

Patient Safety Alert: Test Result Notification

Issue 15 | August 2013

The Academic Medical Center Patient Safety Organization (AMC PSO) recently held a collaborative convening session of its Ambulatory Patient Safety Leaders. Key opinion leaders from member outpatient medicine divisions and patient safety departments gathered to offer and share their expertise and opinions regarding the most current issues in Ambulatory Care. The AMC PSO's goal in sponsoring this meeting was to:

- Discuss current issues in Ambulatory Care and what can be done to improve patient safety and quality
- Propagate the natural progression of CRICO's established mission of helping health care providers turn credible patient safety data into effective action

To encourage didactic discussion, issues related to communication of abnormal test results were presented in a round-table format.

“FAILURE TO FOLLOW-UP:” AN EVOLVING MALPRACTICE ISSUE

Diagnostic errors are the most frequent claim basis for medical malpractice suits in the United States (Phillips et al. 2004; Studdert et al. 2006) and mistakes related to patient testing can directly lead to serious diagnostic errors (Fernald et al., 2004). Recent peer reviewed studies estimate that 15% to 54% of medical errors reported in the primary care setting are related to the patient testing process (Dovey et al. 2002; Makeham et al. 2002; Fernald et al., 2004). One of the more obvious safety issues regarding patient laboratory and imaging diagnostics is the failure of clinicians and staff to follow-up with patients on their test results, particularly abnormal ones (Muff and Bates, 2001; Poon et al. 2004).

A health care professional's failure to follow-up on abnormal diagnostic test results represents one of the most problematic safety issues in the practice of outpatient medicine (Murff and Bates, 2001; Poon et al. 2003) and is an issue that has garnered national attention in the courts, the press, and among

professional medical associations. When test results are not acted on in a timely and appropriate manner, clinicians risk jeopardizing patients' safety and satisfaction and expose themselves to issues of liability. Data from medical malpractice carriers point out that 30% of office-based, diagnosis-related malpractice cases can be attributed to failures in the patient-testing follow-up system, as well as that increases in patient volume and testing options have made “failure to follow-up” one of the most rapidly growing areas of outpatient medical malpractice litigation (Murff et al. 2003). This area is of concern to both patients and clinicians (Murff et al. 2003; Poon et al. 2003), which only further highlights the ongoing need to address these lapses.

As discussed by Poon et al. (2004), previously published peer reviewed papers examining the communication of test results to patients indicate that:

- 36% of clinicians do not routinely inform their patients about test results
- Only 23% of physicians have a reliable system to ensure their patients of abnormal test results
- Approximately 33% of abnormalities in thyroid stimulating hormone, pap-smears, and mammograms do not receive timely follow-up in accordance with established clinical guidelines

Research documenting the actual failure rates of clinicians to inform patients about abnormal test results is sporadic. However, recently Casalino et al. (2009) conducted a retrospective medical record review of almost 5,500 patients and asked (a) how frequently do primary care physicians fail to inform patients of abnormal results, (b) does the structure and type of process that a private practice has in place to gather, record, track, and communicate test results influence the notification failure rates across different physicians and, (c) does the use of electronic medical records (EMRs) compared to partial EMRs (the use of both paper and electronic records) or pure paper records influence the notification failure rate?

These investigators found an overall failure rate of 7.1% (1 in every 14 tests) for physicians to either inform, or document informing, their patients of abnormal test results, suggesting this error was relatively common among the primary care practices sampled. Interestingly, the failure rate to notify patients of test results was significantly higher in practices that used a combination of paper and EMRs compared to those that used either all EMRs ($p=0.03$) or all paper records ($p=0.007$). The single greatest factor influencing the communication of test results, however, appeared to be the quality of the system, or process, through which practices managed results. Simply put: practices with better, more structured systems in use had lower notification failure rates and also had physicians who were more satisfied with the process used.

THE NATURE OF THE TESTING PROCESS

The National Ambulatory Medical Care Survey (NAMCS) of 2002 reported that family physicians and general internists order lab testing in 29% and 38% of patient encounters respectively, and request imaging studies in 10% and 12% of the individuals they treat (Hickner et al. 2005). Clearly, the results from these requests produce an inordinate amount of information for clinicians to appraise, implement, and act upon. A recent review of an internal medicine practice at the Brigham and Women's Hospital in Boston, MA, estimated that a full-time primary care physician on average reviewed 60 pathology/radiology reports and 930 hematology/chemistry data points in a given week (Poon et al. 2003).

