The Joint Commission

Sentinel Event Alert

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Safely implementing health information and converging technologies

As health information technology (HIT) and "converging technologies"—the interrelationship between medical devices and HIT—are increasingly adopted by health care organizations,1,2 users must be mindful of the safety risks and preventable adverse events that these implementations can create or perpetuate. Technology-related adverse events can be associated with all components of a comprehensive technology system and may involve errors of either commission or omission. These unintended adverse events typically stem from human-machine interfaces or organization/system design.3 The overall safety and effectiveness of technology in health care ultimately depend on its human users, ideally working in close concert with properly designed and installed electronic systems. Any form of technology may adversely affect the quality and safety of care if it is designed or implemented improperly or is misinterpreted. Not only must the technology or device be designed to be safe, it must also be operated safely within a safe workflow process.

Previous *Sentinel Event Alerts* have addressed specific technology-related safety issues: infusion pumps (issue 15), ventilators (issue 25), patient-controlled analgesia (issue 33), tubing misconnections (issue 36) and MRI (magnetic resonance imaging) (issue 38). In addition, technology-related adverse events in health care can involve, but are not limited to, computerized provider order entry (CPOE), automated dispensing cabinets (ADCs), electronic medical records (EMRs), clinical decision support (CDS), bar coding or RFID (radio frequency identification), virus threats to information security, CT (computed axial tomography) scanning technology, and the loss of patient data. According to a 2007 study conducted by the American Society of Health-System Pharmacists, approximately 83 percent of hospitals in the U.S. have ADCs, 44 percent have smart pumps, 43 percent have EMRs, 24 percent have bar code medication administration, 18 percent have CPOE, 13 percent have intelligent medication carousel systems for pharmacy inventory picking, and 10 percent have robots for unit-dose packaging and dispensing.1 There is extensive literature available about the uses and potential risks of these technologies. This *Alert* focuses on how to safely implement HIT and converging health technologies.

There is a dearth of data on the incidence of adverse events directly caused by HIT overall. The United States Pharmacopeia MEDMARX database includes 176,409 medication error records for 2006, of which 1.25 percent resulted in harm. Of those medication error records, 43,372, or approximately 25 percent, involved some aspect of computer technology as at least one cause of the error. Most of the harmful technology-related errors involved mislabeled barcodes on medications (5 percent), information management systems (2 percent), and unclear or confusing computer screen displays (1.5 percent). The remaining harmful errors were related to dispensing devices, computer software, failure to scan barcodes, computer entry (other than CPOE), CPOE, and overrides of barcode warnings. (See the sidebar for a breakdown of these data.) In addition, a 2007 survey4 conducted by the Institute for Safe Medication Practices (ISMP) showed that safety improvements with ADCs have not kept up with the growing popularity of the technology. According to the 800 respondents to the survey, 94 percent are using ADCs and of those, 56 percent are using the technology as the primary means of drug distribution.4,5,6 ISMP recently released the first set of interdisciplinary guidelines to promote safety practices with ADCs.7

Contributing factors

Inadequate technology planning can result in poor product selection, a solution that does not adapt well to the local clinical environment, or insufficient testing or training. Inadequacies include failing to include front-line clinicians in the planning process, to consider best practices, to consider the costs and resources needed for ongoing maintenance, or to consult product safety reviews or alerts or the previous experience of others. Implementing new clinical information systems can expose latent problems or flawed processes with existing manual systems; these problems should be identified and resolved before implementing the new system. An over-reliance on vendor advice, without the oversight of an objective third party (whether internal or external), also can lead to problems. "There's often an expectation that technology will reduce the need for resources, but that's not always true," says Bona Benjamin, BS Pharm, director of Medication-Use Quality Improvement, American Society of Health-System Pharmacists. Instead, technologies often shift staffing allocations, so there is not typically a decrease in staff.

Technology-related adverse events also happen when health care providers and leaders do not carefully consider the impact technology can have on care processes, workflow and safety. "You have to understand what the worker is going through – whether that worker is a nurse, a doctor, a pharmacist or whoever is using the technology. The science of the interplay between technology and humans or 'human factors' is important and often gets short shrift," says Ronald A. Paulus, M.D., chief technology and innovation officer, Geisinger Health System.

If not carefully planned and integrated into workflow processes, new technology systems can create new work, complicate workflow, or slow the speed at which clinicians carry out clinical documentation and ordering processes. Learning to use new technologies takes time and attention, sometimes placing strain on demanding schedules. The

USP MEDMARX Computer Technology-Related Harmful Errors (2006)

Cause	Number	%
Barcode, medication mislabeled	20	5
Information management system	1,176	2
Computer screen display unclear/ confusing	137	1.5
Dispensing device involved	3,181	1.3

resulting change to clinical practices and workflows can trigger uncertainty, resentment or other emotions that can affect the worker's ability to carry out complex physical and cognitive tasks.8 For example, through the use of clinical, role-based authorizations, CPOE systems also exert control over who may do what and when. While these constraints may lead to much needed role standardizations that reduce unnecessary clinical practice overlaps, they may also redistribute work in unexpected ways, causing confusion or frustration. Physicians may resent the need to enter orders into a computer. Nurses may insist that the physician enter orders into the CPOE system before an order will be carried out, or nurses may take over the task on behalf of the physician, increasing the potential for communication-related errors. Physicians have reported a sense of loss of professional autonomy when CPOE systems prevent them from ordering the types of tests or medications they prefer, or force them to comply with clinical guidelines they may not embrace, or limit their narrative flexibility through structured rather than free-text clinical documentation.8 Furthermore, clinicians may suffer "alert fatigue" from poorly implemented CPOE systems that generate excessive numbers of drug safety alerts. This may cause clinicians to ignore even important alerts and to override them, potentially impairing patient safety.9

Patient safety is also impaired by the failure to quickly fix technology when it becomes counterproductive,10,11 especially because unsolved problems engender dangerous workarounds.12 Additionally, safety is compromised when health care information systems are not integrated or updated consistently.10, 11,13,14,15,16,17,18 Systems not properly integrated are prone to data fragmentation because new data must be entered into more than one system. For example, when the CPOE system is not interfaced with the pharmacy system, each order must be printed manually and then electronically transcribed into the pharmacy system. Multiple networks can result in poor interoperability and increased costs.2 If data are not updated in the various systems, records become outdated, incomplete or inconsistent.

