PATIENT SAFETY: MODIFYING PROCESSES TO ELIMINATE MEDICAL ERRORS

Barry P. Chaiken, MD, MPH Donald L. Holmquest, MD, PhD, JD

Healthcare marketplace pressures come from patients, employers and payors who insist on safe care with positive outcomes. Regulatory and watchdog organizations, such as the Leapfrog Group, are quickly moving to establish stronger standards for patient safety, quality and information system use. Physicians and other clinicians, along with the integrated delivery networks (IDNs) that support them, also demand the finest care for their patients. The provider constituents firmly believe, however, that they must also achieve a solid return on investment in solutions that enhance the care process. As these financial, regulatory and consumer pressures mount, executives at many healthcare organizations are determining how they can deliver safe, high-quality patient care efficiently and cost-effectively.

In its second report on the state of the U.S. healthcare market, the Institute of Medicine (IOM) recommends fundamental changes within the system to better deliver uniform, quality healthcare. In particular, Crossing the Quality Chasm: A New Healthcare System for the 21st Century calls for all stakeholders to "continually reduce the burden of illness, injury, and disability, and to improve the health and functioning of the people of the United States."

Additionally, the report identifies five organizational challenges:

- *Redesign care processes*
- *Effectively use information technologies to automate clinical processes*
- *Properly manage the growing clinical knowledge base*
- *Modify clinical roles*
- *Incorporate process and outcome measures into daily work*

In its 1999 report, *To Err is Human: Building a Safer Health System*, the IOM addresses the overabundance of medical errors, particularly adverse drug events (ADEs). It chronicles the frequent and unfortunate medical errors that allegedly claim more lives each year than U.S. highways. This report garnered much attention for its accounting about the abundance of ADEs that are potentially avoidable through specific overhaul of medication prescribing and administering processes.

In both of these respected studies, the IOM says information technology solutions, access to clinical guidelines at the point of care, and support and redesign of clinical workflows is key to improving patient safety.

The IOM is not alone when it comes to advocating the benefits of information technology to improve patient safety. A *Journal of the American Medical Association* (JAMA) study done by international medication errors expert Lucian Leape, M.D., determined that lack of knowledge about the drug and lack of knowledge about patient history are the two most common causes of drug errors. Dr. Leape concluded that physicians, nurses and pharmacists all need ready access to the latest drug and patient information to prevent errors. Dr. Leape also noted in his report that computers were well-suited to collect, retrieve and display needed information.

Other reports compiled by the Advisory Board detail the causes of errors as well as the benefits of clinical decision support, computerized order entry, alerts and reminders. Advisory Board reports also quantified the potential for significant savings by implementing error-reduction initiatives.

At state and national levels, various groups are focused on the need to combat ADEs. The recent passage of California law 1875 puts great pressure on hospitals in that state to invest in information technology to help caregivers reduce errors. Other states are expected to pass similar laws. At the federal level, recent congressional hearings mark a first step toward addressing patient safety.

Comprised of Fortune 500 companies and other large healthcare purchasers, the Leapfrog Group was formed to use its members' substantial power as purchasers of healthcare to drive improvements in patient safety. The group adopted several voluntary purchasing principles toward this end, and it is actively encouraging other large healthcare purchasers to join the crusade by committing to specific purchasing strategies and partnering to implement specific patient safety initiatives. The group is initially focusing on three patient-safety measures:

- *Computer physician order entry*
- *ICU physician staffing*
- *Evidence-based hospital referral*

The group plans to gather hospital performance data on these three measures so that employers can share the results with their employees.

Despite overwhelming attention from regulatory advocates and the media, quality and patient safety have consistently taken a back seat as healthcare organizations struggle with declining reimbursement rates, staff shortages and increasing costs. However, increasing public interest in patient safety gives the healthcare industry notice that bold and innovative measures must be adopted to satisfy consumers, payors, purchasers, providers and government entities while still meeting organizational financial requirements.

In addition to market pressures for improved patient safety, healthcare organizations must do more with less. The Balanced Budget Act of 1997 (BBA), enacted in part to control the federal government's spiraling healthcare costs, substantially reduced reimbursement rates paid to participating organizations by the Centers for Medicare and Medicaid Services (CMS) and state Medicaid agencies. Insurers and other at-risk organizations followed suit and negotiated lower reimbursement rates for services. In some instances, provider organizations took on risk by signing fixed-fee and disease-specific contracts.

