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Leveraging IT to Improve Patient Safety¹

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Medical errors and issues of patient safety are hardly new phenomena. Even during the dawn of medicine, Hippocrates counseled new physicians, “To above all else do no harm.” In the U.S., efforts to improve the quality of healthcare can be seen in almost every decade of the last century. In the early 1900s, Dr. Ernest Codman failed in his efforts to get fellow surgeons to look at the outcomes of their cases. In the 1970s, there was an outcry that the military allowed an almost blind surgeon to continue to practice and even transferred him to the prestigious Walter Reed Hospital. More recently, two reports by the Institute of Medicine (IOM) caught the attention of the media, the American public and the healthcare industry. *To Err Is Human* highlights the need to reduce medical errors and improve patient safety, and *Crossing the Quality Chasm* calls for a new health system to provide quality care for the 21st century.

Healthcare has a problem

The IOM is not the only source indicating that the delivery of healthcare has significant shortcomings. A Rand Foundation report describes the U.S. healthcare system as “substandard” and medical errors as “rife.” Only 60 percent of the chronically ill receive the care they need. Of the care given to the chronically ill, about 20 percent are “unnecessary and potentially harmful” [1].

According to a Kaiser study, 71 percent of consumers – who are increasingly involved in making their own healthcare decisions – are concerned or very concerned about patient safety [2]. Sixty-one percent fear being given the wrong medication and 56 percent fear complications in a medical procedure [3].

Furthermore, more than half of U.S. physicians believe their ability to deliver quality care has decreased in the past five years and 30 percent rate their hospitals as fair or poor at finding and addressing medical errors [4].

In a Robert Wood Johnson Foundation survey, *Pursuing Perfection*, four of five providers believe that “fundamental” changes are needed to ensure patient safety. Seventy-eight percent feel their organizations should take responsibility for developing solutions to the quality challenge. Fewer than 10 percent find the system close to error-free. The number of physicians (95 percent), nurses (89 percent) and administrators (82 percent) who report having witnessed a serious medical mistake is appalling [5].

And then there are the numbers. According to the IOM, medical errors account for an estimated 44,000 to 98,000 deaths per year in U.S. hospitals, making it a leading cause of death in the United States. Although some have questioned the validity of these numbers, the reality is that people are dying from medical errors. One study of 182 deaths of patients hospitalized for CVA (stroke), pneumonia, or heart attack found at least 14 percent and potentially as many as 27 percent of the deaths might have been prevented [6]. If morbidity and the outpatient

environment are considered, the numbers may be far worse than the IOM suggests. A growing number of these studies in peer reviewed literature document the problem. Just over one-fifth of these studies define errors and adverse events, while 65 percent are medication related. Only recently did a small number of studies begin to examine costs involved [7].

According to the Agency for Healthcare Research and Quality, adverse drug events cause 777,000 injuries and deaths a year [8]. Medication-related deaths in the U.S. increased 2.37-fold in hospitalized patients and 8.48-fold among outpatients between 1983 and 1993. This equated to one out of 854 inpatient deaths and one out of 131 outpatient deaths in 1993 [9].

Researchers found 5.5 adverse drug events per 100 outpatients coming for care. Of these, 38 percent were preventable and 23 percent were serious. Even these numbers must be considered suspect as there is general consensus that errors are underreported for a host of reasons. One study indicated that while 92 percent of hospital CEOs reported they were knowledgeable about the frequency of medication errors in their facility, only eight percent said they had more than 20 per month, when probably all of them did [10]. In another recent prospective study of surgical units, almost 80 percent of errors identified by trained observers were not officially recognized or recorded [11].

The Challenge in Medicine Today: To Apply What We Know

It is not surprising that healthcare is experiencing difficulty. We are at a time of unprecedented discovery. All told, “the science and technologies involved in healthcare – the knowledge, skills, care interventions, devices and drugs – have advanced more rapidly than our ability to deliver them safely, effectively and efficiently” [12]. For example, in 1998 the FDA approved 90 new drugs, 30 new molecular entities and 124 new uses for already approved drugs [13]. New medical technologies are at an all time high and our medical knowledge is growing exponentially. In 1995, more than 10,000 articles were published on randomized clinical trials, our best source of data for evidence-based care, 100 times as many as in 1966 [14]. Except for rare and exceptional clinicians, it is just not possible to keep up-to-date on all the advances in medical knowledge.

