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## Health Information Technology

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# FORUM

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# HITs and Misses

by Luke Sato, MD

Dr. Sato is Chief Medical Officer for CRICO/RMF.

The total number of malpractice cases we see during each year is miniscule compared to the overall activity of health care being delivered during the same time period. Health information technology (HIT) systems are key to reducing opportunities for medical errors—and they are continuously increasing efficiency, reducing risk, and keeping malpractice frequency low.<sup>1</sup> Nonetheless, the errors that do prompt malpractice claims and suits provide us with a unique view into the mechanics and processes of how health care is being delivered...and where systems break down. Thus, some malpractice cases can be considered as Health IT use-case scenarios: examples of where implementation of select IT solutions could have prevented a medical error and impacted the quality and safety of care being delivered at that time. These are particularly evident in two major categories of concern:

1. Cases stemming from a lack of decision-making where an individual clinician's knowledge and judgment comes into play. In other words, cases which could have been mitigated if the providers had access to systems that assisted them in making the right decision.

2. Cases with a lack of follow-up and communication—after the provider made the right decision. In these cases, we see a process that fails the provider by not carrying out his or her intended actions, thereby allowing important steps to be missed.

The holy grail of health care's technical revolution is finding HIT solutions that guide clinicians through logical and evidence-based decision making, and then ensure that providers and patients follow the appropriate steps to close the loop for optimal diagnosis and treatment. The quest began several decades ago; our *Forum* contributors offer expert insight into where we are now, and where we are headed. ■

Note

<sup>1</sup> In the CRICO system, the number of malpractice cases filed averaged 2.7 per 100 insured physicians over the past 10 years. The rates for each of the most recent five years, were all below that average. In 2007, the rate was 2.2 per 100 insured physicians.



Decision Making Related Cases		
Process of care step	Contributing factors	Average total incurred*
Decision support (N=444)	<ul style="list-style-type: none"> <li>■ inadequate assessment</li> <li>■ narrow diagnostic focus</li> <li>■ delay/failure in ordering diagnostic test</li> <li>■ insufficient documentation of history</li> </ul>	\$673,000
Medication prescribing (N=67)	<ul style="list-style-type: none"> <li>■ incorrect ordering of medication, drug, dose, route</li> <li>■ incorrect administration of medication drug, dose, route</li> <li>■ selecting wrong medication for the specific condition</li> </ul>	\$479,000
Follow-through Related Cases		
Process of care step	Contributing factors	Average total incurred*
Test result management (N=214)	<ul style="list-style-type: none"> <li>■ failure/delay in scheduling/performing tests</li> <li>■ failure/delay in reporting findings</li> <li>■ failure to rule out or misinterpretation of test results</li> </ul>	\$830,000
Referral management (N=215)	<ul style="list-style-type: none"> <li>■ failure/delay in obtaining consult/referral</li> <li>■ failure to identify provider for follow up</li> <li>■ failure in patient follow up</li> <li>■ insufficient/lack of documentation on follow-up efforts</li> </ul>	\$777,000
Handoffs and signouts (N=266)	<ul style="list-style-type: none"> <li>■ communication among providers; between patient/family and providers</li> <li>■ supervision issues</li> <li>■ failure to identify the provider</li> </ul>	\$679,000

\*Aggregate of expenses, reserves, and payments on open and closed cases asserted 1/1/03–5/2/08.

# CRICO Medical Malpractice Cases Identifying Opportunities for HIT System Solutions

by Deborah LaValley, BSN, RN, CPHQ

Ms. LaValley is a Program Director for Loss Prevention and Patient Safety for CRICO/RMF.

From the medical malpractice perspective, it is often apparent how HIT systems might enhance patient safety and prevent the recurrence of breakdowns that led to a case being asserted. The following examples from suits filed against CRICO-insured providers highlight that point.

## Case 1

A 40-year-old female with a history significant for obesity and smoking was seen for symptoms of fatigue and a skin rash. Laboratory tests indicated that her blood count and platelets were normal, but that her blood sugar was elevated at 843 (nl=65-110). She was diagnosed with Type II Diabetes Mellitus and placed on an oral antidiabetic medication.

Over the next five months, the patient was seen multiple times for various complaints (continued fatigue, thirst, rectal bleeding, and abdominal pain). An abdominal ultrasound revealed an enlarged liver consistent with fatty infiltrates; her liver enzymes were also slightly elevated. A rectal exam was deferred during a gastroenterology consult secondary to menses; stool cards were given but never returned. Her sedimentation rate was found to be elevated; her EKG was slightly abnormal (non-specific T wave changes) but a follow-up echocardiogram/stress test was normal.

Four months later, the patient saw her PCP for the sudden onset of a rash and was given Medrol and Atarax. Three weeks after that, she returned for lab testing. Her results were available within two days, but they were not reviewed by her PCP for an additional week. Those results included a platelet count of 59 (nl=150-450)—a drop from 302 (the previous year); continued abnormal LFTs; and an elevated HgA1c (10.8). The physician documented “labs awful.”

At an appointment four days later, the patient admitted to not following her diet or checking her blood sugars. She continued to complain of skin problems, was diagnosed with recurrent sebaceous cysts, and was prescribed antibiotics. Glucophage was also prescribed and she was encouraged to check her blood sugars and see the dietician. She was also instructed to discontinue any Aspirin and Motrin secondary to her decreased platelet count. She was told to return in two weeks.

Within two days the patient again developed abdominal pain, followed several days later with feelings of confusion and slurred speech. She was taken to her local ED. Her lab results revealed a low hematocrit (16.3), platelets=8, and ABGs, LFTs, electrolytes, and blood sugar also abnormal. A head CT showed no sign of an acute bleed.

Within three hours, the patient suffered a grand mal seizure. She was intubated and given two units of blood. Her heart rate (120-140) and temperature (101.6) were elevated and she was

transferred to a tertiary hospital. Lab work revealed increased multiple schistocytes, diagnostic of thrombotic thrombocytopenic purpura (TTP) a rare, life-threatening disease.<sup>1</sup> Within less than one hour of her transfer, the patient had a cardiac arrest and died.

The case filed by the patient’s estate, alleging that her PCP failed to diagnose TTP, was settled for more than \$1 million.

## Key Lessons

- Systems that allow too much time to pass before physicians receive abnormal test results put patients at risk for delayed diagnosis and treatment.
- Information not in the medical record is often more troublesome than what is recorded. Include your diagnostic rationale, especially for cases in which the medical record might suggest another course was overlooked (the physician documents that the lab results are “awful” but doesn’t explain what he thinks their significance is or what differential diagnoses he is considering). A claim of negligence may be considered defensible if the documentation supports the clinician’s decision-making process.
- Proper test reporting is an essential part of a good practice. Best practices for physician offices include systems that allow them to reconcile outstanding labs and referrals, to ensure that the provider is aware of the results and that appropriate action is taken. Certain EMR systems can provide such things as best practice alerts and chronic disease management functionality; can track delinquencies within the medical records, and generate follow-up messages/alerts.

## Case 2

An 80-year-old male with a history significant for hypertension, coronary artery disease, a myocardial infarction, and mild chronic renal insufficiency, was admitted to the hospital for a revision of a recent total knee replacement secondary to continued pain. He underwent the surgery without complications and went from the operating room to the post-anesthesia care unit—then into a four-patient room on the orthopedic unit.

Two days post-operatively, the patient was given two medications and was told by the nurse that she was calling the pharmacy for a third medication which, she said, “was missing.” While she waited for the patient’s medication to arrive from the pharmacy, the nurse proceeded to give the other patients in his room their medications; however, one declined his medications (until “later”).

About 30 minutes later, the 80-year-old patient’s son went to the nurse informing her that his father was not feeling well; he

was nauseous and having dry heaves. At about the same time, the pharmacy called and told the nurse that it had no order for the medication she called about earlier. At this point, the nurse realized she had given this patient the wrong medications—his roommate’s medications—in error.

Once the mistake was discovered, the patient’s vital signs were taken as well as an EKG, which revealed an acute episode of AV block with a very slow heart rate (~ 40 beats / minute). He was transferred to the ICU and treated with IV fluids, IV Dopamine, IV Calcium, and IV Zofran. He responded well and within 24 hours was back to his baseline.

A claim alleging administration of wrong medications was settled in the low range.

#### *Key Lessons*

The frequency of medication errors can be significantly reduced when physicians and nurses always check to see that they have the right patient, right medication, right dosage, right time, and right route. HIT has come a long way in assisting clinicians in the safe administration of medications to their patients. For instance the use of:

- Computerized Physician Order Entry helps to minimize the ambiguity of handwritten orders (e.g., inappropriate drugs, dosages, or routes), alerting providers of potential contraindications, e.g., drug allergies or interactions.
- Automated medication dispensing systems, accessible on the nursing units, allow nurses to open only the drawer containing a specific patient’s medications.
- Barcoding helps ensure that the right patient receives the right medication and the right dosage by scanning the bar code on the patient’s ID wristband and the bar code on the medication container. Once scanned, the information also gets transmitted electronically into the patient’s electronic medical record.
- Despite numerous systems designed to prevent medication errors, they can still occur, sometimes because the physician or nurse relies on the system too much. Even the best systems work better when users keep the human element in mind.