Compounding the problem, pharmaceutical costs have risen dramatically, with some managed care companies reporting drug cost increases of more than 20 percent per year for the past several years. Labor costs also continue to rise and staffing shortages

worsen as mainstream industry attracts workers away from healthcare jobs in key areas such as nursing, pharmacy, therapy and information technology. Increased labor costs from recruiting and overtime also threaten financial stability. All of these factors put great economic pressure on healthcare organizations, and in turn physicians, to prescribe and deliver only services that are "necessary" or, more specifically, only services that CMS or other payors will cover. Additionally, organizations are trying to increase revenue while focusing on patient satisfaction, physician retention and loyalty, and expanding services.

Advances in medical technology promote the treatment of more patients on an outpatient basis. While fewer hospital beds are filled, the patients who are admitted require more acute care. This change in the composition of the inpatient population puts more pressure on healthcare providers to improve operational efficiencies – a challenge that will only worsen as baby boomers age.

For more than 25 years, starting with work done by John Wennberg, M.D. at Dartmouth, researchers documented that the variability in healthcare delivery has produced a broad range of financial and healthcare outcomes. Although research clearly shows the benefit of following standardized, evidence-based treatments, few physicians or organizations use these proven methods. Unlike other industries that continually re-engineer their processes to enhance performance, healthcare rarely does. Healthcare organizations often lack the infrastructure, technology solutions and organizational matrix to effectively change processes, particularly when physicians are involved.

For organizations to succeed, they must deliver safe and effective patient care at a cost that is less than the amount they are paid for providing it. Healthcare organizations that implement the best and most comprehensive solutions incorporating appropriate, proven technologies and effective processes will survive these difficult and ever-changing times. It is crucial, however, to incorporate the right technology system – a system whose expert decision-making technology assists a physician rather than impeding his approach to patient care.

PATIENT SAFETY

Patient safety encompasses prevention of accidents; inappropriate, harmful or mistaken treatment planning; poorly performed procedures; and questionable or missed diagnoses.

Although some formal, basic processes exist to address patient safety, most of these evolved from risk management efforts. Such initiatives included bed rails, patient transport via wheelchairs, and banning of over-the-counter medication from patient hospital rooms. These measures represent only the first steps to ensure patient safety and do not take advantage of the more sophisticated, second tier efforts that utilize information technology. To truly achieve acceptable levels of patient safety requires the implementation of clinically intelligent, flexible information systems that standardize processes, remove the potential for human error and place the physician and others in the pure role of decision-maker and caregiver, offering their services with the maximum amount of patient information, medical knowledge and clinical decision support.

The knowledge base that comprises clinical medicine expands dramatically each year, making it almost impossible for physicians and other clinicians to keep pace with the changes. In an average year, more than 200,000 new peer-reviewed medical journal articles are printed. The inherent complexity of healthcare forces physicians to establish individual "internal guidelines and rules" which each physician follows in an effort to optimize patient outcomes and reduce potential treatment errors. For this reason, physician behavior closely parallels that taught during the physician's training and historically has been slow to change.

Treatment management and clinical decision support can provide physicians and other clinicians access to evidenced-based medical knowledge at the point of care. This support can be customized to be relevant to each individual patient. Unlike static reference sources, these tools are dynamic and "intelligent," offering physicians useable information that can have a direct impact on treatment planning, patient care and subsequent outcomes.

APPLYING EVIDENCE-BASED MEDICINE

Historically, physicians practiced medicine autonomously with almost complete sovereignty over their actions. Over the past half-century, however, this situation has progressively changed. Payors seek to control spending by intervening in the care process. Healthcare organizations search for tools that can help reduce the variability in the patient care process so that they can improve quality and control the cost of delivering care. For example, Blue Cross of California recently established a bonus plan for physicians based upon specific quality measures. Patients also demand greater control over their treatments. All of these individuals and organizations have one goal in mind: to improve the quality of medical care. Applying validated therapies through the application of evidence-based medicine is one proven way to improve healthcare outcomes while conserving resources.