Barcode, failure to scan	114	<1
Computer entry (general, other than CPOE)	24,715	<1
CPOE	10,752	<1
Barcode, override warning	41	0
Total	43,372*	

* From a total of 176,409 medication error records.

Existing Joint Commission requirements
The Information Management chapter covers electronic information. With respect to patient safety and technology, organizations should pay particular attention to the following standards:

- IM.1.10 (IM.01.01.01*) addresses planning the management of information.
- IM.2.20 (IM.02.01.03*) requires the safeguarding of data and information against loss, destruction and tampering.
- IM.2.30 (IM.01.01.03*) requires a disaster recovery plan for information systems and the periodic testing of the plan to ensure its effectiveness.

Leadership standards LD.4.20 (LD.04.04.03*) and LD.4.40 (LD.04.04.05*) address designing new processes and establishing a safety program. In addition, since technology is prevalent in health care – from patient admission to the surgical suite to the ordering and administration of medication and the use of equipment and medical devices – any Joint Commission standard could potentially be tied to technology. Users should consider the use of any technology in relation to the standards and be aware of potential dangers to patients, as in any clinical situation.

Joint Commission suggested actions
Below are suggested actions to help prevent patient harm related to the implementation and use of HIT and converging technologies.

1. Examine workflow processes and procedures for risks and inefficiencies and resolve these issues prior to any technology implementation. Involving representatives of all disciplines—whether they be clinical, clerical or technical—will help in the examination and resolution of these issues.
2. Actively involve clinicians and staff who will ultimately use or be affected by the technology, along with IT staff with strong clinical experience, in the planning, selection, design, reassessment and ongoing quality improvement of technology solutions, including the system selection process. Involve a pharmacist in the planning and implementation of any technology that involves medication.
3. Assess your organization's technology needs beforehand (e.g., supporting infrastructure; communication of admissions, discharges, transfers, etc.). Investigate how best to meet those needs by requiring IT staff to interact with users outside their own facility to learn about real world capabilities of potential systems, including those of various vendors; conduct field trips; and look at integrated systems (to minimize reliance on interfaces between various vendor systems).
4. During the introduction of new technology, continuously monitor for problems and address any issues as quickly as possible, particularly problems obscured by workarounds or incomplete error reporting. During the early post-live phase, consider implementing an emergent issues desk staffed with project experts and champions to help rapidly resolve critical problems. Use interdisciplinary brainstorming methods for improving system quality and giving feedback to vendors.
5. Establish a training program for all types of clinicians and operations staff who will be using the technology and provide frequent refresher courses.
   Training should be appropriately designed for the local staff. Focus training on how the technology will benefit patients and staff, i.e. less inefficiency, fewer delays and less repeated work.12 Do not allow long delays between orientation and system implementation.
6. Develop and communicate policies delineating staff authorized and responsible for technology implementation, use, oversight, and safety review.
7. Prior to taking a technology live, ensure that all standardized order sets and guidelines are developed, tested on paper,

and approved by the Pharmacy and Therapeutics Committee (or institutional equivalent).

8. Develop a graduated system of safety alerts in the new technology that helps clinicians determine urgency and relevancy. Carefully review skipped or rejected alerts as important insight into clinical practice. Decide which alerts need to be hard stops when using the technology and provide appropriate supporting documentation.
9. Develop a system that mitigates potential harmful CPOE drug orders by requiring departmental or pharmacy review and sign off on orders that are created outside the usual parameters. Use the Pharmacy and Therapeutics Committee (or institutional equivalent) for oversight and approval of all electronic order sets and clinical decision support alerts. Assure proper nomenclature and printed label design, eliminate dangerous abbreviations and dose designations, and ensure MAR acceptance by nurses.
10. To improve safety, provide an environment that protects staff involved in data entry from undue distractions when using the technology.
11. After implementation, continually reassess and enhance safety effectiveness and error-detection capability, including the use of error tracking tools and the evaluation of near-miss events.19 Maximize the potential of the technology in order to maximize the safety benefits.
12. After implementation, continually monitor and report errors and near misses or close calls caused by technology through manual or automated surveillance techniques.19,20 Pursue system errors and multiple causations through the root cause analysis process11 or other forms of failure-mode analysis. Consider reporting significant issues to well recognized external reporting systems.
13. Re-evaluate the applicability of security and confidentiality protocols as more medical devices interface with the IT network. Reassess HIPAA compliance on a periodic basis to ensure that the addition of medical devices to your IT network and the growing responsibilities of the IT department haven't introduced new security and compliance risks.2

Contributing to these actions for successfully implementing and maintaining new technologies in support of patient safety were: Bona Benjamin, BS Pharm, and Karl F. Gumpper, BS Pharm, American Society of Health-System Pharmacists; David C. Classen, M.D., CSC Consulting, Inc.; Donald Mon, Ph.D., American Health Information Management Association; Tony Montagnolo, M.S., and Ronni Solomon, J.D., ECRI Institute; Ronald A. Paulus, M.D., Geisinger Health System; and Patricia Wise, R.N., Healthcare Information and Management Systems Society.

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* The 2009 standards have been renumbered as part of the Standards Improvement Initiative.