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PERSPECTIVE

Diagnostic Tests: Improving Timely Completion, Ensuring Professional Review and Executing Appropriate Intervention. A Six Step Approach to Reduce Errors

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ABSTRACT

Diagnostic tests are an important part of clinical medicine. They help screen for disease in asyptomatic patients, establish or rule out a diagnosis in symptomatic patients, provide important prognostic information and allow for objective monitoring of the disease process and its management. Diagnostic errors can therefore result in significant medical harm. A major burden of diagnostic errors resides not in the improper ordering or performance of the test, but rather in the improper follow up of a properly completed test – system errors. This study provides a six step program to abolish the potential for these errors.

Keywords: diagnostic errors, morbidity, mortality, malpractice, patient dissatisfaction

Abbreviations: AIDS: acquired immune deficiency syndrome; BMJ: British Medical Journal; CAT: Computer axial tomography; ECG: electrocardiogram; HIV: Human immunodeficiency virus; INR: international normalized ratio; MRI: Magnetic resonance imaging; PSA: prostate specific antigen

1. INTRODUCTION

Diagnostic tests are invaluable in medical practice. They are generally ordered to establish or rule out a diagnosis based on a high clinical suspicion of disease in symptomatic patients. Once a disease is ruled in, they help provide objective evidence of the nature, severity and prognosis of the illness and are often instrumental in proper monitoring. They also help screen for diseases in asymptomatic patients. Diagnostic tests may be not ordered or improperly requested due to lack of proper examination or cognitive assessment by the health care provider. (Norman et al, 2010) Overconfidence (Berner et al, 2008) and bias could also play a role. (Kostopoulou et al, 2008) According to a recent study, 44% of the diagnostic pitfalls occur in the testing phase, with failure to order, report or follow up. (Schiff et al, 2009) Tests are also

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subject to misinterpretation by the physician. A late or misplaced report results in a delay in diagnosis and potential harm to the patient. (Hickner et al, 2006) The health care burden is often significant. (Newman-Toker et al, 2009) Although several methods and systems exist to help monitor these reports, surveys indicate that many physicians still lack a reliable way to track and report test results to their patients. (Singh et al, 2012) Even more problematic is communicating test results to the patient and ensuring an appropriate follow up after discharge from an emergency room or an inpatient hospital unit. These situations entail significant medical and legal implications. (Tehrani et al, 2012) We investigated and implemented a six step system to ensure test completion, professional interpretation and appropriate intervention.

2. METHODS

In the past many tests would result in either the test not being done, no report being sent to the office, reports being filed in the patient's chart without a physician review, report not being communicated to the patient or the lack of an appropriate intervention. The causes were usually multi-factorial. Work was done in a physician's private clinic. It involved the physician, medical assistants, secretary and as an extension of the clinic, the test sites. The study design was observational. A daily and an end of month review of all ordered tests was done. Any tests not marked completed are rescheduled. Appropriate notation is made in the patient's chart indicating the reason behind non-completion and the corrective action taken. These problems were overcome by implementing the following six steps and evaluating the impact:

2.1 Involve

The patient is counseled as to why the test is needed and how it will be done.

2.2 Implement

This includes scheduling the test, getting insurance authorization if required, making transportation arrangements if needed, reminding the patient on the day of the test, confirming completion of the test and finally ensuring receipt of the report. A copy of the test request is filed in a separate binder. All laboratories and outside testing sites are also instructed to communicate significant results to the practice by phone and fax, in addition to the formal report being sent mail.

2.3 Interpret

The reports are presented to the physician daily for review and signature.

2.4 Inform

The patient is informed of the results. If an intervention is needed, an appointment is scheduled.

2.5 Insert

All received reports are checked daily and the copy of the order is stamped indicating completion and review. The report is only then filed in the patient's chart.

2.6 Intervene

Appropriate medical intervention, if needed, is instituted.

2.7 Impact

The result of the implication of this six step program was judged after a twelve month period.

3. RESULT

In the past, many ordered tests resulted in either no report or no proper follow up. Following implementation of this program, major improvements were noted. A retrospective twelve month review revealed no loss of follow up, except for an occasional incidence of non-compliance. The latter almost always resulted in the patient rescheduling and completing the test. The six step program also resulted in better patient care and increased patient and staff satisfaction. As a result patient referrals increased and the risk of malpractice diminished.

4. DISCUSSION

Abraham Verghese, MD, MACP, Professor, Stanford University School of Medicine, California, may have rightly said: *"I joke, but I only half joke, that if you come to one of our hospitals missing a limb, no one will believe you till they get a CAT scan, MRI, or orthopedic consult."* Physical observation and examination is a dying art. (Glover, 1996) Since a strong dependence exists on diagnostic tests and the reports, it is mandatory that these tests are done properly and timely and the reports are properly interpreted and the resultant information translated into patient management.