#### **Case 3**

A 38-year-old woman noted a lump in her right breast while showering and, although she had no family history of breast cancer, was alarmed by her finding. She immediately called her physician and was able to be seen the same day. Upon examination, the physician was unable to palpate any lumps and told the patient that the exam was normal. Seeing that the patient was almost 40 years old, the physician did recommend a mammogram.

The patient made arrangements to have the baseline mammogram four months later. On the Radiology Department’s routine questionnaire she was asked to complete, the patient chose not to indicate any history of a lump in her breast (as her physician hadn’t been able to feel one). The results of the mammogram revealed only dense breast tissue, no focal abnormalities or other findings suggestive of malignancy.

Six months later, the patient went back to her physician, suspecting she might be pregnant again. An internal exam and blood tests indicated she was not pregnant. During this office visit, there was no mention or examination of her breasts documented.

Six months after that appointment, the patient returned to her physician for her annual exam. This time the physician noted changes and thickening within the patient’s right breast and recommended she see a surgeon. Following her visit to the surgeon, the patient underwent an ultrasound, a diagnostic mammogram, a breast biopsy, an MRI, and lab work. The results revealed a 2.5cm mass with 8/16 lymph nodes positive for cancer. The patient underwent a radical mastectomy, radiation to her chest wall, chemotherapy, a bilateral oophorectomy, and treatment for multiple compression fractures. Her prognosis remains poor.

A lawsuit alleging that a delayed diagnosis of breast cancer resulted in a poor prognosis was settled in the high range.

#### *Key Lesson*

Failure to diagnose breast cancer affects health care providers across a spectrum of specialties. To reduce the likelihood of such events, a task force of breast care specialists has developed, and regularly updates, the *CRICO/RMF Breast Care Management Algorithm*. The algorithm is designed to help providers choose the most appropriate diagnostic tools available. Having such decision support tools embedded within physician offices’ electronic medical records system makes for a quick reference. In this particular case, had the algorithm been used, a diagnostic mammogram and an ultrasound might have been ordered initially rather than a baseline mammogram. ■

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#### Notes

- 1 TTP is characterized by a widespread aggregation of platelets throughout the body, neurological dysfunction, and renal insufficiency...resulting in blood clots in small blood vessels throughout the body.

# Pizza, Netflix, and Healthcare Information Technology: An Interview with David Bates, MD

by Jock Hoffman and Deborah LaValley, BSN, RN, CPHQ

Jock Hoffman is Editor of Forum. Deborah LaValley is Issue Editor for Forum and a Program Director in Loss Prevention and Patient Safety for CRICO/RMF.

**D**r. David Bates is Chief of the Division of General Internal Medicine at Brigham and Women's Hospital (BWH) in Boston, a Professor of Medicine at Harvard Medical School, and a Professor of Health Policy and Management at the Harvard School of Public Health (HSPH), where he co-directs the Program in Clinical Effectiveness. Bates also serves as Medical Director of Clinical and Quality Analysis for Partner's Healthcare Systems, is chairman of the Board of the American Medical Informatics Association, and serves as external program lead for research for the World Health Organization's Global Alliance for Patient Safety. Bates recently sat down with the editors of *Forum* to discuss the present (and future) of health care information technology (HIT) systems.

**Forum:** When physicians hear "health information systems," what do they think that is?

**Bates:** Most think of the computer systems that they interact with, but what people use is quite variable and health information systems are quite a bit broader than that, extending to things like pumps and monitoring systems. Electronic records generally include most test results, but most organizations do not yet have computer order entry. In the outpatient setting, practices are increasingly converting to electronic records, but many use these applications at a relatively low level, and another large fraction are still paper-based. So, what those physicians think of when they hear "health information systems" is quite variable.

**Forum:** What do patients expect in terms of health care information systems?

**Bates:** Patients think we are much more computerized than we actually are. Many assume that all their health information is computerized and accessible to providers in a variety of settings, even across entities. After all, when I call and order a pizza from my local pizza place, they know what my telephone number is, they have my cell phone number, and they even know what kind of pizza I have ordered previously. We are a long way from that level of sophistication in health care.

**Forum:** Your preference for pepperoni pizza is certainly personal. What kind of illnesses you have, medications you are on, is much more personal. Does the sensitivity of the information inhibit the health care industry?

**Bates:** To a degree, definitely, but a bigger factor is that health care is a fragmented industry and has not invested very much in health information technology. Health care entities in the United States spend, on average, about

2.8 percent of gross revenues on HIT; the average in other information intensive industries (for example, banking) is in the 7–10 percent range. That's a large part of the reason things are the way they are.

**Forum:** Are institutions justified in holding back money for systems they fear won't be around in five years?

**Bates:** Absolutely, that is a real concern, with multiple facets. Many institutions have been burned on big investments for systems that didn't work. The transience of vendors is also an important issue. Currently, there are several hundred outpatient HIT vendors, and there is going to be some weeding out that will occur. Nobody wants to pick the wrong one.

Recently, an entity called the Certification Commission for Healthcare Information Technology (CCHIT) was set up to certify vendors—I've served as a commissioner for this organization. CCHIT certification will assure that certain components are included in an electronic medical record. One of the keys is that CCHIT-certified vendors are required to represent certain data in standard electronic formats. If that actually becomes the norm, then moving data around (e.g., outpatient to inpatient) will be much easier than it is today. Establishment of CCHIT has been an enormously positive step, but there are still issues. One is that more than 75 outpatient vendors have already been certified—that's more than will be operating in a mature marketplace. So, for a while at least, some organizations may still be picking the wrong system, even if they select one that is certified.

**Forum:** Where is the United States today in terms of adoption of electronic medical records, EMRs?

**Bates:** As of 2005, EMRs were used in 24 percent of outpatient settings, nationally, but a recent paper in the *New England Journal of Medicine* suggested that only a few percent are using records that include good decision support. In Massachusetts, about half the outpatient providers are now using them. The proportion of hospitals using computerized physician order entry (CPOE) is in the 15–25 percent range. Nonetheless, even the hospitals using CPOE still don't have physicians entering all the orders, which means they don't get many of the benefits. The orders are being entered electronically, but only after the doctor has written them down on paper and then a secretary enters them.

**Forum:** What are some of the frustrations or the difficulties getting providers to accept HIT systems?

**Bates:** Providers do frequently have a hard time when they make the conversion from paper to electronic, but after people have made the conversion, essentially nobody wants to go back. Another is that using these systems requires workflow change, and this can be hard for providers.

**Forum:** Is it hard to use trial and error when implementing IT systems in medical settings?

**Bates:** It is, but we need to move forward, and learn from the experiences of others who have gone ahead. Some are waiting for stronger evidence, but we just are not going to get controlled trials for lots of the things that we need (or want) to do. We would probably be better off using more trial and error, as long as patients aren't placed at risk.

**Forum:** Is the impact HIT systems have had on patient safety, so far, more positive than negative?

**Bates:** Yes, definitely based on the single-institution studies to date, although it is also clear that HIT systems can create new problems. In the broader marketplace, though, we don't know how much safety will improve with adoption of clinical information systems, but there is every reason to believe that it will be substantially better because so many decisions rely on providers having the right information about people at the right time. There also ought to be large cost benefits. One model projected that standardized and coded electronic health information exchange would save the U.S. health care system \$337 billion over a 10-year implementation period.

**Forum:** Are we training enough people in college and medical schools to be focused on implementing and developing these kinds of new systems?

**Bates:** There is a big gap there. We need many more providers of all types: nurses, pharmacists, physicians, and others who know more about health information technology. There is proposed legislation in Congress which would provide substantial support for training more health care professionals in health information technology.

**Forum:** Does that mean attracting people with an IT inclination into medicine, or attracting people with a health inclination into the technology side?

**Bates:** Both are important, and we need boundary crossers. For example, every hospital will want to have a few

physicians and nurses who are knowledgeable in both their specialty and in health care information technology. And we need people from the IT sector to learn more about health care.

**Forum:** Is the health care industry doing enough looking outside of health care settings for IT solutions?

**Bates:** Maybe not. Certainly, there is a lot that we could learn from entities like Netflix and eBay and Amazon, which do try and anticipate what you are going to need.

**Forum:** We know that new technology like EMRs and CPOE can create new errors. What are some of the risks?

**Bates:** One alarm comes from Ross Koppel, who published *Unintended Consequences of Computerized Physician Order Entry*. The area of unintended consequences must be addressed by all institutions. Any time you introduce some new technology it is important to find out what new errors you are creating and then to go back to re-engineer things and fix it to make sure that you eliminate as many of these as possible.