The Nature of Medical Errors

Analysis of the nature and causes of medical errors has made it clear that they arise from a variety of causes and impact virtually all medical activities. Furthermore, they do not readily point to a common set of causes. More often than not, errors result from a combination of a series of latent errors built into the system. A recent prospective study could identify the individual who “might” be responsible in only 37.8 percent of the cases. In more than a third of the cases, it was “simply not possible to assign any responsibility.” More than 60 percent of all errors were in the system. Even when an individual could be identified, the person was acting within the system [11]. This complex and pervasive nature of medical errors means they cannot be eliminated by efforts that are simplistic or narrowly focused.

Taking Action to Improve Patient Safety

The push to improve patient safety remains slow going, although definite efforts continue to arise. The Joint Commission on Accreditation of Healthcare Organizations made its new patient safety standards effective July 1, 2001. They call for internal reporting of medical errors, design of remedial steps to prevent future occurrences of these errors, prospective analysis and re-design of vulnerable patient care systems, and, finally, telling patients and their families when they have been hurt by a medical error [15].

The American Hospital Association offers its members educational materials to use in creating “a culture of safety.” The Leapfrog Group is bringing the influence of private sector employers to bear upon the issue. The government also has taken steps. In 2001, Congress allocated \$50 million to establish the National Center for Quality Improvement and Patient Safety within the Agency for Healthcare Research and Quality (AHRQ). Through 2003, AHRQ expects to award up to \$25 million annually to establish centers for safety research and practice and to support research and education in key areas, including best practice guidelines.

The states also have taken some initial steps to improve patient safety. California legislation requires hospitals to implement a formal plan for eliminating or substantially reducing medication safety related errors by 2005. Other states have also passed laws related to medical errors. For example, fifteen states have mandatory reporting from hospitals for adverse events. Five states and the District of Columbia have voluntary reporting.

Making Patient Safety Happen

To reach the goal of patient safety, each health care organization needs:

- Its own vision for patient safety that is clear, realistic, achievable and measurable.
- An understanding of what constitutes “best in class performance” outside its walls.
- A carefully selected and limited set of strategies and unambiguous measures.
- Organization-wide deployment and development of leadership across the organization to align its daily work with the vision.

Each and every one of these components is essential to developing a “culture of safety” and none can succeed without leadership and commitment of the medical staff, nursing, and other leaders. Several steps can be taken to ensure that the process of improving patient safety is ultimately successful.

The education component brings all participants to a common level of understanding and recognition of the possibilities. The diagnostic component allows a healthcare organization to gain an overview and clearly define the scope of patient problems within the organization. Process improvement is critical to providing safer patient care and better outcomes. Applying what is known about “best practices” to clinical processes is the first step in continuous quality

improvement. Healthcare organizations gain real value from access to an up-to-date, wide-reaching knowledge base of what actually works in other organizations similar to theirs. Evaluation follows on an ongoing basis. Every process change and every new tool must be evaluated to determine whether it does indeed improve care. By gathering and analyzing its own data, and comparing those data to national benchmarks when appropriate, healthcare organizations can create their own evidence-based practices. In such an environment, evaluation and process improvement are concurrent and continuous.

Education

- Understand the problems associated with patient safety and solutions that have been proven effective.
- Benefit from the experience of other institutions in identifying types of medical errors and applying clinical solutions.
- Understand the tools available to assist in the process and the cultural dimensions involved in creating a culture of safety.
- Establish a patient safety advisory team, including information technology staff, clinicians, and administrative staff, to advise on clinical solutions.

Diagnosis

- Involve the patient safety advisory team throughout the assessment process, eliciting their input to strengthen “buy-in” across the organization.
- Identify a proven methodology to assess the extent of the problem across the organization.
- Apply the methodology to generate an evidence-based picture of patient safety across the organization.
- Create an inventory of all sources of medical errors in all areas to be studied.
- Review the evidence to develop a prioritized listing of problems.
- Identify strategies and tools to address prioritized problems.
- Evaluate and select specific problem or problems for action.
- Provide an accurate projection of the hospital’s return on investment resulting from an investment of resources and a reduction in medical errors.