Access to clinical content at the point of care is as important as the development of useful and practical evidence-based medicine guidelines. Historically, guidelines have been deployed with very limited results. The nature of clinician workflow requires the clinical content to be presented in a format that matches that workflow; otherwise the guidelines never reach the caregiver to affect the care delivery. Heavy patient loads do not offer clinicians much time to access most clinical content, whether in the form of paper guidelines, medical textbooks or Medline searches during care delivery.

With the advent of computerized physician order entry systems and the integration of legacy systems through new technologies and computer architectures, clinical decision-makers are getting their first opportunity to effectively apply evidence-based guidelines to patient care. Using these tools, disease-specific, evidence-based guidelines can be presented proactively as part of the clinical decision process, thereby influencing the care that is delivered. Clinical content at the point of care matches the natural workflow needs of the clinician, and it allows for easy application to the current patient. In addition, these electronic versions of evidence-based medicine are automating many processes such as pharmacokinetic calculations, drug-error checking, and CMS documentation compliance checking.

By incorporating evidence-based medicine at the point of care, clinicians can now access the best available clinical content when making treatment decisions. As medical treatments change, these same workflow interfaces can deliver the new clinical content through revised evidence-based clinical guidelines. Clinicians are able to apply this new knowledge without having to change their basic care processes. In paper-based systems, extensive education and training would be necessary to effect behavior change and maintain those gains. Incorporation of evidence-based medicine at the point of care allows for the inclusion of education while eliminating the need for special training. Without such an integrated approach to offering content, it is unlikely that the clinician will access and then apply most newly delivered evidence-based medicine guidelines.

COMPUTERIZED PHYSICIAN ORDER ENTRY

The many definitions of computerized physician order entry (CPOE) make comparisons of clinical experiences with such technology difficult. The American Hospital Association defines CPOE as "a system for direct entry of one or more types of medical orders by a physician into a system that transmits those orders electronically to the appropriate department."

CPOE provides numerous benefits including elimination of illegible orders, reduction in transcription, rapid routing of orders to the appropriate destination and, with decision support capabilities, the checking of orders against varied clinical knowledge bases. Decision support enhances care delivery by searching for potential treatment conflicts.

Alerts and reminders, automatically generated in real-time, notify clinicians of therapeutic actions that may positively or negatively impact care. These automatic alerts free clinicians to concentrate on collecting and synthesizing patient information to develop effective treatment plans rather than engaging in routine memory tasks. In addition, the sheer volume of medical information today makes it impossible for any clinician to effectively and efficiently do the checking that is possible with clinical information technology tools.

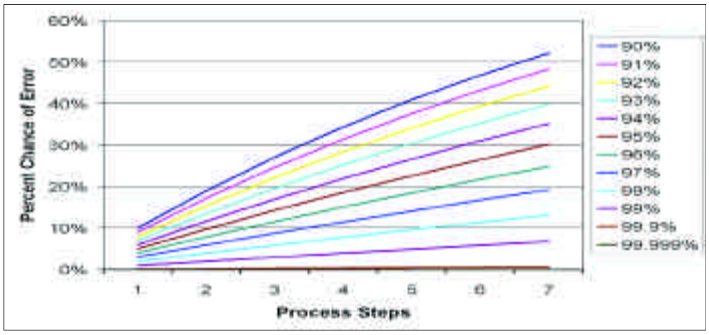
To reduce variation and make outcomes more predictable, some organizations may deploy CPOE to implement standard orders and clinical guidelines. CPOE offers organizations a way to introduce evidence-based medicine quickly. By using these standardized, up-to-date clinical knowledge bases and automatic alerts and reminders, patient treatment plans are regularly evaluated against accepted clinical practice, thereby increasing the probability of consistent care and reproducible outcomes across patients with similar disease processes.

UNDERSTANDING THE IMPORTANCE OF PROCESSES

Starting with the early theories of Deming and Juran, and extending to the work of Berwick, Leape and others, errors occur because of defects in processes, not the unpredictability of human error. In fact, human error is quite predictable and should be expected in all processes. As Leape writes: "(Errors) result from defects in the design and conditions of medical work that lead careful, competent, caring physicians and nurses to make mistakes that are often no different from the simple mistakes people make every day, but which can have devastating consequences for patients."

