to changes in the environment so that patient safety is maintained as the highest priority.[97] In a systematic literature review outlining lesson learned form HIT implementations in seven countries they found that strong project leadership, appropriate project management techniques, standards and staff training are all important.[98]

Special circumstances in Academic Medical Centers

Trainees and the EHR

Several authors have pointed out the value of housestaff in finding system defects that lead to patient harm. Trainees represent the majority of end-users at teaching hospitals, but are often not incentivized to report their experience.[99-102] House officers are in effect a migrant work force in healthcare and are transient part of organizational life. Padmore and colleagues examined the literature on residents' attitudes and behaviors in response to medical error within the context of their institutions and published their results in Academic Medicine in 2009.[103] The identified barriers that make residents reluctant to engage in error identification and/or reduction included fear of retribution and the perception of residents as transient care providers. Because of the barriers, their voice is not heard by decision makers. They often discuss the travails of working with the EHR and the glitches they discover only among themselves. By not working on "availability and affability" of reporting systems we miss out on their significant insights. We would also be wise to consider the response of the organization to this input. The key to engaging house staff in improvement activities is demonstrable changes in the system in response to their input. A strategy that employs changing the social structure of academic health care centers may well be an effective part of improving design and implementation strategies for HIT.

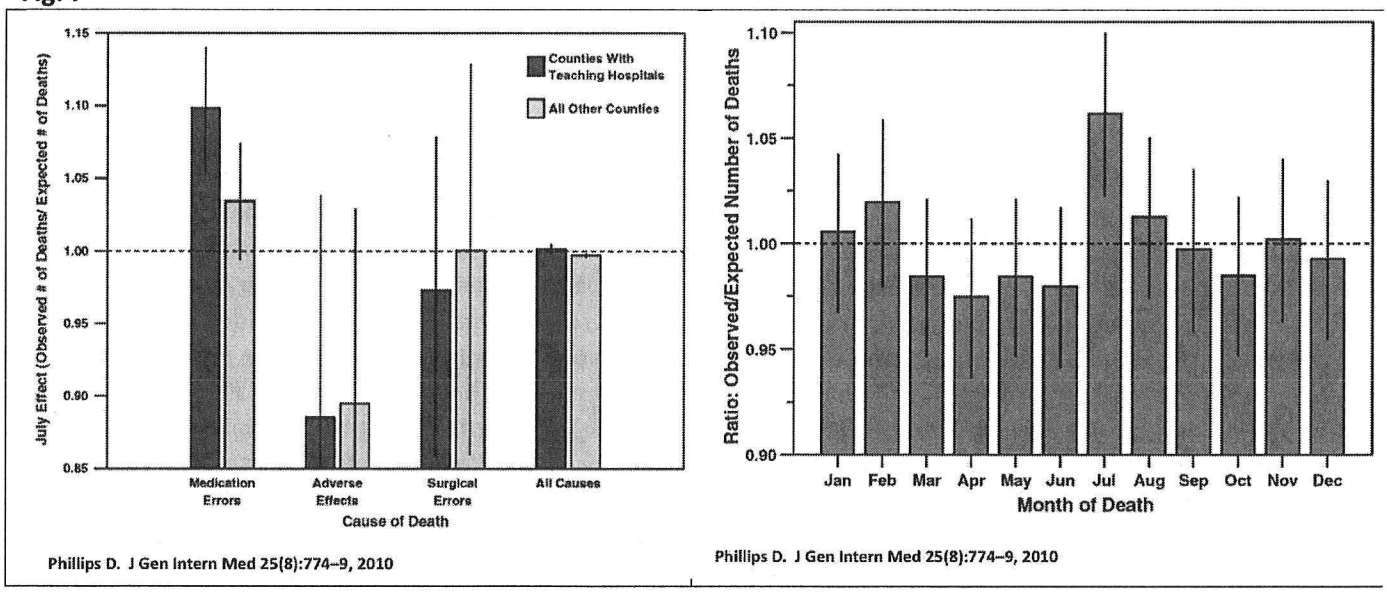
"The July effect"

Young et al Annals July 11, 2011 systematically reviewed the literature describing the effects of trainee changeover on patient outcomes.[104] They found that mortality increases and efficiency decreases in hospitals because of year-end changeovers. The heterogeneity of the literature does not permit firm conclusions about the degree of risk posed. Their review looked at literature from 1989 through 2010 and ultimately included just 39 studies all of which were based inpatient settings. There is no mention in the data review of use of the EHR as a factor considered in these studies.