**Forum:** What types of errors did Koppel find?

**Bates:** A wide array, although several categories were especially important. One example is that there were many instances in which providers did not have key views of information they needed, like medication orders. Another was that there were many issues with transfers, which are quite complex. One thing that I found interesting was that we had experienced essentially every type of error described in his work at one time or another.

With respect to unintended consequences, another study which was more troubling (from the University of Pittsburgh) looked at children who were transported in for special care—often via helicopters or special ambulances. They found that the mortality rate in that population increased threefold after introduction of a commercial CPOE application that didn't allow order entry until the patient had actually entered the hospital and been logged into the system. Analysis suggested there were a number of reasons for this. In the past, they could write the orders while the child was in the helicopter on the way in and have everything ready when the child arrived.

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# HIT: The Risks of Sub-optimal Implementation and Management

by John Glaser, PhD, and Robert Damiano

Dr. Glaser is Vice President and CIO for Partners HealthCare. Mr. Damiano is Director, Internal Audit, for Partners HealthCare.

New technologies are neither inherently good nor inherently bad. Technologies can be implemented in ways that lead to advances and their implementation can also create problems. The automobile has greatly increased the efficiency and effectiveness of commerce and led to the creation of suburbs. Automobile use has also led to deaths on the highways and increased levels of pollution.

An important challenge for any technology is leveraging its strengths while, at the same time, reducing its ability to cause ill. New technologies create risks. If those risks are not managed, the net value of the technology can be diluted. Health information technology (HIT) is no different.

We no longer doubt the potential of HIT to improve the safety of patient care. Studies of computerized provider order entry (CPOE) have shown a significant reduction in serious inpatient medication errors.<sup>1</sup> Analyses of the impact of bar code-based electronic medication administration records have found a reduction in potential adverse drug events of 63 percent.<sup>2</sup> Test results reporting systems have the ability to reduce errors that can result from the inability to locate the patient chart. Error reporting systems enable provider leadership to assess safety problems and devise remedial clinical and management strategies.

Despite its power, however, there are two classes of risk factors that can reduce the ability of HIT to improve the safety of care: sub-optimal implementation and sub-optimal management.

## The Risk of Sub-Optimal Implementation

Health information technology does not possess magic powers. The implementation of an application such as CPOE does not automatically improve safety. Indeed, HIT can reduce the safety of care,<sup>3</sup> but new systems can sometimes create new risks: a study of the implementation of CPOE at Children's Hospital in Pittsburgh found an increase in unadjusted mortality from 2.8 percent before CPOE implementation to 6.6 percent after implementation.<sup>4</sup>

The ability of any HIT application to enable an organization to achieve its desired goals is dependent on a wide range of organizational, clinical, and management factors. Effective implementation of applications designed to improve the safety of patient care requires:

- a clear linkage between the application capabilities and the organization's patient safety goals;
- well-designed structure and processes for governing the organization's safety initiatives, including the implementation of desired applications;

- a culture that promotes safety and ensures the necessary trust, honesty, and absence of inappropriate punitive actions;
- the full engagement of the clinical staff who will use the application;
- a solid understanding of the process problems that lead to unsafe care and the design of system features needed to address those problems;
- well-executed training and support;
- mechanisms to ensure ongoing assessment of progress in improving safety with feedback loops that identify any needed changes in application capabilities, clinical and operational processes, and training; and
- integration of applications and system operations to ensure data continuity and integrity.

If these requirements are not in place, or are poorly executed, the organization risks a failure to achieve its safety goals. Moreover, a poor implementation can lead to a deterioration of safety—in effect the organization has taken sub-optimal processes and made them worse.

## The Risks of Sub-Optimal Management

Even when a desired HIT application has been successfully implemented, clinicians are using the system, and gains are seen in the safety of care, patient safety risks can result from sub-optimal management of the application. These risks generally are associated with an inadequately managed knowledge base or a misunderstood workflow.

An essential capability of HIT applications is the provision of clinical decision support (CDS). CDS logic can be used to alert a physician to drug-drug interactions associated with his or her medication order. The logic can inform a physician of a sudden deterioration in a patient's blood potassium levels and challenge the dosage entered in a smart infusion pump. CDS logic must be reviewed by clinical experts, its use monitored to ensure clinician conformance to the logic, and be periodically checked to ensure that logic remains current with medical practice. The failure to manage the knowledge base in CDS can lead to clinicians receiving out-of-date guidance or ignoring prompts and alerts.

When an HIT system's fit with the clinician's workflow is imperfect, users may not employ important features or use features inconsistently. For example, if the application's sup-

port of e-prescribing is substandard, physicians may continue to write large numbers of prescriptions using the pen and pad. Key metrics of effective use, e.g., completeness of the problem list and timeliness for notes completion, must be developed and monitored. If these metrics show unsatisfactory usage, the organization can begin to identify and implement needed changes in applications capabilities, training, or process re-engineering.

### Reducing Risks

It is not possible to reduce all risks associated with an HIT application, but those risks associated with sub-optimal implementation and sub-optimal management can be addressed. The steps that can be taken to tackle these risks, while requiring effort and resources, are well understood. Primarily, the acquisition and implementation of an application intended to improve the safety of care involves the organization developing strategies and processes to manage and mitigate the risks that the technology introduces. The organization's leadership needs to ensure that:

- governance over the implementation and management of the application are delineated and include appropriate checks and balances;
- risks are systematically identified and managed;
- risks are explicitly considered when evaluating new HIT applications;
- informed decisions are made regarding the risk/reward tradeoffs; and
- risk indicators are developed and monitored, and remedial steps taken as necessary.

Failure to understand and manage risks can lead to situations in which, after considerable effort and expense, the desired safety gains from HIT are incompletely realized or are offset by new problems. ■

#### References

- 1 Bates D, Leape L, Cullen D, et al. Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. *JAMA*. 1998;280:1311–16.
- 2 Poon E, Cina J, Churchill W, et al. Medication dispensing errors and potential adverse drug events before and after implementing bar code technology in the pharmacy. *Ann Int Med*. 2006;145(6):426–34.
- 3 Ash J, Berg M, Coiera E. Some unintended consequences of information technology in health care: The nature of patient care information system-related errors. *J Am Med Inf Assoc*. 2004;11(2):104–12.
- 4 Han Y, Carcillo J, Venkataraman S, et al. Unexpected increased mortality after implementation of a commercially sold computerized physician order entry system. *Pediatrics*. 2006;116 (6):1506–12.

### *Continued from page 5*

Another problem was due to a decision made, after they implemented CPOE, to locate all drugs—including the vasoactive drugs which have to be given relatively urgently—in the central pharmacy. At the same time, they implemented a rule that said that the pharmacy couldn't process medication orders until after they were activated, which took a while. (Again, before CPOE, the pharmacy didn't have to wait for this activation step.) At some point in setting up the CPOE system, that may have seemed like a good idea, but the net result was that it was taking people much, much longer. They found that they had to have two providers admit a child, one just to work on the computer and another one to be taking care of the patient. The result was substantial delays in care delivery. Clearly, it is possible to have serious adverse consequences with implementation.

Then, a year or so later, a report from the University of Washington on the same CPOE application found a trend towards a *lower* mortality rate after their implementation...but they did many things around the implementation differently. The importance of the socio-technical side of implementation of technology is increasingly clear. This is important for CPOE, and for all other applications too. There has been a lot of discussion and debate about this, which has been healthy.

#### Forum: Where do you see us in 10 years?

Bates: We will be using a lot more health information technology than we are today. In Massachusetts, CPOE will be in place in all the hospitals and EHRs will be ubiquitous in physician office. And, we will have begun to set up clinical data exchange that will occur routinely.

The problems ahead of that vision are largely political, not technical. There is an enormous potential benefit from doing a better job of linking systems within hospitals, and we will see some hospitals in which all the systems really do talk to each other—in which the computer system does talk to the smart pumps and the bar coding is all linked in. Once we begin to make all those connections, take the data from all the monitors and bring that in, then we will be able to have substantial improvements in safety. ■

# Surprises on the EMR: Unexpected Risks in Advance Care Planning and Results Management

by Claus Hamann, MD, MS

Dr. Hamann is Associate Medical Director for the LMR<sup>1</sup> at the Massachusetts General Hospital Physicians' Organization

The dynamic nature of electronic medical record (EMR) development requires constant communication among designers and stakeholders for maximum safety and quality of care. Two recent examples from Partners Health-Care's LMR illustrate that even established modules (advance care planning and results management) can surprise users with unanticipated effects on information retrieval and communication that risk harm to patients.<sup>2</sup>

## Advance Care Planning

A clear medical practice benefit is found in documenting patient's advance care planning (ACP) preferences and proxy decision-makers: giving wanted, appropriate care at the end of life. While clarifying the patient's wishes is best accomplished in the outpatient office setting, inpatient care providers (or emergency department personnel)—who have not known the patient—need quick access to that ACP documentation.

