

The Case for Critical Test Result Management:

Closing the Communications Loop
to Enhance Patient Safety

Contents

Summary..... 1

Introduction..... 1

Patient Safety Issues 2

Joint Commission Steps-in..... 2

Massachusetts Leads the Way 3

Individual and Institutional Issues, Responsibilities 4

Challenge to Management..... 4

Technology-based CTRM Solves the Problem 5

Successful CTRM Implementation 6

From Desirable to Mandatory..... 7

Summary

The Joint Commission, the Institute of Medicine, the American College of Radiology, and other healthcare authorities have identified delays and failures in the communication of critical test results as a threat to patient safety. As the operator and host of diagnostic departments such as radiology, clinical labs, and cardiology, hospitals have a duty to ensure that there are systems in place to ensure the timely communication of critical test results. Now, for the first time, affordable, user-friendly Critical Test Result Management (CTRM) technology is available, enabling hospitals to automate the communications process and measure the performance of clinicians against performance goals. The experience of more than 130 hospitals nationwide reveals best practices.

Introduction

Communication and information technologies are advancing at breathtaking speed. Logistics services can electronically track a letter or a package from the time it is picked up until it is received, and monitor it every step of the way. Toll road authorities can electronically record the payments or violations of tens of thousands of vehicles every day. Retailers and suppliers can automatically track, order and ship products as needed.

Hospitals, too, are struggling to keep up with advances in information technology, both in the clinical units and in administrative and support functions. Indeed, departments such as Radiology, Clinical Laboratories, and Cardiology employ a dizzying array of diagnostic technology. And yet, this is a paradox of modern medicine: diagnostic clinicians have at their disposal remarkably powerful tools to identify disease processes, but communicating critical test results in a timely manner remains a dangerously weak link in healthcare delivery. As the courts and professional committees have pointed out, failure to communicate critical test results in time to make a difference for the patient renders advanced technology and professional expertise meaningless to the patient.

Fortunately, affordable, user-friendly technology for verified medical communications has been available since 2004, and a growing number of hospitals are embracing it. Similarly, as the solution has gained traction, hospital administrators are beginning to recognize that they have a role to play, too. Hospital administrators must ensure that diagnostic clinicians have the systems necessary for the timely communication of critical test results, and administrators must be able to measure individual and institutional performance against established goals. This new institutional focus is called Critical Test Result Management (CTRM), and advances in technology now make it not only feasible, but mandatory.

A Patient Safety Issue

Despite the proliferation of advanced communications devices – digital landline phones, video phones, mobile phones, pagers, PDAs, voicemail, answering systems, fax, e-mail – technology, until now, has failed to ensure that a diagnostic clinician can communicate critical test results in a timely manner to an ordering physician. It seems at times that we have more devices but no advancements in communication. The problem threatens patient safety and has drawn the attention of the Joint Commission on Accreditation of Healthcare Organizations, now referred to simply as the Joint Commission. The main accreditation body for hospitals and other healthcare organizations is placing new emphasis on communication problems.

It is a longstanding problem. Radiologists, such as Leonard Berlin, MD, chairman of Radiology at Rush North Shore Medical Center, Skokie, IL, addressed it in detail in the April 2002 issue of American Journal of Roentgenology (AJR). The results of a study by Gracey and Associates for the Florida Radiological Society confirmed the seriousness of the communication problem. In short, communication delays, failures, and errors account for a shockingly high proportion of medical malpractice claims against radiologists. This is both intolerable and preventable. Critical test results, especially from ancillary services such as Clinical Laboratories and Radiology, are subject to systematic errors partly because of the large numbers of tests that are ordered and the relative infrequency of urgent results that require immediate attention, as well as the lack of direct consultation in the ordering of such studies. In a 500-bed hospital, there may be more than 2,500 laboratory tests and 300 imaging studies requested each day.

Freestanding outpatient facilities face the same issues in terms of quality assurance and risk management. A recent study involving the Physicians Insurers Association of America, a national consortium of physician-owned liability carriers which pool claims data, highlights the problem: delay or ineffective communication in diagnosis of breast cancer resulted in malpractice awards twice as high as when effective communication was employed. Indemnity payments were 15-fold as high as a percentage of the total awards to plaintiffs due to miscommunication.