Businesses and organizations experience turnover throughout the year and generally involving a small number of employees at any one time. The economics literature has identified several factors that predict the effect of turnover on performance including the nature of the task, the degree of hierarchy in the organization, whether turnover is voluntary and predictable and absolute amount of turnover. Teaching hospitals are unusual in that we experience "cohort turnover". Young et al make the point that this is more comparable to military units in combat and new political administrations than to business organizations. Cohort turnover leads to decreased productivity due to disruption in operations and loss of embedded knowledge held by the more experienced workers who leave. Each year in July up to 100000 house staff across the US change roles along with about 32000 in Europe. Concerns that this large cohort turnover may create increased risk for errors in patient care prompted discussion of the "August killing season" in the UK and the "July phenomenon or "July effect" in the United States.

In their paper "A July spike in fatal medication errors: a possible effect of new medical residents." Phillips and colleagues examined more than 62 million death certificates from the years 1979 to 2006 focusing on medication errors (n = 244,388). They looked for the July Effect by comparing the observed number of deaths in July with the number expected, along with those occurring inside versus outside medical institutions with teaching hospitals. In counties containing teaching hospitals, fatal medication errors spiked by 10% in July and in no other month. (Fig. 7) In contrast, there was no July spike in counties without teaching hospitals. They also noted that with greater the concentration of teaching hospitals in a region the July spike was larger. These findings held only for medication errors, not for other causes of death.

Fig. 7



Mortality and efficiency of care tend to worsen in July but the literature to date does not describe the contributing causes or suggest guidance to ameliorate the risk proposed by this "cohort turnover". The "July effect" encompasses both a decrease in the clinical experience of the physicians in the system and the number of physicians who have experience within a given healthcare system. One study found that undesirable events occurred just as commonly in fifth-year trainees who were new to the hospital as in interns suggesting that unfamiliarity with the work environment is a significant factor that decreases quality of care.[105] Others have pointed out a diminished capacity for teamwork when new physicians are introduced into a ward or unit.[106]

There is less literature about the impact of trainee turnover in the ambulatory setting, but some authors suggest there is high-risk associated with patient handoffs when residents graduate. [107]

In 2010 the ACGME proposed increased supervision, limited duty hours for the most junior trainees and graded responsibility based on acquisition of competence as a potential solution for these types of concerns. The great experiment began this July 1, and the outcome is uncertain. Thus far there is no good evidence that discerns to what extent worsened mortality and efficiency are due to clinical inexperience, inadequate supervision of trainees and loss of system knowledge due to cohort turnover. I believe that the EHR is a significant component of system knowledge. Academic medical centers will do well to standardize their EHRs in the areas of CDS, CPOE and other components that are likely to attenuate harm to patients when thoughtfully deployed.

Current Efforts to optimize the benefits of HITECH

The US Department of Health and Human Services launched a "Partnership for Patients: Better Care, Lower Costs" by committing $1 billion dollars to improving patient safety.[80] At the same time EHR vendors and health care organizations are focusing efforts on meeting the standards for meaningful use of EHR systems as required by DHHS for incentive payments. The Joint Commission issues annual National Patient Safety Goals which outline the highest priorities for quality care. Ideally the NPSG should be incorporated into the EHR certification process so that vendors specifically engineer solutions that will help health care organizations meet the National Patient Safety Goals.[108] Several of the 2011 NPSG priorities for hospital quality improvement address medication safety. They are: patient identification, staff communication, medication labeling, medication reconciliation and medication interactions. EHRs with CPOE, CDS and BCMA if designed, developed, implemented and used correctly can play critical roles in addressing the 2011 safety goals.

The EHR should highlight patients or medications with look-alike or sound-alike names, possibly by integrating photographs of the patient or the medication into the MAR.[109] EHRs can reinforce staff communication by automatically notifying responsible clinicians about abnormal test results and achieve closed loop communication by requiring response or acknowledgement within a certain time frame that is predicated on severity. CDS and BCMA functionality of an EHR should be integral in the medication order verification administration work flow. Well-designed CDS can help ensure appropriate dosing, monitoring and consideration of important drug interactions. In the operating room sterile containers can be prepped before surgery with accurate medication information including bar codes for preventing medication identification and concentration errors.