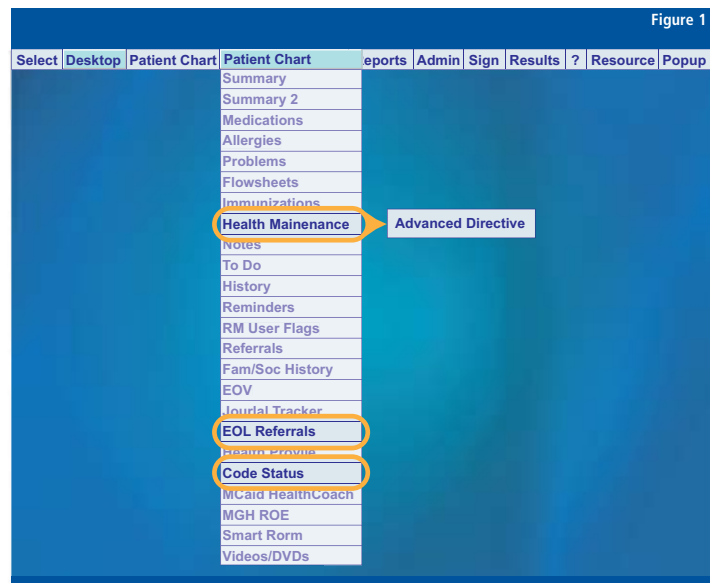
Over time, Partners' outpatient LMR has evolved three modules containing partially redundant, non-interoperable information within the Patient Chart section (see Figure 1): the original Advance Directives within Health Maintenance, and the more recent Code Status and End-of-Life Referral (developed by different sets of clinical users and information systems designers). Code Status has a link to Advance Directives but not vice-versa; no other links among modules exist, and none of the redundant information on proxies or preferences carries over from one module to the others. None of these three outpatient modules is linked to the advance directives module in the inpatient order entry systems.

The potential for conflicting advance care planning (ACP) information and the risk for inappropriate care are high. An interdisciplinary Partners task force is developing an ACP repository, analogous to the successful Allergy/Adverse Reaction repository. Challenges include agreeing on the vision for ACP, identifying and aligning all the stakeholders this time around, applying design and programming resources, and prioritizing the ACP effort within the LMR development cycle. Partners' goal is to facilitate improved ACP communication among providers through integrated inpatient and outpatient entry and display of all the relevant information and actions. As a first step, the multiple data modules will be brought into a summary view with actionable links.

## Results Management

Like many of my Partners colleagues, I fully depend on the LMR's elegant Results Manager module for electronic and paper communication with our patients about test results. We rarely receive calls about missing result letters because the module facilitates timely acknowledgement and response. Our patients also like the flexibility of having blood tests done at labs of hospitals closer to their residences than hospitals at which we care for them. Through the LMR patient selection, providers are identified with several institutions and can select to receive the results from many of those labs.

Imagine our surprise, then consternation, when we starting getting the calls about missing result letters again! Results from labs of hospitals where providers do not have admitting privileges were not assigned to those providers and went unacknowledged—a significant safety risk and quality decrement. We discovered that hospital lab databases do not retrieve provider identification from registration databases of other hospitals within Partners where primary care physicians' names are associated with patients.



An interim work-around—electing patients from practice schedules for a watch list—relies on daily provider recall to accomplish the task. The desired solution will integrate patient and lab registration with the needed provider information throughout the institutions in our system, likely via the NPI number and in a manner that is invisible to providers. As with advance care planning documentation, the key challenge is to

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# Managing Test Results: Strategies and Potential IT Solutions

by Anuj K. Dalal, MD

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## Case I

A new patient presented to an ambulatory practice with a positive HIV test. A repeat HIV test was performed and was negative. The result was never communicated to the patient. The patient's CD4 count was within normal limits and the viral load was undetectable. Although the patient was never placed on anti-retroviral medications, he claimed to have suffered significant emotional trauma. The mistake was discovered eight years later.

## Case II

While hospitalized, an elderly female was found to have a complicated urinary tract infection and was started on an oral antibiotic. A urine culture—pending at the time of her discharge—grew an organism resistant to the prescribed antibiotic—but was not acted upon. Several days later, the patient was readmitted with severe sepsis. Although she was started on appropriate antibiotic therapy at the time of readmission, her status quickly deteriorated—requiring mechanical ventilation and vasopressor support—and she eventually died.

**T**hese cases describe some of the extreme consequences associated with failing to follow-up on test results in a timely manner, which unfortunately can occur even in an integrated health care system. Missed test results leading to clinically important treatment delays are an underappreciated source of diagnostic error.<sup>1</sup> CRICO malpractice claims data suggest that 15 percent of diagnosis-related malpractice cases are due to missed test results. Moreover, an increasing number of malpractice lawsuits allege failure of communication of important test results.

Despite the associated morbidity and mortality, physicians and health care delivery systems have not developed effective solutions to address this increasingly recognized problem. In general, there is lack of consensus as to what constitutes “best practices” in managing test results across the continuum of care. Although individual providers have developed their own systems to deal with management of test results, most physicians (75 percent according to one study) do not notify patients of normal results and many (33–36 percent) do not notify patients of abnormal results.<sup>2</sup>

In the ambulatory setting, primary care providers (PCPs) spend, on average, 72 minutes managing test results per clinic-day. The majority (57 percent) are dissatisfied with the way test results are managed.<sup>3</sup> In the inpatient setting, there is often a time lag (approximately 2.5 hours according to one study) from the time a critical lab result is generated to when an appropriate action is taken, with most delays due to an inability to locate the responsible provider.<sup>4</sup> The emergence of hospitalists and resident work-hour restrictions has led to an increased number of handoffs. Consequently, care transitions (hospital discharge in particular) have become critical and complex points of in-

formation exchange between providers. Patient safety can be jeopardized if important information is lost or not followed-up in a timely manner. In a recent study, Roy et al, found that 41 percent of patients left the hospital before all imaging and laboratory test results were reported; of these, 9.4 percent were potentially actionable and could have altered the patient care plan. The most concerning finding was that physicians were aware of only 38 percent of pending test results.<sup>5</sup>

In an effort to address these issues, the Joint Commission has declared test result management a high priority area for patient safety. Among its National Patient Safety Goals, the Joint Commission encourages institutions to “measure, assess and, if appropriate, take action to improve the timeliness of reporting and receipt by the responsible licensed caregiver of critical test results and values.”<sup>6</sup> In its *20 Tips to Help Prevent Medical Errors*, AHRQ encourages patients to take initiative to track down their test results: “If you have a test, don't assume that no news is good news.”<sup>7</sup>

The high degree of variability in individual clinician practices, the murky delineation of responsibility for pending tests at care transitions, the need for redundancy, malpractice claims, and potential patient morbidity and mortality, argue for a systems solution to test result management. Although information technology will play an integral role in the development and implementation of a solution, certain policy issues need to be clarified a priori.

**A responsible provider** should be identified and available at all times to ensure tests are followed-up in a timely manner. For most cases, this will be the ordering clinician. When the ordering clinician is unavailable (i.e., nights, weekends, or vacations) back-up providers should review high-priority actionable test results. This is particularly true for urgent test results which impact decision-making. For the patient in Case 2 above, timely review of urine culture antibiotic susceptibilities may have prompted the responsible provider to change antibiotics sooner and perhaps may have prevented her death. For other non-urgent results, a prioritization system would help triage results so that covering providers do not get over-burdened.

**In the inpatient setting** where teams of clinicians provide care, patients transfer from service to service, and clinicians routinely transfer primary patient responsibility, determining the responsible provider can be difficult. Particularly in (complex) academic settings, the responding and responsible providers must be clearly identified at any given point in time.

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identify all the stakeholder clinicians at the beginning of the (re)design process for new or transforming EMR modules.

### Missed Opportunities

The two examples of HIT solutions illustrate a common missed opportunity: complete stakeholder involvement in EMR design improvement. For advance care planning documentation, not engaging all the relevant clinician users (e.g., primary care physicians who had been using the original Advance Directives module) at the time that other specialty groups spearheaded the development of the Code Status and End-of-Life Referrals modules produced “tunnels to nowhere.” In the case of results management, a successful solution was threatened by not anticipating a needed connection among databases. Risks to safety and quality of care increased unexpectedly in HIT applications that had “solved” important clinical care challenges.

The evolution of IT design toward service-oriented architecture<sup>3</sup> may further improve the connection among “above-ground” user interfaces and applications and the vast underground of interconnected programs and databases. Our HIT systems need to transition quickly from separate applications containing their own data and not sharing it with other applications (e.g., separate problem lists in outpatient EMRs and inpatient Order Entry systems) to:

- information delivery and repository systems that use similar services to extract and share data (e.g., order entry using the same problem dictionary as the EMR), or better yet,
- disaggregate data from applications into separate repositories and emphasize programming services that shuttle data between repositories and applications or user interfaces (e.g., multiple clinical and financial applications, such as EMR, outpatient and inpatient order entry and billing, use a common array of programs to transfer data from single, enterprise-wide problem/diagnosis and medication dictionaries via linked decision-support engines to the user interface).