Effective communication of critical test results is an inherent component of healthcare delivery. Federal regulations applying to Clinical Laboratories expressly state (Sec. 493.1234, subpart K, Quality Systems for non-waived testing, Department of Health and Human Services, Centers for Disease Control and Prevention) [a] laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized individual who orders or receives test results. Unfortunately, the laboratory and radiology communities have been slow to respond and have not adequately addressed the problem at the local level. On the national level, the American College of Radiology revised its Guidelines on Communication in 2005 to reflect the need for direct communication where findings suggest the need for immediate medical intervention, where conclusions differ in substance from prior interpretations, where findings suggest a condition that is likely to worsen over time if not promptly addressed, and where findings are unclear and follow-up is required. The Clinical Laboratory community's response at a national level has been less specific.

Joint Commission Steps In

The new, broader communications standard from the Joint Commission, which took effect Jan. 1, 2004, spotlights this weak link in healthcare delivery. The standard and National Patient Safety Goals state:

Goal 2 Improve the effectiveness of communication among caregivers.

2A For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person receiving the information record and “read-back” the complete order or test result.

2B Standardize a list of abbreviations, acronyms, symbols, and dose designations that are not to be used throughout the organization.

2C Measure and assess, and if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by the responsible licensed caregiver, of critical test results and values.

2E Implement a standardized approach to “hand off” communications, including an opportunity to ask and respond to questions.

According to the Joint Commission, beginning in January 2004, the existing “read-back” recommendation also applies to all “critical test results” reported verbally or by telephone, not just medication orders. The Joint Commission says the term “critical test results” refers to all diagnostic tests including imaging studies, electrocardiograms, laboratory tests and studies, http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/08_hap_npsgs.htm. In plain language, getting the diagnosis right is only half the battle for a radiologist or other diagnostic clinician, according to the Joint Commission. Healthcare providers have not done their job unless the communications loop is closed and error-free. Radiological communications are expected to follow well-established but still evolving rules and standards. These rules and standards are spelled out in statutes, in 20 years of case law, and in professional guidelines, namely those of the American College of Radiology.

California radiologist R. James Brenner, MD, JD, points out, however, that the ACR guidelines are important, but legal standards of care arise not from professional guidelines but rather from appellate court decisions and legislation. In the landmark 1979 case, *Phillips v. Good Samaritan*, in Montgomery County, Ohio, the state courts held that **“communication of the result so that it may be beneficially utilized may be altogether as important as the diagnosis itself.”** Dr. Brenner notes that this ruling has been cited by other courts more than 60 times since it was first issued.

Massachusetts Leads the Way

Perhaps no state has exerted more leadership on the issue of Critical Test Results (CTR) reporting and management than Massachusetts. In March 2002, an advisory group of hospital representatives was convened by the Massachusetts Coalition for the Prevention of Medical Errors (the Coalition) and the Massachusetts Hospital Association (MHA). The group reached a broad consensus that errors in the process of communication of test results were both frequent and had the potential for serious harm.

The initial meeting led to a patient safety initiative during 2002-2003 that ultimately resulted in comprehensive guidelines for communicating and managing critical test results. The final report and an editorial were published in the February 2005 issue of *The Joint Commission Journal on Quality and Patient Safety*:

<http://www.macoalition.org/Initiatives/docs/CTRgriswold.pdf>
and
<http://www.macoalition.org/Initiatives/docs/CTRbates.pdf>

The consensus group defined "critical test results" as "values/interpretations for which reporting delays can result in serious adverse outcomes for patients. The scope included laboratory, cardiology, radiology, and other diagnostic tests in inpatient, emergency, and ambulatory settings".

In their accompanying editorial, Drs. David W. Bates and Lucian Leape noted that a fundamentally sound policy and system for handling critical test results includes four elements:

1. Organizations must reach consensus about which results are considered critical.
2. The organization must have an effective process for communicating the results to the key clinicians involved.
3. The organization needs a fail-safe program to ensure that backup procedures are implemented if the initial communication efforts break down for any one of a number of reasons.
4. It is essential for the organization to have in place monitoring systems for it to know how it is doing with respect to the above dimensions.

Individual and Institutional Issues, Responsibilities

Both clinicians and institutions share responsibility for communicating critical test results. Individual physicians are responsible for issuing an authenticated, substantive report with a reasonable interpretation. The institution's systems must enable the physician to communicate diagnostic test results in a reasonable and expeditious manner, especially when the findings are urgent and/or unexpected. Above all, the system must ensure that the communications loop is closed. This means it is not enough to report an urgent or unexpected finding to an anonymous or open-ended system. There must be documentation of the communication and verification, i.e. date and time, that the communication was received by the responsible clinician.

