

# Saint Luke's Regional Laboratories Clinical Laboratory Letter

# **April 2014**

#### **Economics of Inpatient Laboratory Tests**

Laboratory testing for inpatients is not directly reimbursed but is folded into a single fixed global payment for an episode of care under a diagnostic related group (DRG). Payers are not concerned with how many tests are performed on a given patient admission because they will only reimburse a fixed global payment. However, hospitals and physicians need to be cognizant of test utilization, because ordering more tests than are necessary to care for a patient increases expenses and decreases the revenue margin from the global payment.

## Incidence of Inappropriate Laboratory Testing

Researchers from Beth Israel Deaconess Medical Center recently published a meta-analysis of 42 articles published between the years 1997 and 2012 that specifically addressed appropriateness of laboratory tests [Zhia etal. PLOS ONE 2013;8(11)e78962,1-8]. They determined the appropriateness of 1.6 million results of the 46 most commonly ordered tests. Using either permissive or restrictive review criteria, they determined that the rate of inappropriate laboratory test utilization ranged from 21% to 45%, respectively. Inappropriate testing occurred six times more often during initial orders than during repeat testing (44% vs 7%). Inappropriate testing was three times higher for low volume than high volume tests (32% vs 10%). In addition to overutilization, the authors also found a 45% rate of inappropriate underutilization. They did not detect a change in the appropriateness rate over the course of the 15 year study. This recent study corroborates the findings of all of the previous studies that have been published on test utilization during the past 30 years. Together, all of these studies have convincingly documented that the rate of appropriate test utilization by physicians remains dismally low.

## **Chance of One Test Being Abnormal**

For most tests, laboratories establish reference ranges by performing testing on healthy individuals and then excluding the upper and lower 2.5% of results.

The lab values of the central 95% of results from healthy individuals are included in the reference range. Therefore, 5% of test results from patients without disease will fall outside the reference range. For example, if hemoglobin levels were measured on 100 healthy individuals, 5 would be expected to have abnormal results.

Ordering several tests further increases the chances of a healthy person having at least one abnormal result. If two tests are ordered on a healthy individual, the chances of both being normal are 0.95 X 0.95 = 0.90. The following table illustrates that the chance of at least one test being abnormal increases with the number of tests ordered.

Number of Tests Ordered	Probability of Abnormal Result
1	5%
5	23%
10	40%
15	54%
20	64%

Therefore, ordering unnecessary tests increases the likelihood of an abnormal result, even though it may be totally unrelated to the underlying medical condition. If a health system laboratory reports 5 million test results per year, 150,000 of them will be falsely abnormal.

Patients can be harmed directly or indirectly from follow-up of these abnormal results. Often times, additional confirmatory tests are ordered and patients may be referred to a specialist, who may perform an invasive procedure. Patients can be harmed indirectly when false positive tests divert a physician's attention from more important patient care issues or unnecessarily result in postponement of a therapeutic procedure. This phenomenon has been called the Ulysses Syndrome in which a healthy patient undergoes a series of costly, painful and possibly dangerous investigations as a result of an initial abnormal lab result only to discover than nothing was ever wrong in the first place. Clearly, it is better medical practice to order only those tests that are needed to manage the patient during their hospital admission.

### **Screening for Prostate Cancer with PSA**

Since its introduction in 1991, PSA testing has dramatically changed the landscape of prostate cancer, creating a significant rise in cancer incidence and shifting the stage of disease at the time of diagnosis to a much earlier and potentially more curable stage. Today only 5% of men have metastatic disease at the time of diagnosis compared to 50% before the advent of PSA testing. Overall, PSA appears to detect cancer 5 to10 years sooner than DRE.

Although prostate cancer mortality has declined approximately 30% during this time, some experts argue that this decline is more attributable to improvements in treatment than screening.

Although the evidence remains conflicted regarding whether prostate cancer screening is associated with a reduction in mortality, it is clear that any benefit is accompanied by a significant rate of overdetection and overtreatment. Overdetection increases with age, rising from about 27% in men age 55 to about 56% at age 75. The European Randomized Study of Screening for Prostate Cancer (ERSPC) study demonstrated that 1410 men would need to be screened and 48 cases of prostate cancer would need to be treated to prevent one death over 10 years. Despite the fact that active surveillance is an option, more than 90% of men in the United States choose to undergo aggressive treatment, even if they have low grade cancer. This degree of potential overdetection and overtreatment is greater than that for any other cancer for which routine screening occurs. Potential adverse effects of overtreatment include bleeding, infection, erectile dysfunction and urinary and fecal incontinence. Moreover, the harms of screening accrue immediately, whereas potential benefits are realized only many years later.

Amid this continuing controversy regarding the merits of early detection of prostate cancer, the Prostate Cancer Advisory Committee of the American Cancer Society (ACS) revised its guideline on the early detection of prostate cancer (CA Cancer J Clin 2010;60:70-98). The revision states that prostate cancer screening should not occur without an informed discussion about risks and benefits. If the patient decides to undergo screening, PSA is the recommended screening test

with or without digital rectal exam (DRE). The age at which screening should be initiated depends on the patient's estimated risk of developing prostate cancer:

- Age 50 years for men at average risk
- Age 45 years for men at higher risk including African American men and men who have a father or brother diagnosed with prostate cancer before age 65 years
- Age 40 years for men at appreciably higher risk such as those with multiple family members diagnosed with prostate cancer before age 65 years
- Asymptomatic men with less than 10-year life expectancy should not be offered screening.

The American Urological Association (AUA) revised their Prostate Specific Antigen Best Practice Policy in November 2009 (J Urol 2009;182:2232-2241). This policy differs significantly from the ACS guideline. AUA stated that prostate cancer testing is an individual decision that patients of any age should make in conjunction with their physician or urologist. It recommended that prostate cancer screening with both PSA and DRE should be offered to men beginning at age 40 years and repeated annually. AUA no longer recommends a single PSA threshold value to prompt prostate biopsy. The decision to proceed to biopsy should be based primarily on PSA and DRE results but should also consider free and total PSA, patient age, PSA velocity, PSA density, family history, ethnicity, prior biopsy history and comorbidities. The AUA guidelines have been criticized because they are not supported by any convincing evidence.

At the other extreme, the US Preventive Services Task Force (USPSTF) concluded in 2008 that for men younger than age 75 years, the benefit of screening for prostate cancer was uncertain and the balance of benefits and harms could not be determined (http://www.ahrq.gov). They recommended against screening.

These 3 sets of discordant guidelines have done little to quell the controversy regarding prostate cancer screening. Physicians are still left with a bewildering array of disparate guidelines.