Through improved communication with stakeholders and improved, service-oriented HIT design, we expect a transparent underground: fewer surprises and risks, and better safety and quality benefits from our IT innovations. ■

### References

- 1 Partners Healthcare Longitudinal Medical Record (LMR, CCHIT-certified in 2006).
- 2 Johnson CW. Why did that happen? Exploring the proliferation of barely usable software in healthcare systems. *Qual Saf Health Care*. 2006;15 Suppl 1:i76–81.
- 3 Wright A, Sittig DF. SANDS: A service-oriented architecture for clinical decision support in a National Health Information Network. *J Biomed Inform*. 2008 Mar 14. [Epub ahead of print]

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Information technology can improve clarity in these settings and promote orderly transfer of information, such as pending test results, in a standardized manner.

**Finally, it is paramount** to establish clear lines of responsibility at the transitions of care. The ordering inpatient provider should have ultimate responsibility for reviewing, communicating to the PCP, or acting upon the test result in a timely and definitive manner. If the ordering provider is unavailable, then there must be an assigned back-up provider to take responsibility. A system of “planned redundancy” is safer than one of “diffused responsibility.”

### IT Strategies and Solutions: Current Systems

Harvard hospitals have developed several IT innovations to improve management of test results. These interventions are described below.

#### *Inpatient Interventions*

Brigham and Women’s Hospital (BWH) has developed a rules-based event engine as a part of its clinical information system. This innovation allows automatic routing of laboratory results (once finalized) to an identified provider. Critical laboratory results automatically trigger a text message to be sent to the identified provider’s pager. This has greatly diminished the time-lag to review critical laboratory results such as an elevated serum potassium level. It also allows clinicians to request automated real-time notification of any laboratory result that they choose. For example, a clinician may request automatic notification of serial cardiac enzymes, thus liberating him or her from logging onto the clinical information system to review these results. This feature has gained much popularity, particularly among busy housestaff, and is widely used.<sup>8</sup>

Massachusetts General Hospital has implemented an application that assigns a single responding provider to every patient in the inpatient setting. The application allows inpatient providers to instantly transfer responsibility of a group of patients to another provider after they complete their shift and sign-out. Nurses and support staff can access this application to identify the correct responding clinician. The application incorporates a standardized signout that allows transfer of relevant patient information, such as pending studies and laboratory tests, so that this information is not lost during the handoff. BWH is in the process of implementing this application in the inpatient setting.

### Outpatient Interventions

Partners Healthcare has developed a browser-based, provider-centric, results management application called Results Manager to help ambulatory clinicians review and act upon test results in a safe, reliable, and efficient manner. Results Manager prioritizes test results by severity; presents guidelines to help clinicians manage abnormal results; allows clinicians to generate result letters to patients with predefined, context-sensitive templates; and prompts physicians to set reminders for future testing.<sup>9</sup>

In a 30-month study conducted by Poon et al, PCPs at 26 adult primary care practices were able to expedite communication of outpatient laboratory and imaging test results to patients with the help of Results Manager. Patients of physicians who participated in the project reported greater satisfaction with test results communication and with information provided about their treatment and/or condition than did a control group of similar patients.<sup>10</sup>

### IT Strategies and Solutions: Future Directions

#### Automated Systems

With complex institution- and individual-specific workflows, multiple clinical information systems, and a multitude of tests, any solution attempting to improve management of test results will almost certainly include automated notification as an essential feature. Importantly, the notification should be reliably sent to devices or messaging systems which are in widespread use by practicing clinicians. Alphanumeric pagers are an obvious first choice. With the growth of wireless networks, increasing use of multimedia handheld devices that can access institution e-mail, and the development of applications that improve inbox management, e-mail is becoming an increasingly attractive option. An automated e-mail notification system may improve clinician awareness of pending tests (particularly those with a time lag prior to finalization) as often occurs at the time of hospital discharge and other care transitions. Importantly, these systems should not overburden clinicians with irrelevant results as this would undermine their utility.

#### Personally Controlled Health Records

Typically, patients become aware of test results by calling their provider or by receiving copies of test results by mail. In an electronic world, applications integrated within an electronic medical record, such as Results Manager, will be increasingly

used to automatically generate and deliver test results to patients. In the inpatient setting, engaging patients by providing copies of relevant tests can be useful, particularly at care transitions. For example, incorporating test result information such as pending tests on discharge instructions for patients transitioning from the inpatient to outpatient setting should be the rule.

Patients and family members are ultimately interested in and can act as their own advocate with regard to following up their tests. In addition, patients should be encouraged to maintain personal health records. With the emergence of web-based personal health records, patients increasingly will be able to look up test results online as they become available. Patient portals already exist at BIDMC (PatientSite) and at Partners (Patient Gateway); both allow patients to review their laboratory results online. Recently, Microsoft and Google have announced development of personally controlled health records that could provide a means for patients to organize and view their health information, including test results, online.<sup>11</sup> Making pending tests available to patients online via personal health records is another mechanism of increasing patients' awareness of outstanding tests, enhancing redundancy, and ensuring follow-through. ■

#### References:

- 1 Wahls TL, Cram PM. The frequency of missed test results and associated treatment delays in a highly computerized health system. *BMC Fam Pract.* 2007;22(8):32.
- 2 Boohaker EA, Ward RE, Uman JE, McCarthy BD. Patient notification and follow-up of abnormal test results. A physician survey. *Arch Intern Med.* 1996;156(3):327-31.
- 3 Poon EG, Gandhi TK, Sequist TD, Murff HJ, Karson AS, Bates DW. "I wish I had seen this test result earlier!": Dissatisfaction with test result management systems in primary care. *Arch Intern Med.* 2004;164(20):2223-28.
- 4 Kuperman GJ, Boyle D, Jha A, et al. How promptly are inpatients treated for critical laboratory results? *J Am Med Inform Assoc.* 1998;5(1):112-19.
- 5 Roy CL, Poon EG, Karson AS, et al. Patient safety concerns arising from test results that return after hospital discharge. *Ann Intern Med.* 2005;143(2):121-28.
- 6 The Joint Commission. National Patient Safety Goals: 2005 Laboratory Services National Patient Safety Goals. Available at: [http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/05\\_lab\\_npsgs.htm](http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/05_lab_npsgs.htm). Accessed May 20, 2008.
- 7 Agency for Healthcare Research and Quality. Patient fact sheet: 20 tips to help prevent medical error. Available at: <http://www.ahrq.gov/consumer/20tips.htm>. Accessed May 20, 2008.
- 8 Poon EG, Kuperman GJ, Fiskio J, Bates DW. Real-time notification of laboratory data requested by users through alphanumeric pagers. *J Am Med Inform Assoc.* 2002;9(3):217-22.
- 9 Poon EG, Wang SJ, Gandhi TK, Bates DW, Kuperman GJ. Design and implementation of a comprehensive outpatient results manager. *J Biomed Inform.* 2003;36(1-2):80-91.
- 10 Matheny ME, Gandhi TK, Orav EJ, et al. Impact of an automated test results management system on patients' satisfaction about test result communication. *Arch Intern Med.* 2007;167(20):2233-29.
- 11 Mandl KD, Kohane IS. Tectonic shifts in the health information economy. *N Engl J Med.* 2008;358(16):1732-37.

## Designing for ACCORD with Patients

by Henry C. Chueh, MD, MS

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The disparity between evidence-based practice guidelines and clinical practice has never been wider. As the Institute of Medicine notes, this “quality chasm” represents an increasingly significant fault in our health delivery system.<sup>1</sup> Information technology has been often touted as a solution to this problem. Approaches include improving access to online knowledge bases and guidelines, clinical decision support systems at the point of care, and incentives to adhere to standards of care. Most of these interventions are directed at clinical providers. All of these have their place, but there is also an increasing awareness of the need to empower patients in promoting the right health care for themselves. The Internet, personal health records (PHR), and mailings have all been used to enhance patient awareness. That said, what if the fundamental issue is not one of *knowing* the right thing to do, but of *doing* the right thing, and perhaps more importantly, making sure that the right thing gets done?

The risk of doing the wrong thing may be clear, but what about the risk of *not* doing the right thing? In addition to likely poor clinical outcomes, failure to follow-up is the fastest growing area of malpractice claims. In a recent survey, one-third of physicians had no system for tracking follow-up, and less than one-third who do had a system were satisfied with it. Systems to address the issue of follow-up are in fact emerging. The need to have systems that perform follow-up of blood testing are increasingly commonplace, for example. The focus, however, remains on clinical decision support systems, but most do exactly that: support the provider in making a clinical decision.<sup>2</sup> Less common are systems that support clinical decisions after they have been made. Focus on the latter activity led to research into designing an Ambulatory Care Compact to Organize Risk and Decision-making (ACCORD) that can be made between patients and providers.