Besides the sheer quantity of results available, the complexity of the testing process is also increased through a number of external influences (Hickner et al. 2005). These include multiple managed care insurers paying for these tests and tests being ordered from a number of different laboratories, hospitals, or imaging centers.

Equally complex is the testing process itself. In a detailed dissection of the steps involved in acquiring tests or images for a given patient, Hickner et al. (2005) divided the procedure into three distinct phases (adapted from Elder, McEwen et al. and Hickner et al. 2005):

- **Preanalytic Phase**

- Ordering: A physician makes a decision to obtain a test and communicates that decision to the appropriate personnel

- Implementation: The order is transmitted to those performing the test and/or obtaining the specimen(s); the patient is prepared for the test and/or the specimen(s) are obtained

- **Analytic Phase**

- Testing is conducted

- **Postanalytic Phase**

- *Tracking*: The test order is monitored internally (within the primary care practice) until the results are returned
- *Return of results*: The results are sent back to the office (and to the physician) from testing facilities or locations
- *Response*: The physician makes a decision as to the meaning of the results and creates an action plan
- *Documentation*: Physician and/or staff note in the medical record that the result has been reviewed; that the physician has responded to the result; and that the patient has been notified
- *Notification*: The patient is informed of his/her test result and the physician's recommendations for action
- *Follow-up*: The process whereby abnormal results and/or results require additional communication with the patient or health care colleagues

An error in any one of these steps can have lethal consequences (Elder, McEwen et al. and Hickner et al. 2005). In inpatient and most-likely outpatient settings, errors in the pre- and postanalytic settings account for over 90% of the mistakes made in patient testing.

While little research has been conducted specifically regarding the communication of test results to patients, a review of the subject by Hickner et al. (2005) brings forth several notable points in the published literature:

- Patients prefer their clinician to initiate the process of notification
- Patients want their test results even when they are normal

- Written notification of abnormal results can often reduce patients' anxiety and may reduce rates of loss to follow-up

The documentation of patient notification by clinicians is also a crucial step in the testing process, particularly for reasons of remuneration and liability. The legal defense of malpractice claims can often depend upon evidence of proper patient notification of test results.

BEST PRACTICES, GUIDELINES, AND RECOMMENDATIONS

Currently, there is no one universal set of guidelines delineating the process for the notification of test results to patients. Results of tests and diagnostic procedures that fall significantly outside the normal range may indicate a life threatening situation. The objective is to provide the responsible licensed caregiver these results within an established time frame so that the patient can be promptly treated. While many health care institutions and private practices have their own individual procedures and standards defining their own best practices, the National Patient Safety Goals from the Joint Commission offer some direction for reporting critical test results.

Elements of Performance for Reporting Critical Results of Tests and Diagnostic Procedures on a Timely Basis (Joint Commission, 2013)

1. Develop written procedures for managing the critical results of tests and diagnostic procedures that address the following:
 - The definition of critical results of tests and diagnostic procedures
 - By whom and to whom critical results of tests and diagnostic procedures are reported
 - The acceptable length of time between the availability and reporting of critical results of tests and diagnostic procedures
2. Implement the procedures for managing the critical results of tests and diagnostic procedures
3. Evaluate the timeliness of reporting the critical results of tests and diagnostic procedures

To address this lack of a clear set of detailed healthcare guidelines, in 2002, an advisory group of hospital representatives convened by the Massachusetts Coalition for the Prevention of Medical Errors and the Massachusetts Hospital Association (MHA) developed a set of safe practice recommendations for communicating critical test results in a timely and reliable way to the clinician who can take action. The Coalition and MHA assembled a multi-disciplinary stakeholder group that included representation from the laboratory, cardiology, radiology, and physicians and nurses from inpatient and ambulatory sites.

The Safe Practice Recommendations that evolved from this coalition directly addressed the following issues:

- Who should receive test results
- Who should receive test results when the ordering clinician is not available
- What specific results require timely and reliable communication
- When the results should be actively reported to the ordering provider, with explicit time frames
- How to notify the responsible provider
- How to design, maintain and support the systems involved

The full details of these guidelines and the specific contexts under which they are designed to be implemented are provided as an appendix in the following peer reviewed article:

Hanna D, Griswold P, Leape LL, and Bates DW. 2005. Communicating Critical Test Results: Safe Practice Recommendations. *Jt Comm J Qual Patient Saf.* 2005;31(2):68–80.