Process improvement

- Continue to work with patient safety advisory team to ensure that the implementation runs smoothly.
- Develop a detailed plan for education and training, using multiple modalities and providing ongoing support to ensure that the clinician’s job becomes easier.
- Install selected software solution.
- Ensure the mission of the safety team is part of the overall strategic plan.

Evaluation

- Analyze data to measure the effectiveness of solutions implemented.

- Monitor data on an ongoing basis to determine problem areas for which there are identifiable solutions.
- Continue to work with the advisory team to provide constant surveillance of patient safety and ensure continuous improvement of clinical care.

Using Technology as Enabler

It is clear that achieving substantial (50 percent or greater) reductions in preventable medical errors is a difficult task. However, there is consensus: IT can improve healthcare. In its report to the President, the President's Information Technology Advisory Committee (PITAC) outlines the role the federal government must play in using IT to transform health care. (16) In addition to calling for a national vision and information infrastructure, PITAC charges the federal government with coordinating its own cross-agency activities – which are numerous and far reaching in scope – and establishing pilot projects and Enabling Technology Centers. PITAC concluded, "Information technology tools can provide the healthcare sector with unprecedented productivity and quality of care if there is a strategic vision and adequate research to ensure success" [16].

The IOM's call for action reviews the medical literature, adds the insights of experts and reiterates the need, first set forth in *The Computer-based Patient Record*, to make use of information technology as an "enabler" in the service of patient care [12, 17]. It is our position that in order to achieve the goal of significant error reduction, a computer-based patient record (CPR) is essential. The use of a CPR is mandatory because of the wide variety of medical errors that can occur and the broad set of tools and capabilities needed to enable a care delivery organization (CDO) to detect, correct and compensate for errors across this diverse environment.

CPR offerings can be defined by five separate generations of CPR systems based on the progressive capabilities they offer. *First-generation CPRs* are simple systems that provide a site-specific encounter solution to the need for access to clinical data. *Second-generation CPRs* are basic systems that allow clinicians to document care adequately. *Third-generation CPRs* include episodic as well as encounter coverage and must work in ambulatory and acute care settings. *Fourth generation CPRs* are more complex, with integrated documentation, workflow and decision support, and must cover more than just the ambulatory and acute-care settings. *Fifth-generation CPRs* are complex, fully integrated systems crossing the continuum of care and designed to be used by healthcare providers and healthcare consumers. Currently, vendors are predominately delivering Generation 2 products. Since different CPRs offer different sets of capabilities it is reasonable to ask, "What degree of error reduction should one expect to be able to achieve with various generations of CPRs?"

Figure 1 gives a high-level answer to this question. Each of the five generations of CPR is plotted on a graph. On the horizontal axis is the anticipated time when such a system will become available and on the vertical axis is the projected efficacy of that generation in reducing

medical errors. Note that the vertical axis deals with preventable errors, not total errors. The 1999 IOM report estimated that roughly 70 percent of medical errors are preventable. It is important to note that no CPR system, no matter how sophisticated, can ever be expected to eliminate errors completely.

In order to estimate the error reduction potential of different CPR generations, the types of errors reported in the IOM report were analyzed and combined with the minimal features required for each CPR generation.