All processes can be reworked to be either more or less complex. Intuitively one would expect that the more complex the process, the more likely that an error will occur. Also, it is intuitive that processes that have more steps are, by definition, more complex than processes with fewer steps.

FIGURE 1: Percentage Chance of Error by Process Ste



For example, a two-step process with a 50% chance of a successful outcome at each step has a 25% chance of success overall. A more complex seven-step process that has a 90% chance of success at each step produces a 52% chance of an error and a failed process. Figure 1 displays various probabilities of success for a step in a process, various numbers of steps for a process and the probability of an error occurring in the process. Only with a step of 99.9% do success rates probably approach acceptable levels (i.e., 0.7%). Incidentally, Web-server reliability of 99.999% (the five nines), the standard for information technology, produces successful process rates 100 times greater than the 99.9% level.

IDENTIFYING THE PROBLEM

Introductory management theory states that "you can't manage what you can't (or don't) measure." This same principle applies to healthcare. Without workable surveillance tools to collect data on each medical error, nothing can be learned from the analysis of the events.

Most critical in a safe and quality-focused system is the establishment of an atmosphere and culture by senior managers and thought leaders that encourages medical error reporting by all levels of the organization. In addition, staff members who report errors must be given some level of immunity and protection for their participation. This may be somewhat easy for those not directly involved in delivering care that are protected by their employee status in the organization (i.e., corporate liability protection), but it is more difficult for nurses and pharmacists.

Physicians, who usually are not employed or controlled by the organization, present the greatest challenge. Nevertheless, a serious effort must be made, and moral suasion can often be an effective tool in this situation to encourage reporting. Even in cases of alleged malpractice, the actual details of each case eventually are discovered, so open reporting, in reality, presents only marginal risk. In contrast, quick admission of mistakes can lead to reduced patient injury and sometimes avoidance of litigation altogether. Further, if the recommendations of the Institute of Medicine are followed by Congress, legislation is likely to offer some degree of confidentiality and liability protection for properly implemented error reporting systems.

SUMMARY

Poor processes, not error-prone people, are the main cause of medical errors. In the words of researcher Lucien Leape, MD: "Errors result from faulty systems, not from faulty people, so it is the systems that must be fixed."

Medical errors are the result of system and process failures that directly lead to errors or contribute to human mistakes that directly or indirectly result in poor outcomes. Medical errors cannot be significantly reduced without systematic changes in processes. Our experience during the last 40 years of space flight and commercial aviation has demonstrated how failure analysis can lead to stronger, more error-resistant systems that can reduce the likelihood of poor patient outcomes and avoid medical errors. Front-end analysis and definitive preventive steps are critical to identify potential problems before they occur.

To understand what is needed to improve outcomes, healthcare organizations must first identify the medical errors that are occurring, categorize those errors, examine the processes associated with those errors, and rework the processes that are producing the poor outcomes. Ignoring the problem by not measuring errors, denying their existence, or blaming the individuals involved in the processes does nothing to eliminate the preventable morbidity, mortality and waste of resources that poor processes generate each day.

Organizations that do systematic analyses of their systems and processes will be able to identify their weak points. With this knowledge, they will be able to configure effective measures that can improve their solutions to reduce poor outcomes. Effective implementation of process changes and attention to the steps in medication management and other clinical processes can deliver significant positive changes to outcomes and patient safety.

Achieving the goals of patient safety, treatment optimization, and physician adoption, while obtaining a return on investment, requires a new view of care delivery and acceptance of new ways of doing business. Ease of use, customization, ease of access and preservation or enhancement of personal workflow drive the acceptance of clinical information tools.

Author Biographies:

Barry P. Chaiken, MD, MPH, Vice President, Medical Affairs, McKesson Information Solutions, provides client medical management, product development and marketing support for this medical informatics solutions company.

Donald L. Holmquest, MD, PhD, JD, Practice Leader, McKesson Information Solutions, served as Scientist-Astronaut at NASA where he studied the role of process design and error analysis in the prevention of system failures.

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