MANAGEMENT OF PATIENT TEST RESULTS

Recent advances in health information technology (HIT) offer tremendous opportunities to manage patient healthcare information and increase patient safety through the use of EMRs, computerized physician order entry (CPOE) and clinical decision support systems (CDSS), (Bates & Gawande, 2003; Parente & McCullough, 2009). The EMR provides clinicians with a longitudinal source of patient information including medical history, previous encounter history, known drug

allergies, and additional relevant patient information. CPOE allows clinicians more precision in ordering patient imaging and laboratory diagnostics and helps prevent the duplication of such tests. There is some evidence the CDSS is effective in changing providers behavior, and CDSS could be used to capture abnormal test results, store them, and present them to providers with patient-specific, evidence-based reminders for follow-up actions (Murff et al. 2003).

The effective use of EMRs can help create a healthcare environment that better ables providers to protect themselves in today's medical liability climate (Chiang and Hier, 2010). Studies specifically show improved patient safety in hospitals and ambulatory care centers that use EMRs specifically through reducing five of the most common medical errors: (1) prescribing erroneous medications, (2) inappropriately ordering laboratory tests for the wrong patient and/or at the incorrect time, (3) filing system errors, (4) dispensing incorrect medications, and (5) failing to promptly respond to abnormal laboratory test results (Dovey et al. 2003).

The potential of these and similar electronic systems was even recognized by the United States Congress which passed the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act, providing financial incentives to physicians and hospitals to adopt HIT (Chiang and Hier, 2010). HITECH, in part, makes Medicare or Medicaid funds available for physicians who meet "meaningful use" criteria.

Even though the acceptance of new HIT by health care practitioners and their supporting staff remains critical to the successful use of EMRs and CPOE to increase patient safety and reduce healthcare costs, survey research has revealed that clinicians often view EMRs as costly, awkward, and disruptive to their daily workflow (Chiang and Hier, 2010).

In spite of this, a recent study found that as of 2011 more than half of all office-based physicians were using EMRs or some form of HIT (Decker et al. 2012). Only one-third of these systems, however, had the basic features considered important to achieve the potential of HIT, such as the ability to record information on patient demographics, view laboratory and imaging results, maintain problem lists, compile clinical notes, or manage computerized prescription ordering. The lowest use of HIT was found among non-primary care specialists, physicians aged 55 and older, and in clinicians working in smaller practices (1-2 providers) (Decker et al. 2012). A separately published analysis

reported that 91% of physicians were eligible for Medicare or Medicaid HITECH funds and about 51% of all physicians intended to apply (Hsiao et al. 2012). However, only 11 percent both intended to apply for the incentives and had HIT or EMR systems with the capabilities to support even two-thirds of the core objectives required to meet the criteria for HITECH "meaningful use" (Hsiao et al. 2012). Together, these two investigations suggest that there are widespread gaps in readiness for HIT, particularly among older physicians and smaller practices.

Progress has also been observed in hospitals adopting and implementing HIT (DesRoches et al. 2012). From 2010 to 2011, the percentage of hospitals with any HIT rose from 15.1% to 26.6% and the share of hospitals with a comprehensive HIT increased from 3.6% to 8.7%. In 2011, 18.4% of these same hospitals had systems that met the criteria for "meaningful use" in at least one unit and 11.7% achieved "meaningful use" across all units. Definite gaps between hospitals have been observed, though, based upon an institution's teaching status, location, and size. Generally speaking, smaller, nonteaching, rural hospitals lag behind their counterparts in embracing HIT.

CONCLUSIONS

- The failure to follow-up with patients when abnormal test results are received is a common, avoidable medical error, particularly in primary care settings
- "Failure-to-notify" errors are one of the fastest growing bases for medical malpractice suits
- Health care professionals should be aware of the multiple steps involved in patient testing and where errors can occur within each phase
- Clearly established systems and guidelines for the ordering, tracking, managing, review, and notification of patient test results greatly reduce the probability of a "failure-to-notify" error
- The use of HIT such as EMRs, CPOEs, and CDSS can provide valuable support to clinicians in managing all phases of patient testing, including notification

- The majority of practitioners appear open to HIT and believe it can help them be more effective
- The use of HIT is increasing in both private practice and hospital settings
- Some of the largest stumbling blocks to HIT use includes: cost, a potential negative impact on workload, and the perception that such systems are awkward to use and interact with
- Non-teaching, small, rural hospitals are the slowest to adapt HIT as are smaller, private practices with specialist non-primary care physicians and physicians over the age of 55 in general

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