Medication reconciliation is the most complex of the processes targeted by the NPSGs. Meaningful use criteria should be aggressively aligned with this goal in particular. The most important innovations will be improved interoperability or medication lists across organizations and EHRs. Information for interchange services will facilitate the availability of updated prescription information that will improve the quality of the human verification process that must occur at each site of care.[83,110]

Studies of ADEs and medication errors initially were designed to determine the rates of these events and the best methods for detecting them.[111] Techniques for measurement and detection such as administrative review of discharge codes and diagnostic codes, medical record review using "trigger events" and various reporting methods (voluntary, prompted) were investigated as strategies.[112-116] Unfortunately, the more time consuming method of record review demonstrated superior sensitivity and specificity. Attempts to automate the process without the benefit of clinical insight lead to high rates of false event detection.[115] In a study of one commercially available system only 38% of alerts were true events.[20]

A recent publication by David Classen and colleagues demonstrated that the "global trigger tool" developed at the Institute for Healthcare Improvement produced a higher PPV and detected more serious events than other methods of adverse event detection methods.[5,117] They studied hospitals with electronic health records in their review. In its current form the global trigger tool still requires manual record review, but full automation of the tool has already been accomplished at Kaiser Permanente.[118] Now data mining tools including neural networks, decision trees and decision rules may be useful in manipulating the huge amounts of information in large electronic databases. With refinement, data mining will increase the positive predictive value of ADE algorithms and the incorporation of real time event monitoring systems to alert clinicians to suspicious circumstances and perhaps contribute to our drug safety surveillance.[8,119-121]

HIT implementations are opportunities to review existing workflow processes and make sure that all are effective and up to date and identify modification that need to be made to the off-the-shelf HIT products. Some processes will need to undergo "system apoptosis".[45] The roll out may blur role distinctions among traditional role lines such as those of clinicians and information technology providers and administrators. It is necessary to balance system standardization with flexibility to allow customization when appropriate for clinical workflow and HIT users' preferences. Sittig recommended measures to assess system availability, benefits and potential hazards, while Campbell et al addressed the pervasive problem of system downtimes.[30]

The biggest problem that remains is ineffective implementation of tools already shown to help improve medication safety. Current systems suffer from problems of both sensitivity (inability to detect errors) and specificity (over-alerting about unimportant issues). To make major advances in medication safety it is insufficient to just have technology based solutions. Process redesign that considers how the technology is used in the workflow of delivery of care is critical and requires iterative refinement.[122]

Is HIT worth it?

Do the negative consequences of implementing HIT in hospitals overwhelm or wash out the positive ones, as some have suggested?[16,26] Studies like Amarasingham's support the merit of HIT implementation. The question of whether the benefits in hospitals using vendor applications will be as good as those seen in a few hospitals that have developed homegrown systems remains. More analyses should be done, and they are likely to be helpful in developing policy going forward.[15] To date, system-wide learning has been limited by an inadequate feedback loop funneling data on care and outcomes back to clinicians.[13,123] A Health IT Expert Panel (HITEP) was convened by the National Quality Forum to prioritize data types most often used in quality assessment. They suggested the critical importance of easy capture in certified EHRs of medications, allergies, side effects, lab test results and a problem list.[124]

In Horsky's commentary on the interaction of complex technology and user cognition he points out that the analogy between healthcare and aviation is not accurate. He makes the point that a clinicians' decision making is more similar to that of a fire brigade captain. In the clinical domain as during a firefight, decisions are sometimes made with little or unreliable evidence; and changing circumstances can require quick adjustments in the planning of action. In the practice of clinical medicine tasks are often context-dependent, nonlinear, interrupted and dependent on clear and timely communication.[125] Those who have emphasized the unintended consequences of HIT have made many valuable points about the importance of evaluating any new technology after implementation and making multiple changes to it—points that are all too often ignored.

The future of HIT?

At the Center for Clinical Innovations at Parkland Health and Hospital Systems, Ruben Amarasingham is doing work to optimize use of the tremendous amount of data in the EHR. His efforts include a nascent project to develop a Health Information Exchange Portal with other organizations who provide care to the Parkland

patients thus providing effective transmission of important historical information and accurate medication lists among entities. The informatics tools he is creating could mine both EHR data and clinical text using natural language understanding and allow the potential to perform pharmacovigilance and determine which patients may be suffering an adverse drug event or medication error during the hospitalization.

Conclusions

Fiscal considerations, policies and regulations all govern the design, implementation and use of HIT. ARRA promises incentives for acquiring and implementing HER systems, but these efforts and the pace of the implementation across large numbers of providers and organizations is not without hazard. The insidious risks of HIT are found in the nature of clinical work itself, and in the human factors surrounding the people who do that work. We have to deal daily with the resource and time constraints involved in patient care and, of necessity, have become masters of the workaround. Workarounds that improve patient value, safety and efficiency are useful and commendable; they should be integrated into our HIT systems. Those that circumvent safety features solely in the interest of saving time are an ever present danger. We should move forward with a cognizance of unintended consequences that may arise from the rapid market growth of HIT vendors and software that tend to be unregulated and potentially not evidence-based. Our overarching goal should be to evolve the care culture and to refine tools like the EHR to our patient's best advantage.

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