The basic premise of ACCORD is that providers know the right thing to do (or already have clinical decision support systems to help them know it), but are often missing systems to help them track the plan of care they advise. Moreover, since the patient is the one who needs to commit to some activity (take a medication, get a blood test, have a procedure performed, etc), it is imperative that they understand the particulars of a plan of care and why keeping the plan on track is important.<sup>3</sup> ACCORD addresses these issues through a system design that breaks down the process of agreeing on a plan of care into a few key steps.

First, ACCORD maintains a database of different clinical conditions that commonly need some form of follow-up care. These conditions may fall into the realm of preventative care such as colon cancer screening, follow-up of abnormal findings such

as a pulmonary nodule, or the need for medication monitoring through blood lab tests, among others. For each condition, templates are authored that establish the most commonly used options for care plans. For colon cancer screening, example of options could be “Routine screening for average risk: colonoscopy every 10 years,” or “Follow-up of colon polyp: colonoscopy every five years.”

Second, the provider and patient would come to agreement about selecting an option for a specific ACCORD. In this step, the patient will have the opportunity to learn about his or her options and understand the importance of keeping to the plan. Third, for ACCORDs that are established through this explicit, consensus process between patient and provider, documentation will be generated into the electronic health record that reflects the choice being made. This is critical because one option present on every ACCORD will be “Do nothing: review again in X months/years.” Both agreed upon “watching and waiting” and informed refusal are perfectly acceptable options—as long as they are clearly understood and documented.

Finally all ACCORDs are tracked by the system in a fail-safe manner over time. If the care plan is kept, the ACCORD system remains silent. But if the care plan is not completed, ACCORD will alert both patient and provider to create transparency around the lack of appropriate follow-up.

Many details of the ACCORD system are not described here due to both ongoing design work, but many interesting challenges have emerged already. Can patients propose an ACCORD for a provider to agree to? Can ACCORDs be used for lifestyle plans? How does the interaction occur if patient and provider cannot come to agreement easily? What is the best way to link in knowledge for the patient? For the provider? Can ACCORD be integrated into provider and patient workflow without significant disruption?

Though many more challenges remain, the primary characteristics of ACCORD are clear: patient-provider centered decisions with preference and choice, self-documenting, explicit agreements with high visibility, and fail-safe monitoring. As providers (and patients) get busier every day, more systems like ACCORD will be needed to bridge the quality chasm and to help reduce the risk of missed follow-up care in the future. ■

### References

- 1 Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century. Institute of Medicine. Washington, DC: National Academy Press, 2001.
- 2 Sittig DF, Wright A, Osheroff JA, et al. Grand challenges in clinical decision support. [Review] [35 refs] [Journal Article. Research Support, N.I.H., Extramural. Review] *J Biomed Inform.* 41(2):387–92, 2008 Apr.
- 3 Poon EG, Haas JS, Puopolo AL, et al. Communication factors in the follow-up of abnormal mammograms.[see comment]. [Journal Article. Multicenter Study] *J Gen Int Med.* 19(4):316–23, 2004 Apr.

# HIT Privacy, Security, and Safety Risks: A Legal Perspective

by Kenneth N. Rashbaum, Esq.

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“Imagine, if you will” were the words the writer Rod Serling would intone at the beginning of each episode of the classic television series *The Twilight Zone*. What followed would be a tale, with a cautionary bent, a lesson for the future which, as Mr. Serling would clearly imply, was already here.

Such is the case with Health Information Technology (HIT). Even if your hospital or practice is not yet up to cyber-speed, electronic health information is as present as the stethoscope—and so are the risks of inappropriate disclosure, security breaches, and compromises in patient safety.

So let us accept Rod Serling’s invitation and enter the HIT twilight zone. Imagine, if you will:

1. Cap Spaulding<sup>1</sup>, a second-year resident in Oncology, having finished an extended shift, throws his dog-eared spiral aid books, and his laptop into his backpack and heads home, only to realize that he failed to complete his charts. He smiles, remembering that his hospital has an electronic medical record (EMR) system, and he can complete his entries remotely. He leaps from the bus, enters a nearby coffee shop, orders a double espresso, fires up his machine, logs onto the record system and begins to type. He reaches for his coffee but his hand stops in mid-air, frozen by the words spoken from six inches behind his right shoulder, “Oh my God! Debbie Jones! I work with her. I didn’t know she had cancer!”
2. Marcia Ballard, Attending in Plastic Surgery, needs to review four extensive charts for the QA review tomorrow. But her daughter’s play is in two hours. She downloads the charts onto a USB thumb drive, so she can complete her review at home. The download is interrupted a few times by error messages, so when the transfer is complete, Dr. Ballard has only 20 minutes to pick up her daughter. She flings the USB drive into her bag, where it lands on top of her sunglass case. When Dr. Ballard throws the bag onto the front seat of her car, the USB drive tumbles onto the street. Two days later, the entertainment section of the local newspaper features an article about the recent facelift of Jennifer Jones, international film star—and a patient whose chart Dr. Ballard had loaded onto her USB.
3. Physician’s assistant, Darren York, is asked by Dr. Michael Field to check the hematocrit on an 85-year-old man who had fallen the previous evening. The patient is responding poorly, and Dr. Field is concerned that there may be a bleed. York assures Dr. Field that the hematocrit has not varied appreciably in the last 12 hours. Suddenly, the patient’s blood pressure drops and he becomes unresponsive. Resuscitation fails and the patient dies. Autopsy reveals a large hemothorax and a perforation

of the thoracic aorta. An audit trail, located during the ensuing QA investigation, shows that York viewed only lab results from the day before the patient’s fall.

Dr. Field, suspecting that the patient may have had a bleed, fires off an angry e-mail to his resident in which he asks the resident to check on another patient because “I don’t trust York. He’s got a history of ignoring labs or even reading the wrong ones.” The e-mail makes its way into the patient’s chart, as per protocol for patient and treatment-related e-mail to automatically be entered into the EMR. The e-mail is disclosed during the discovery phase of the ensuing lawsuit, and the case is settled before trial for far more than its objective value.

## HIPAA and Beyond: Regulations and Enforcement

Despite the reports of the demise of HIPAA, it has been ramped up for 2008 due, in no small measure, to the ubiquity of electronic information from technological advances, coupled with news stories of theft or loss of sensitive personal information. In the next six months, hospitals and medical practices in various parts of the United States will be subjected to spot security audits by the U.S. government.<sup>2</sup>

In its Privacy Rule, HIPAA sets forth the minimum standards for protection of medical information traceable to a particular patient (known as protected health information, or PHI). The HIPAA Security Rule provides specifications for the use, storage, transmission, and disclosure of identifiable medical information in electronic form.<sup>3</sup>

Required specifications for PHI include:

- implementation of security management processes, including risk analysis, risk management, workplace use and security protocols, and audit controls;
- security incident procedures; and
- sanctions policy for enforcement of those procedures.

“Addressable” specifications, which must be implemented so long as administrative and financial wherewithal is present include encryption of e-mails containing PHI.

The Centers for Medicare and Medicaid Services (CMS) has authority to enforce the HIPAA security rule and, contrary to popular misconception, CMS is quite serious about its enforcement mandate. In December 2006, CMS issued a Security Guidance focusing special attention on remote access to PHI, and security risks in portable media.<sup>4</sup> CMS stated “there is growing concern” about laptop computers, personal digital assistants

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and USB thumb drives. The CMS Guidance also notes that the HIPAA security rule *requires* regular review and modification of information security policies, revision where necessary, and training on those policies. CMS, in the introduction to the Guidance, noted that it “may rely upon this Guidance” in determining whether violations of the security rule have occurred, “and it may be given deference in any administrative hearing” pursuant to the HIPAA enforcement rule.

In 2007, CMS paid an unannounced visit to Piedmont Hospital in Atlanta for a HIPAA Security Audit. Auditors were on site for weeks. Areas of concern included conduct which provided a risk of inappropriate disclosure, loss or theft of electronic PHI storage devices, and lack of attention to security.

While institutions cited in news stories on sub-standard compliance (such as UCLA<sup>5</sup> and Kaiser Permanente<sup>6</sup>) have not been audited as of this date, the frequency of such data security breaches has not been lost on CMS. It recently announced that it was retaining an accounting firm to assist in security compliance reviews, and that it anticipates at least 10–20 reviews in 2008.<sup>7</sup>

Yet, those who focus only upon the dragon of HIPAA ignore, at their peril, the sharp-toothed gremlins of state laws on data breach prevention and health privacy. Most states now have statutes which require security measures for sensitive personal information and provide for costly, time-consuming, and expensive procedures in the event of loss of data, as recently experienced by a hospital in New York whose patient database backup tape went missing. Additionally, juries look rather severely upon hospitals which fail to comply with patient privacy. An appellate court in New York recently ruled, in the case of *Randi v. Long Island Surgical Center*, that a jury’s award of \$300,000 in punitive damages where the Center *inadvertently* disclosed information about the plaintiff’s abortion to the plaintiff’s mother, was consistent with the facts of that case and appropriate (though the verdict was reversed on other grounds).<sup>8</sup>

While it may go without saying that these matters siphon off scarce financial and personnel resources, the damage to reputation from privacy or security breaches—while more difficult to quantify—is an injury from which recovery can take years and whose costs may be incalculable.

