Health IT and Maryland Adverse Events

In 2009, the Centers for Medicare and Medicaid Services (CMS) started an incentive program to encourage hospitals to implement health information technology. The program also includes providers and provider groups, referred to as Eligible Professionals (EPs). This program, called Health Information Technology for Economic and Clinical Health (HITECH) provides financial incentives for hospitals and providers to meet milestone in the implementation of health information technology (HIT). Hospitals and EPs must certify that their HIT meets program content guidelines called "meaningful use," meaning that the HIT meets objectives related to clinical quality measures for outcomes, clinical processes, patient safety, efficient use of resources, and other National Quality Strategy Domains.

The HITECH program, along with the inexorable march of technology, is driving the rapid rate of implementation of new electronic health records (EHR) in hospitals and other health care settings. These systems may function exactly as pro-grammed, yet cause unintended and unanticipated consequences, both for workflow and for patient care. These unintended consequences may affect clinician perceptions of the utility of the HIT systems by changing workflow in undesirable ways by requiring more precision in data entry; requiring more steps to complete tasks; eliminating the nurse and clerk double checks on orders with computerized provider order entry (CPOE); clinician resistance to the systems based on frustration and manifested by entering most information in the miscellaneous or free-text sections rather than in the designated areas; and assuming someone, or everyone, will read what's been entered, thus eliminating a lot of the usual face-to-face communication and creating an "illusion of communication." These practices all have real world consequences for patient care.

From March 2013 through March 2014, the Office of Health Care Quality received eight adverse event reports from Maryland hospitals which mention computer systems or health information technology (HIT) as causative or contributing factors. The Office of Health Care Quality Patient Safety unit does not have a separate category for HIT-related events, so we rely on the anecdotal reports of adverse events and the submitted root cause analyses to identify those events in which the outcomes were affected by HIT.

In Maryland, five of the eight reported IT-mediated adverse events reported were fatal. While the IT or EHR system problem was not the proximal cause of any of the deaths, the EHR contributed to the adverse event that was ultimately the cause of patient's death. For instance:

A patient was admitted with what was thought to be minor smoke inhalation from a small fire at home. Three days after admission, the patient became hypoxic and had a rapid heart rate with a fever. The physician ordered telemetry (remote physiologic monitoring) for the patient via CPOE but did not tell the nurse, apparently believing she would see the order in the EHR. The hospital had recently implemented an early warning system that would analyze the trend of a patient's vital signs in the EHR and alert the staff when intervention was likely to be needed. Even though this system was supposed to spur action for patients that might otherwise "look OK," in this case, because the patient looked OK, the staff and physicians ignored the early warning system. After 24 hours with no definitive treatment, the patient arrested and died.

CMS recommends the use of an Interactive Sociotechnical Analysis (ISTA) framework to help identify and understand unintended consequences of EHR implementation. ISTA has four key elements:

1. The EHR (as designed), or how the developers envision the EHR would be used.

2. The work environment. The organization's policies, priorities, and hierarchies.

3. The technical and physical infrastructure. Other IT, medical devices, building design and layout.

4. The EHR as used. The outcome of the inter-actions between the EHR and the work environment.

Along with an illusion of communication, the adverse event above is an example of ISTA number four. EHRs usually have alerts to aid in clinical decision making also called clinical decision support services (CDSS). In this case, the number and frequency of the alerts caused "alert fatigue" in several clinicians. The following adverse event is an example of ISTA number one. The EHR functioned exactly as designed with a pre-loaded order set based on the most common expected outcome of knee replacement surgery: Discharge home on post-op day three. Unfortunately, this was not a typical patient.

The patient was placed on an injected anticoagulation agent for deep vein thrombosis (DVT) prophylaxis after undergoing a routine joint replacement. Because of previous heart surgery, the patient was already taking two platelet aggregation inhibitors, which were restarted after surgery. The routine post-op joint replacement order set contained in the EHR called for checking the anticoagulation status of patients for two days post-surgery. This patient suffered some respiratory-related complications and was not discharged on the third post-op day as expected. Even though the patient was seen by multiple specialists, neither they, the pharmacists that filled the orders, nor the nurses that administered the drugs noted that he was on anticoagulation without an order for blood tests to monitor his anticoagulation status. On the ninth day post-surgery, the patient exhibited profuse gastrointestinal bleeding and arrested and died.

In an example of the ISTA element number two, the physician's office for an elderly patient called the hospital to schedule a non-invasive kidney ultrasound. Instead of being routed to the ultrasound department, the call was sent to a clerk in the interventional radiology (IR) department. The IR clerk did not have kidney ultrasound listed in the computer as one of the choices for procedures done in the department, so he entered a kidney biopsy for the patient and wrote "ultrasound only" in the free text part of the order. The scheduler looked at the order, and, knowing that biopsies are always done with a CT scan, scheduled the patient for a CT-guided kidney biopsy. When the patient arrived at the hospital, the radiologist got informed consent for the kidney biopsy and performed the procedure. Since the priority was to schedule patients for procedures as quickly as possible, the clerk and the scheduler were used to working around the set functions of their HIT system because they perceived the system to be outdated and inflexible.

Even if your HIT system was flawlessly planned and implemented, problems can and do arise after the "go-live' date. CMS recommends the following practices for monitoring and avoiding unintended consequences:

1. Involve clinicians and staff in on-going monitoring and quality improvement of your HIT systems. If your system allows for the use of cut and paste for clinical documentation, audit the total usage and appropriateness. Monitor the use of paper work-arounds to the automated controls and limits inherent in the electronic system.

2. Continuously monitor for problems and address as soon as possible. Use an Issues Log to track what the problem was, and when and where it occurred. Be especially vigilant for problems obscured by work-arounds or incomplete error reporting.
3. Use interdisciplinary brainstorming for quality improvement and providing feedback to vendors.
4. Review all skipped or rejected alerts in the clinical decision support system.
5. Require departmental or pharmacy sign-off of orders outside the usual parameters.
6. Protect data entry personnel from undue distractions.
7. Continually reassess and enhance safety effectiveness and error detection capability, including the use of error-detection tools and the evaluation of near-miss events.
8. Use manual or automated surveillance techniques to report errors and close calls caused by HIT.
9. Perform RCAs and FMEA on serious system errors.
10. In addition to problems identified after initial implementation, every upgrade or update to the system will require additional training and trouble-shooting.

Health IT systems have already changed the way we deliver care. Quality assurance and patient safety systems need to adapt as well in order to maximize the benefits and minimize the risks of HIT. Since we cannot make HIT completely fool-proof, we have to rely on skills that much of the patient safety literature says do not consistently work well: human memory and vigilance. Greater automation and standardization will make healthcare delivery more efficient and possibly more effective, but the basics concepts and skills inherent in assessing and treating patients cannot be lost in the rush to adopt HIT. With vigilance, we can have both population-based care and patient-centric, individualized care, especially for those patients who fall outside the average parameters.

[1] http://www.healthit.gov/providers-professionals

[2] http://www.healthit.gov/unintended-consequences/

[3] http://www.healthit.gov/unintended-consequences/content/why

[4] http://www.healthit.gov/unintended-consequences/current-ehr-users.html