The legal concept of negligence consists of four elements: Duty, Breach, Causation, and Damages. In the case of radiology, for example, a radiologist has the duty to produce satisfactory images, make a reasonable interpretation, and effectively communicate those findings to the referring physician. If the radiologist fails to fulfill his/her duty in any respect, and the patient suffers in any way, the physician could be held negligent and liable for damages. Clear, error-free, timely communication is fundamentally important to effective medical care. The challenge is to harness the power of 21st century technology to eliminate this weak link and support the optimal delivery of medical care.

Challenge to Management

It is one thing to establish guidelines and policies for communicating critical test results, but hospital administrators face the daunting challenge of managing and measuring hospital-wide performance against established goals and targets. This requires verification and documentation of each communication. Considering that multiple diagnostic departments and hundreds of physicians can be involved, this is no small task. Indeed, without technology to automate the process, it is virtually impossible. Today, if a hospital administrator is asked about systems for communicating CTRs, he or she likely will say they already have procedures and systems in place for that. In reality, these "systems" are mostly prescriptive and manual, inconsistent across departments, haphazard, inefficient, and prone to error. Consequently, management has little visibility into this facet of the enterprise and is essentially flying blind – ignorant about the potential risk to patients. These inefficient manual "systems" also drain staff productivity and reduce time that can be devoted to patient care. The problem vividly illustrates how inefficient systems and patient safety are very much related.

Even computer-based work flow and reporting systems typically lack the capability of real-time reporting and verification of receipt by the ordering physician. The systems and technology are passive in nature. They provide *electronic notification*, not CTRM. Reports might be available online, but it is up to the referring physician to remember to check. There is no verification, and there is no special notification for critical test results. Nevertheless, as the adoption of electronic health record (EHR) systems grows, there is a misconception that this will solve the problem of communicating critical test results (CTR) because the systems can include an electronic notification feature for CTRs. Similarly, some radiology work flow systems also include electronic notification. It is a prescription for disaster and only provides a false sense of security. A recent article in the Journal of the American Medical Informatics Association shows why.

Author Hardeep Singh MD, MPH, and his colleagues looked at the effectiveness of an EHR system for CTR notification at the VA medical center in Houston. Although the authors feel the automation of CTR reporting is basically a good thing, the results of the study show the inadequacy of EHR systems for critical test result management (CTRM). The authors found that critical test results continue to be lost to follow up in a computerized test result notification system that alerted physicians through the electronic health record, and specifically that:

- Providers failed to acknowledge receipt of over one-third (368 of 1,017) of transmitted alerts.
- In 45 of these cases (4% of abnormal results), the imaging study was completely lost to follow-up four weeks after the date of study.

View a summary of the article at <http://www.jamia.org/cgi/content/short/14/4/459>. The lesson here is that electronic notification is not the same as CTRM. These kinds of results simply would not occur with an effective system for CTRM.

Technology-based CTRM Solves the Problem

CTRM is a technology-based strategy that ensures the prompt and verified communication of critical test results from a reporting clinician to the responsible ordering clinician in time to benefit the patient. It also provides hospital administrators with the ability to set communication goals, i.e. turn-around time, and monitor performance in real time.

So far, only one technology company has focused on the specific challenge of CTRM, although others are expected to enter the market. Nuance Healthcare, www.nuance.com/healthcare, in 2004 introduced the first and so far only technology-based CTRM solution on the market. The company has developed and marketed a hosted, software-based system for CTRM in one affordable and easy-to-implement enterprise solution (U. S. Patent No. 6,778,644). Its solution, called Veriphy™, is the industry leader.

Nuance Healthcare has found that the technology itself must have certain key attributes in order to enable CTRM. The goal is to ensure that a report of a critical test result reaches the ordering clinician in a timely manner and the receipt is verified automatically. This active, as opposed to passive, technology leads to better, faster care for the patient. The essential attributes of an effective system for CTRM are:

- *Universal Access.* The system is accessible to every ordering clinician.
- *A unified, customizable solution for all diagnostic departments.* The CTRM technology works the same, regardless whether the critical test result is coming from radiology, cardiology, or the pathology lab. The technology also allows each diagnostic department to establish its own rules for reporting and escalation.
- *Active rather than passive technology.* The technology alerts the ordering physician in real time when a report is available to be heard and indicates degree of importance. This enables the referring physician to determine whether a report requires immediate attention.

- *Easy to maintain.* The hospital's physician directory must be integrated with the CTRM system and be easy to update.
- *Enterprise reporting and measurement.* The system enables management to set performance goals and standards and to measure performance on a regular basis.
- *Compliance with communication rules and guidelines is built in to the system.* The technology should make compliance with Joint Commission standards and the Coalition guidelines affordable and easy.