### Prepare for Compliance, Not the Audit or the Law Suit

Creating and implementing sound information management practices can considerably reduce the likelihood of an audit (including those triggered by news stories) or a lawsuit. Admittedly, managing EPHI (Electronic Protected Health Information) when creation, transmission, and storage tech-

nology are advancing daily is difficult. Attention to the basics of privacy, security, and confidentiality preservation, though, can form the cornerstone of a workable electronic information management policy.

- First, form a working group to lead the process; include at least one senior officer.
- Next, focus on the risk areas: remote access to EPHI; e-mail risk management (education for avoidance of “smoking gun” e-mails); patient safety issues in access to and use of electronic medical records; employee blogs (if permitted at all) which may reveal enough about “fictional” patients to permit identification.
- Finally, consider an outside individual or entity (e.g., a consulting company experienced in data management and business processes) or a law firm to lead the initiative, in order to lend the project additional gravitas and credibility.

Document the processes and training so that, in the event of inquiry, you have something to which you can refer to show compliance. In the New York case, *Randi v. Long Island Surgical Center*, the court specifically noted, in holding that punitive damages are appropriate for such a privacy breach, the absence of a written privacy policy or any documentation which reflected the existence of the “unwritten code of privacy.”

Neither federal nor state laws require perfection, nor do they mandate a privacy police force. They do require reasonable efforts to provide for information security and protect patient privacy. The steps described above, if documented and implemented, can go a long way toward convincing a HIPAA administrative judge, a state investigative body, or a court that such efforts have been, and are being, conducted. ■

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#### Notes and References

- 1 All names and examples are fictional
- 2 Vijayan J. HIPAA audit at hospital riles health care IT. *Computerworld*. June 15, 2007.
- 3 The HIPAA Security Rule: Health Insurance Reform: Security Standards, February 20, 2003, 68 FR 8334.
- 4 HIPAA Security Guidance for Remote Use of and Access to Electronic Protected Health Information; 12/28/2006.
- 5 Steinhauer J. California hospital faces sanctions after workers wrongly looked at patient records. *New York Times*. April 8, 2008
- 6 Lee HK Postings ordered halted: ex-Kaiser worker put links to data on patients on Web. *San Francisco Chronicle*. March 24, 2005
- 7 Ferris N. CMS to check hospitals for HIPAA security compliance. *Government Health IT*. January 17, 2008
- 8 *Randi A. J. v Long Is. Surgi-Ctr.* 2007 NY Slip Op 06953 [46 AD3d 74]

# A Blueprint for Implementing HIT Systems

by Lorraine Murphy, RN and Blake Walls

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A large teaching hospital implements an electronic registration system that pre-registers patients who will require emergent care upon their arrival. The system allows physicians to order medications during this preregistration phase, which saves precious minutes and leads to faster, better care. However, Dr. Smith, an attending physician who has been inadequately trained to use the new system, attempts to order morphine but misunderstands the system's coding and inadvertently orders methadone instead. A critically injured patient arrives and, in the heat of the moment, is given a lethal dose of methadone.

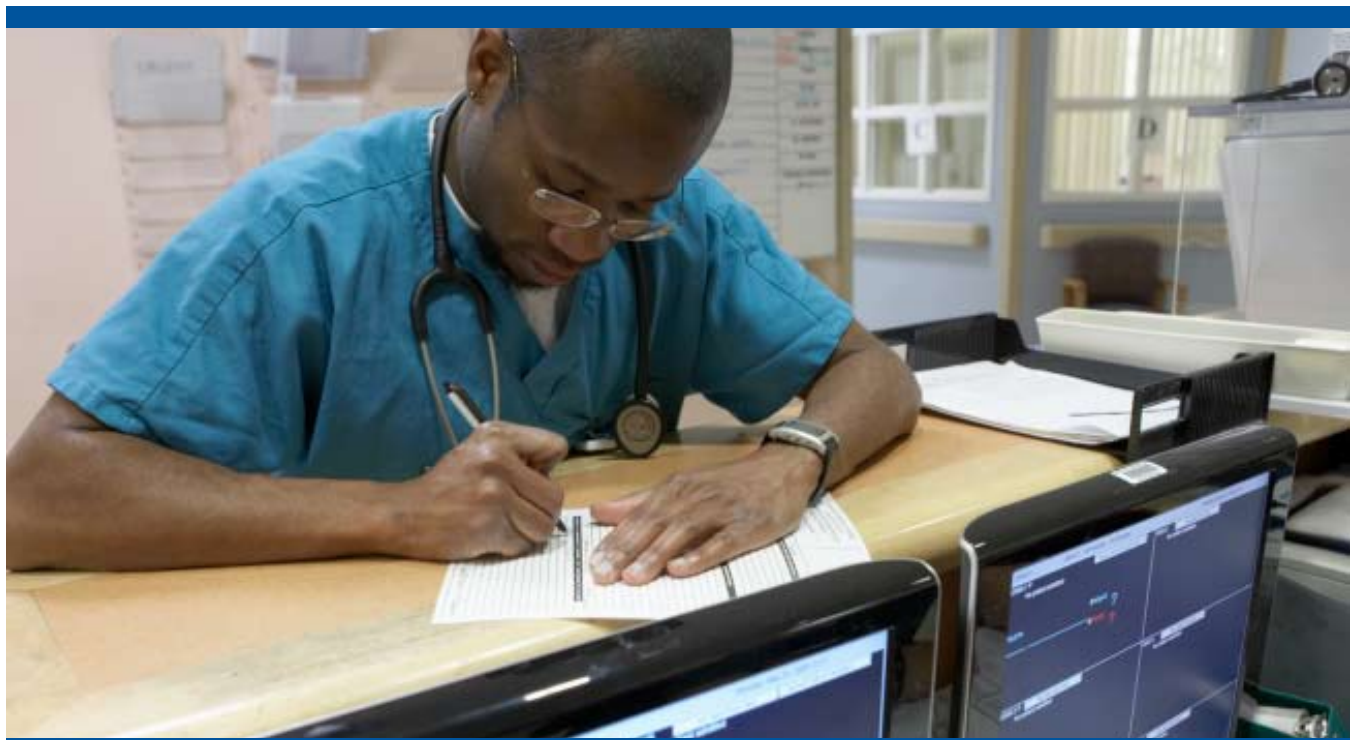
**H**ealth information technology (HIT) systems have the potential to be tremendous boons for clinicians and patients alike, but only when they are used properly and safely. Successfully implementing a new system requires broad thinking and extensive planning.

This process begins in earnest in the project's initial phases. To ensure a seamless implementation, recognize and assemble the team that will offer the project its greatest chance for success. Analogous to the ripple effect of a pebble in a pond, an organization must identify all areas that will ultimately be affected by the implementation of a new technology or system. In recruiting individuals for the implementation team, one must tap valuable resources from each department or area being effected by the implementation. Each team member must thoroughly know his or her specialty and processes, and be committed to ensuring that the final product for implementa-

tion effectively meets the needs of all staff. The sustainability of this team is crucial to ensure the long term success of the HIT system. The lack of engaging and supporting key staff who are empowered in decision making will lessen the positive effects of the HIT system and potentially result in unexpected risks to patient safety.

For example, consider an organization that is installing a new medication-ordering system for its Emergency Department (ED). Involving the pharmacy, nursing and physicians as part of the team along with the IT staff is crucial. Understanding that many outside of the ED—inpatient and outpatient areas, case managers, medical records—may need to access this information is key, as well. Listening to concerns, brainstorming solutions, and presenting value to the end users of the system are also imperative to compliance and success. This serves dual purposes: increasing interdepartmental communication and augmenting the knowledge pool. The various team members will be invaluable in addressing initial and ongoing education and support, as well downtime processes and procedures. The balanced environment that results will have the capacity to uncover and address potentially severe problems before they surface—saving your organization substantial time and energy in the long run.

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## Education and Training

The form and duration of the user instruction will vary with the complexity and specific aim of a given system, but the importance of balancing the roles of both explicit and implicit teaching remains paramount. Formal, explicit teaching (e.g., what the support staff provides to a system's target users) shows the value of the system and bestows upon users the rudimentary skills needed to gain a baseline fluency in its language.

Implicit education is starkly different: it occurs when users begin to explore the various capacities of a given system on their own. Those who explore more than others—who display passion in identifying both the bugs and the bonuses—may lead to discoveries of a system's unforeseen applications or benefits. Integrate those who take great interest in doing such exploration into implementations and ongoing support.