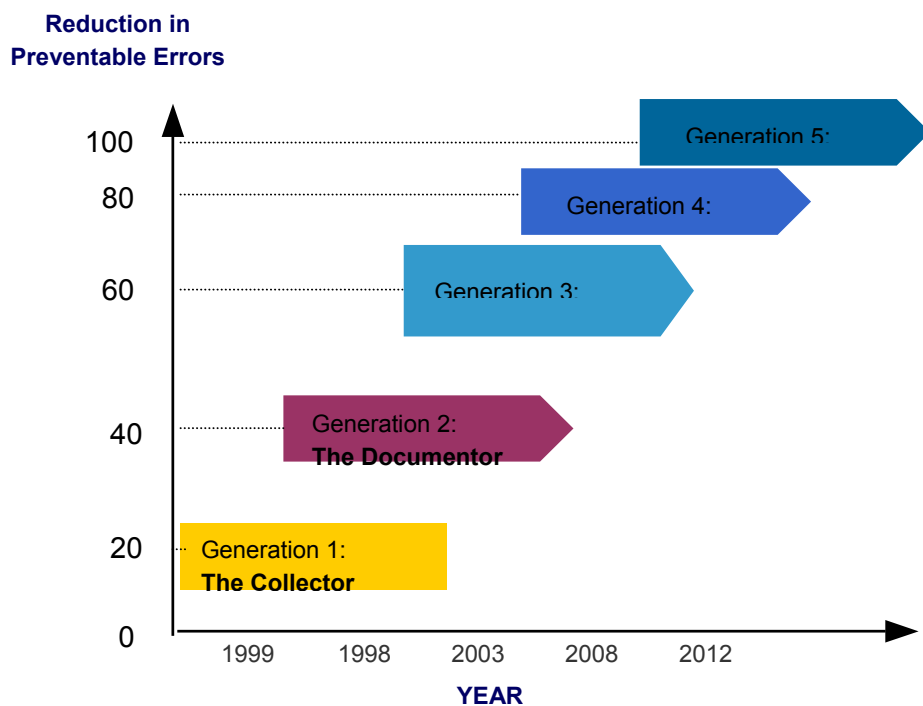


Figure 1: Error Impact of CPR Generations Source: Gartner, Inc.

Generation 1 CPRs are relatively simple systems that create a clinical data repository, where information from a wide variety of sources (such as laboratory and pharmacy systems) can be consolidated. The creation of a single comprehensive location for clinical information makes possible the elimination of approximately 15 percent of preventable medical errors by ensuring that needed information can be located efficiently and reliably.

Generation 2 CPRs make an additional 25 percent reduction in errors possible possibly by adding the capability to handle documentation of clinical activities including physician order entry. A major differentiator from Generation 1 systems is the inclusion of basic clinical decision support systems (CDSS). CDSS, with its associated rules engine, is a key capability for eliminating errors by permitting the CDO to implement a wide variety of checks to ensure mistakes are avoided and serious situations are rapidly brought to the attention of caregivers.

The combination of these capabilities means that generation 2 CPRs can achieve roughly a 40 percent reduction in preventable errors.

Generation 3 CPRs will make possible the single largest incremental improvement in error reduction over a previous generation and is expected to result in the potential for over 70 percent reduction in preventable errors. The combination of improved CDSS, operation across the continuum of care (inpatient and ambulatory), use of a controlled medical vocabulary to normalize medical concepts, and POE to better manage the ordering process will produce dramatic results. These systems also are seeing the emergence of workflow capabilities become progressively important as tools to support the optimal delivery of medical care.

When workflow is combined with CDSS, an even more powerful error reduction capability emerges. Generation 3 CPRs also have the basic infrastructure needed to assess the incidence of potential errors, to measure the effectiveness of interventions to prevent these errors and to document the improved outcomes that result. Since Generation 3 CPRs are now beginning to emerge and will become more capable after 2003, we believe that CDOs now have viable automation options that can help them realistically achieve the IOM goal of at least a 50 percent reduction in preventable medical errors.

It is expected that around 2007, there will be generally availability of **Generation 4** CPRs. With more sophisticated clinical decision support than was included in earlier generations of CPRs, these systems will be aware of the detailed context of each individual patient. Formal workflow capability will be an integral part of these systems and will ensure the proper balance occurs between the medical practice consistency needed to ensure optimal outcomes and the individual variations needed to treat each patient appropriately, given their unique set of circumstances. The combination of context awareness, clinical protocols, knowledge management and formal workflow should lead to an additional 20 percent reduction in preventable errors.