4.1 Indications for diagnostic tests

Diagnostic tests may be ordered to screen for an asymptomatic disease as early diagnosis is cost effective and results in considerable decrease in morbidity and mortality. Mammograms at or after age 40 and flexible sigmoidoscopy every 5 years at age 50 fall in this category. (ACS)

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Similarly in men, PSA testing is routine in men 50 years of age or older. (NCI) Diagnostic tests are most commonly ordered to rule in or rule out a disease, when there is a high clinical suspicion. For example, an ECG in a patient with chest pain has a significant impact on diagnosing an acute myocardial infarction. A negative or normal report is similarly equally significant. A test may confirm the absence of disease, for example cardiac catheterization to evaluate coronary artery disease in patients with suspected angina (Marcus et al, 1991) or a pregnancy test to exclude the diagnosis of ectopic pregnancy. (Lozeau et al, 2005) The knowledge that there is an absence of a serious illness plays an important role in reassuring patients and helps reduce subsequent symptom rates. (Petrie et al, 2007) Diagnostic tests may provide the proper time for intervention. An echocardiogram may dictate the time for a surgical procedure in patients with valvular disease. (Carabello, 1997) The function of prosthetic valves can similarly monitored by regular echocardiograms. (Bach, 2010) Tests are invaluable in obtaining both the timing of initiation of therapy and prognostic information in patients with established disease, like CD4 count in patients with HIV-aids. (Sterna et al, 2009) The effective dosage of a drug to ensure efficacy and prevent complications are often based on testing – for example INR in patients taking warfarin. (Gallus et al, 2000) Diagnostic tests are therefore an extremely important component of medical practice. And finally, patients subjected to diagnostic testing feel they received better care, when compared to those in the non-test group, even if the tests had no diagnostic value. (Sox et al, 1981)

4.2 Diagnostic errors

Diagnostic errors are common in medical practice (Wahls, 2007) and have the potential for moderate to severe harm. (Callen et al, 2011) In the Harvard Medical Practice Study, (Leape et al, 1991) diagnostic error accounted for 17% of preventable errors in hospitalized patients. Using the gold standard of 'autopsy', a systematic review spanning four decades, found that approximately 9% of patients experienced a major diagnostic error that went undetected while the patient was alive. (Shojania et al, 2003) Taken together, these studies imply that thousands of patients may be dying every year due to diagnostic errors. In an ambulatory primary care study, diagnostic tests for further workup (57.4%) were the most common reason for missing common diseases. A breakdown in patient-practitioner relationship revolving around these tests resulted in missing pneumonia (6.7%), decompensated congestive heart failure (5.7%), acute renal failure (5.3%), cancer (primary) (5.3%), and urinary tract infection or pyelonephritis (4.8%). The potential for serious harm is obvious. (Singh et al, 2013) Cognitive errors are not the only cause of diagnostic mishaps. The causes of diagnostic errors resulting in adverse effects are usually multifactorial. In a study by Hickner and associates, the majority of errors occurred in reporting results to clinicians (24.6%), implementing tests (17.9%), and general administrative factors (17.6). Other causes included errors in ordering tests (12.9%), clinicians responding to results (6.6%), notifying patient of results (6.8%), communication (5.7%) and other categories (7.8%). (Hickner et al, 2008) A highly computerized health system is also prone to errors resulting in treatment delays. In a study involving the VA system, missed results emanated from imaging studies (29 percent), clinical laboratory (22 percent), anatomic pathology (9 percent), and other (40 percent). (Wahls et al, 2007) In a recently published study, diagnostic errors accounted for nearly 29% of malpractice claims and were responsible for 35.2% of total payments – more than errors in treatment, surgery or medication. (Tehrani et al, 2012)

4.3 Limiting diagnostic errors

Diagnostic tests are ordered based on a high clinical suspicion of disease and invariably reveal a high incidence of abnormalities. However, errors are a widespread problem. Despite significant estimates of associated harm and death, this phenomenon remains largely understudied and underestimated. Several checklists have been suggested to minimize these errors. (Ely et al, 2011) Although information technology is improving diagnostic monitoring, implementation of the new systems is still in process and studies evaluating the positive effects remain lacking. (El-Kareh t al, 2013) Diagnostic errors have to look beyond those related to cognitive thinking of the health care provider. System-level failures are rarely addressed and may be the most powerful way to reduce these. (Spath, 2000) The six step implementation and monitoring system mentioned above ensures test completion, professional interpretation and appropriate intervention. It is easy to adopt and minimizes the risk of potentially dangerous omission errors.

5. CONCLUSION

Patient safety is often compromised by diagnostic errors. With present day medicine relying heavily on diagnostic tests, errors in all phases of testing – system errors, can lead to harm. Although some errors are inconsequential, many are serious. The toll on patient suffering, disability and death appears to be significant. (Graber, 2013) There are also legal implications for the clinician and the health-care system. Although incorporation of electronic health records has been beneficial, studies indicate that failed or flawed follow up remains at an unacceptable level. Implementation of a simple six step system considerably reduced the error rate in our practice. *'To irr is human'* is unacceptable in medicine. (Kohn et al, 1999) Rigorous outcome based studies are therefore required to further reduce diagnostic errors.

DISCLOSURE STATEMENT

The author has no conflicts of interest to disclose.

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