For instance, imagine a float nurse working with a new HIT system in the Surgery service. While entering data, she recognizes that by making slight changes to the visual display options on her screen, the system becomes much more compatible with the hospital's Obstetrics system than previously thought. Her discovery leads to the elimination of a number of tedious chart-checking processes that the departments' chiefs had implemented to safeguard against error, saving her and her coworkers valuable time.

The float nurse's finding is significant because such demonstrations of value are important. One way to maximize the frequency of positive revelations is to have your team institute departmental forums and encourage open communication about the systems features, strengths, and weaknesses. A collaborative environment also ensures that once the support team leaves, users will still have access to knowledgeable individuals in addition to the implementation team who can operate the system with dexterity and confidence.

## Impediments

Even assuming an abnormally large number of implicit educators and superusers, some individuals will inevitably fall far behind the curve in the system's education process. Three reasons for this have emerged as being particularly insidious:

- initial disagreement with the implementation,
- refusal to ask for help or instruction after the support team has left, and
- the ability to “successfully” work around the system.

Each of these scenarios can detrimentally effect the implementation, or worse, increase the likelihood of an adverse event. Implementation team leaders can circumvent these impediments with some strategic planning.

**Accept the fact that people resist change.** The change from an old system to a new one is not exempt from this bit of human nature. A common reason for resistance is that the users of an existing system may see no significant problems with it. They wonder why they need to be subjected to hours of training and instruction to learn a new way of doing what they believe they were already doing successfully (or working around).

An organization can likely alleviate these potential problems by returning to the concept of demonstrating value. If the reasoning behind an upgrade is not immediately clear, then the implementation team must make a concerted effort to bring that to light and explain the new improvements. The most successful implementations are for systems over which the users can assert a degree of ownership. Making the effort to effectively show value can help transfer ownership from an old system to a new one. Seek out the individuals who are most likely to resist the change and engage them in one-on-one conversation (perhaps in a more personal setting than the classroom). Their concerns often arise more from the foreignness of the new system than any material issue.

**Some people think it is too late to ask for help.** After a support team has completed its formal training, certain users will be tentative to ask for help. Consider a nurse who has worked for 20 years in the aforementioned Emergency Department that is implementing a new medication-ordering system. He sat through the classroom lessons and mostly paid attention, but the instructor took for granted that he understood the simple steps, and thus spent most of his time addressing more complex issues. After the training was over, the nurse did not have a firm grasp on the system's most basic medication-ordering functions. Embarrassed, he did not ask for help. This led to him accidentally ordering the wrong medication on more than one

occasion, resulting in significant delays in much-needed care.

People who think “everyone else seems to get it, so I must not have been paying enough attention” will fear being viewed as inept or inattentive. Most likely the discrepancies in their knowledge are inevitable—everybody learns at a different pace. But instead of asking for help, they might try to figure it out on their own, which can lead to significant issues when sensitive information or complex systems are involved.

One way an organization might remedy the problem of education lags is by having the implementation team acquire as much feedback as possible (via forms, e-mail, committees, or rounding to the staff effected by the system). This can help put people at ease and make them feel freer to voice their problems with the team members who have been involved from the start. This level of comfort between the users and the team is invaluable, as are the implicit educators, who can also be effective in this respect. They can act as a surrogate on-site support staff. Additionally, an organization might host re-training sessions in the months following the go-live date. One of the biggest things to avoid in implementing a new HIT system is complacency after the initial installation. Revisiting the basics after a few months can go a long way in insuring that a department is running with maximum efficiency and safety.

**Workarounds are inherently dangerous.** By their very definition, workarounds undercut standard procedures. One common HIT workaround is documenting patient information on paper and entering it into the system at a later time. Clinicians who do this fail to realize the high likelihood of the data never making it into the system—either because it is lost or because they forget about it. The workaround problem is a vicious cycle: individuals who use workarounds tend to be less proficient in system use than their colleagues for lack of practice. Similarly, individuals who are less proficient in the new system to begin with are more likely to use workarounds so that their efficiency is not curbed. As with other implementation impediments, workarounds can be reduced with open dialogue, active reassessment, and readjustment. ■

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# Additional Reading

by Judith Jaffe, MSLIS

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The following additional resources related to Health Information Technology were selected from the PubMed (Medline) database of indexed biomedical literature published from 2000 through March 2008. Links are provided to abstracts and full text, where available.

## Collaboration

D'Avolio LW, Bui AA. The clinical outcomes assessment toolkit: a framework to support automated clinical records-based outcomes assessment and performance measurement research. *J Am Med Inform Assoc.* 2008 May-Jun;15(3):333-40. [PubMed abstract](#)

Puffer MJ, Ferguson JA, Wright BC, et al. Partnering with clinical providers to enhance the efficiency of an EMR. *J Healthc Inf Manag.* 2007 Winter;21(1):24-32. [PubMed abstract](#)

## Handoffs

Sarkar U, Carter JT, Omachi TA, et al. SynopSIS: integrating physician sign-out with the electronic medical record. *J Hosp Med.* 2007 Sep;2(5):336-42. [PubMed abstract](#)

Van Eaton EG, Horvath KD, Lober WB, Pellegrini CA. Organizing the transfer of patient care information: the development of a computerized resident sign-out system. *Surgery.* 2004 Jul;136(1):5-13. [PubMed abstract](#)

## Implementation

Glaser JP. Seven durable ideas. *J Am Med Inform Assoc.* 2008 May-Jun;15(3):267-71. [PubMed abstract](#)

Walker JM, Carayon P, Leveson N, et al. EHR safety: the way forward to safe and effective systems. *J Am Med Inform Assoc.* 2008 May-Jun;15(3):272-7. [PubMed abstract](#)

## Patient Portals

Wald JS, Burk K, Gardner K, et al. Sharing electronic laboratory results in a patient portal—a feasibility pilot. *Medinfo.* 2007;12(Pt 1):18-22. [PubMed abstract](#)

Walters B, Barnard D, Paris S. "Patient Portals" and "E-Visits". *J Ambul Care Manage.* 2006 Jul-Sep;29(3):222-4. [PubMed abstract](#)

Weingart SN, Rind D, Tofias Z, Sands DZ. Who uses the patient internet portal? The PatientSite experience. *J Am Med Inform Assoc.* 2006 Jan-Feb;13(1):91-5. [Full text](#)

Zickmund SL, Hess R, Bryce CL, et al. Interest in the use of computerized patient portals: role of the provider-patient relationship. *J Gen Intern Med.* 2008 Jan;23 Suppl 1:20-6. [Full text](#)

## Personal Health Records

Halamka JD, Mandl KD, Tang PC. Early experiences with personal health records. *J Am Med Inform Assoc.* 2008 Jan-Feb;15(1):1-7. [PubMed abstract](#)

Mandl KD, Simons WW, Crawford WC, Abbett JM. Indivo: a personally controlled health record for health information exchange and communication. *BMC Med Inform Decis Mak.* 2007 Sep;12:7-25. [Full text](#)

Tang PC, Ash JS, Bates DW, Overhage JM, Sands DZ. Personal health records: definitions, benefits, and strategies for overcoming barriers to adoption. *J Am Med Inform Assoc.* 2006 Mar-Apr;13(2):121-6. [Full text](#)

Tang PC, Lansky D. The missing link: bridging the patient-provider health information gap. *Health Aff.* 2005 Sep-Oct;24(5):1290-5. [PubMed abstract](#)

## Primary Care

Gill JM, Ewen E, Nsereko M. Impact of an electronic medical record on quality of care in a primary care office. *Del Med J.* 2001 May;73(5):187-94. [PubMed abstract](#)

Singh R, Servoss T, Kalsman M, Fox C, Singh G. Estimating impacts on safety caused by the introduction of electronic medical records in primary care. *Inform Prim Care.* 2004;12(4):235-42. [PubMed abstract](#)

## Results Management

Rose AF, Schnipper JL, Park ER, Poon EG, Li Q, Middleton B. Using qualitative studies to improve the usability of an EMR. *J Biomed Inform.* 2005 Feb;38(1):51-60. [PubMed abstract](#)

Wahls T, Haugen T, Cram P. The continuing problem of missed test results in an integrated health system with an advanced electronic medical record. *Jt Comm J Qual Patient Saf.* 2007 Aug;33(8):485-92. [PubMed abstract](#)

## Risks

Ash JS, Sittig DF, Poon EG, Guappone K, Campbell E, Dykstra RH. The extent and importance of unintended consequences related to computerized provider order entry. *J Am Med Inform Assoc.* 2007 Jul-Aug;14(4):415-23. [PubMed abstract](#)

Hartzband P, Groopman J. Off the record—avoiding the pitfalls of going electronic. *N Engl J Med.* 2008 Apr 17;358(16):1656.

Wachter RM. Expected and unanticipated consequences of the quality and information technology revolutions. *JAMA.* 2006 June 21;295(23):2780-3. [Full text](#)





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