Successful CTRM Implementation

As the first company to focus on and solve the challenge of enabling Critical Test Result Management, Nuance Healthcare has acquired from its experience with more than 130 leading medical centers nationwide unsurpassed knowledge and insights about CTRM best practices. These institutions range from leading public and private teaching hospitals to small community hospitals. Nuance Healthcare has found that success in implementing CTRM largely rests on a few fundamental principles:

- *CTRM is institutionally sanctioned, supported and embraced as a strategic process.* This means that top management and the medical staff leaders are totally committed to CTRM as a quality of care and patient safety issue, and are committed to overcoming inevitable resistance and obstacles.
- *Outreach to end-users is essential.* Inertia and passive resistance on the part of ordering clinicians will thwart the best technology. Both ordering clinicians and reporting physicians must feel a sense of ownership of the CTRM solution.
- *Process for continuous improvement.* Testing technology advances. Reporting technology advances. Services and institutions grow and change. The CTRM solution must be able to grow and change, or it will wither on the vine.

Technology Automates Processes

Nuance Healthcare's patented system combines voice messaging and data technologies to create an intelligent and verifiable system for communicating critical test results. As a hosted system, Nuance Healthcare's Veriphy™ requires no investment by the hospital in new software or hardware and can be implemented in as little as 45 days. Veriphy closely adheres to the recommendations of the Massachusetts Coalition. Key features of Veriphy include:

- One-call activation – the diagnostic physician makes one call from a phone or computer, states the finding in as much detail as is necessary, and the system does the rest;
- Automated notification and verification of receipt – the system alerts the ordering clinician that a critical test result message is pending, continues to send alerts until the message is retrieved, and documents when the message is received;
- Color-coding of message alerts – red, orange, yellow – indicates degree of urgency;
- Searchable archive of original voice messages for 10 years or longer;
- Web-based monitoring and documentation of all activity;
- Automated compliance with all legal and professional standards for medical communications;
- Seamless integration with the hospital's physician directory, allowing for simultaneous updates.

And perhaps most importantly, from a manager's perspective: Veriphy automatically and in real time tracks and measures physician and department performance against institutional targets or goals. An administrator simply logs on to a secure area of the web site and views a detailed report showing how well or poorly clinicians are performing in communicating critical test results. The system easily identifies outliers, enabling administrators to take quick corrective action. Technology-based CTRM has ushered in a new era of enterprise visibility for hospital administrators.

As the pioneer of CTRM technology, Nuance Healthcare also is in the unique position of having comparable performance data from a broad range of hospitals. Nuance Healthcare is able to show hospital managers how well their institution is performing compared to other hospitals of similar type and size. Similarly, Nuance Healthcare is able to identify best practices and help hospitals implement them.

From Desirable to Mandatory

Clearly, in the medical field, given the gaps in communication that can directly impact patient care in a negative sense, the adage "no news is good news" is no longer a viable position. In January 2004, the Joint Commission, as part of its National Patient Safety Goals, directed affected parties to institute programs that would reduce or eliminate communication errors and delays, reaffirming these notions in every year since. Five years earlier, the Institute of Medicine published its report, "To Err is Human," drawing attention, among other issues, to this important healthcare related issue. The emphasis on communication errors reflects both a longstanding directive for the medical community as well as an increasing recognition that delays, failures, and errors in transmittal of important test results can and do threaten patient safety.

The evolution of such issues extends beyond the relationship between the ordering healthcare provider and the radiology or pathology department. It involves the institution itself – its compliance with professional standards and its need for a community profile that invites confidence. The institution also bears potential legal liability for such errors and is commonly named as a defendant when things go wrong. Moreover, if the institution is aware or should be aware of shortcomings in its domain, such liability is elevated. Even recognizing such increased potential liability is difficult when there is no enterprise approach that identifies, beyond self-reporting, those conditions that must be redressed.

Enterprise problems require enterprise solutions. The harmful consequences of failures in communication undermine virtually all of the other quality improvement mechanisms that have been initiated within healthcare environments. Proficiency and even excellence in diagnosis and treatment fall flat when such standards cannot be regularly applied in practice. Delivering benefit to the patient requires a system that facilitates, promotes and ensures not the simple issuance of a report but the completed communication of results. Now, for the first time, hospital managers have the tools they need to implement CTRM. The advance in technology will make it easy for clinical staff to communicate critical test results and for hospital managers to assure the quality of a fundamental aspect of patient care. Technology-based CTRM is an enterprise solution for an enterprise problem. When done properly, it is active, cost-effective, easy to use, and not dependent upon individual habits or practices. Yet, it still addresses the needs of all stakeholders – patients, clinicians, hospitals, and regulators.

The experience speaks for itself™