The final step in CPR evolution is predicted to occur sometime after 2010 with the advent of Generation 5 systems. These complex systems will have clinical decision support that is not only aware of the individual context of each patient, but has knowledge regarding the experience of the clinician as well as an understanding of the capabilities of the specific CDO site where the patient is being treated. It will also utilize sophisticated clinician interfaces to ensure that caregivers always have a full and up-to-date picture of the status of each of their patients and will be equipped to efficiently and effectively deal with multiple concurrent medical conditions in the same patient. It also will support interfaces to mobile personal monitoring devices that can provide an up-to-the-minute picture of patient's medical status. True evidence-based medicine will be possible using these systems since they will automatically track the outcomes experience of each episode of care as well as relevant new results as they become available in the medical literature. A Generation 5 CPR should provide the basic infrastructure needed to address preventable errors. Of course, the specific CPR implementation at a CDO site will determine how close that site comes to achieving this ideal.

Evidence to support the use of technology

While the CPR is the best technology used for overall error reduction, there is evidence that components of the CPR can result in definite improvement in patient safety.

Physician order entry

A POE system can reduce the potential for error in increasingly complex CPR environments by ensuring that orders are more legible, complete and appropriate. When combined with clinical decision support to identify serious potential complications, including drug-drug interactions, potentially life threatening allergies and conditions (e.g. an alternative antibiotic if the patient's lab values indicate renal failure and the prescribed medication is renally excreted).

Computerized Alerting Systems

Alerting systems are a type of clinical decision support. By notifying physicians about likely adverse events at the time those events actually occur, online alerts can improve the timeliness of response. The end results: fewer errors, improved quality of care and better patient outcomes. The challenge has been to deliver the message in real time to the physician responsible for the patient to take timely and appropriate action. Messages on computer terminals, email, flashing lights have all been tried - and can be effective.

Institution	Documented Results
Brigham and Women's Hospital, Boston (Included decision support features)	88% drop in serious medication errors 55% reduction in error rates
LDS Hospital, Salt Lake City	70% in adverse drug events
Ohio State University Medical Center, Columbus (pilot)	Average length of stay down by 2 days Turnaround for pharmacy orders 2 hours faster Pharmacy charges down \$910 per admission
Montefiore Medical Center, New York	Medication errors down 50% Turnaround for pharmacy orders 2 hours faster
Wishard Memorial Hospital, Indianapolis	Average length of stay down 0.9 days Average hospital charges down 13%

Evidence:

Email alerts to physicians on markedly abnormal lab values in patients receiving drugs affecting kidney function resulted in medications being adjusted or discontinued 21.6 hours earlier than when no email was delivered [18].

Paging clinicians about "panic" lab values decreased time to therapy by 11 percent and mean time to resolution of an abnormality by 29 percent [19].

Medical Error Reporting Systems

Medical error reporting systems link hospital-based systems to larger data repositories, allowing individual hospitals to benchmark their performance against other provider organizations and to determine how much errors cost and affect patient outcomes.

Case Study: Iowa Health System, Des Moines, OH [20]

A 10,000-patient pilot project at this 11-hospital delivery system is using a data analysis system to electronically flag patients who are at risk from drug/drug interactions or other adverse events. Iowa Health transmits data every week to Active Health Management's databases, which process the data using more than 600 clinical rules. The medical directors at Iowa Health review the analysis and contact the primary care physicians of patients who have been identified. In potential emergency situations, such as drug/drug interactions, Active Health notifies the medical directors immediately. Thus far they have identified 250 "intervention opportunities" and are developing a "Top 5" list of situations warranting immediate intervention.

Conclusion

The current situation regarding patient safety is unacceptable. In addition to the high mortality and morbidity associated with medical errors, there are numerous "secondary" costs. Clinical outcomes are poor because of complications and injuries associated with medical mistakes. This clearly leads to patient dissatisfaction and yields dissatisfaction on the part of caregivers who are unable to provide the quality of medical care they desire because of the limitations of inadequate healthcare automation systems.

In addition, serious errors also can lead to malpractice suits with the concomitant risk of financial losses, as well as injury to the institution's reputation. The challenge of patient safety is twofold. On the one hand more adverse events must be identified, including those without dire consequences, and the number of preventable adverse events that result from such errors must be reduced. Although much of a patient safety initiative will involve process changes, technology must be employed as well. The technology has been shown to work, the time is ripe to implement the necessary systems.

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