

## Optimization of Diagnostic Laboratory Testing

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**Running Title** *Optimization of Diagnostic Lab Testing*

### Abstract

#### Objectives

To assess the degree of overuse of laboratory testing, risks of over testing, causes of over testing and evaluation of approaches to optimize laboratory testing.

#### Methods

Personal observations based on more 90-year experience, and review of literature were used to determine the causes of over-testing and proposed methods for improving the optimization of testing. Opinions from personal experiences and issues about the future are expressed.

#### Results

Laboratory tests drive about 70% of clinical decisions, however, there is marked overuse of testing that adds an appreciable amount to the cost of healthcare, without improving the quality of healthcare. The cost of laboratory testing in the US exceeds the gross domestic product of more than 67% of countries. Despite having the highest cost of healthcare per capita, the US ranks at number 18 in terms of healthcare quality. Over-testing also poses safety risks to patients in the form of misdiagnoses, overtreatment, added cost to patients, society, and phlebotomy-induced anemia.

#### Conclusion

Laboratory testing costs can be curtailed without affecting the quality of healthcare. Issues of testing without specimen collection need to be addressed. National organizations are implored to include standards for optimal laboratory use in the accreditation of laboratories and hospitals.

**Keywords:** *Diagnostic laboratory testing; Appropriateness of laboratory testing; Efficiency of laboratory testing; Risk of excessive laboratory testing; Laboratory testing without specimen collection*

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## Introduction

Laboratory costs of health care in the US account for 0.47% of gross domestic product (GDP) [1]. However, this cost exceeds the total GDP of more than 67% of all other countries [2,3]. In the USA, healthcare costs account for about 18% of GDP and are the highest costs/capita of all countries, yet the US ranks at number 18 in terms of healthcare quality [4]. Thus, it could be argued that improvements in efficiency of healthcare, including diagnostic laboratory testing need not result in deterioration of the quality of healthcare. Various reports mention an overuse of laboratory tests of 20-60% [5-9]. It is generally recognized that laboratory test

results drive about 70% of clinical decisions, however, excessive testing does not add value. Promotion of appropriate utilization of laboratory testing can increase the efficiency of healthcare.

### Paradoxes in Laboratory Cost Controls

#### In-patient vs. out-patient testing

Cost of diagnostic testing, including laboratory tests, for hospitalized patients (in-patients) is included in the Diagnosis Related Groups (DRG) based reimbursements and the laboratory is a cost center for hospitals, as there is no separate reimbursement for laboratory testing [10]. Thus, the hospital administration is

generally and appropriately concerned with reducing laboratory costs. On the other hand, testing done on non-hospitalized patients (out-patients) is reimbursed by Centers for Medicaid and Medicare Services (CMS) and insurance companies, thereby removing incentives for controlling laboratory testing costs. It bears noting that before 1980s, the federal government reimbursed hospitals on a cost-plus basis. This changed markedly with the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) passage. In a series of steps, the funding for hospitals was based on the admitting diagnosis, e.g., a patient admitted with community-acquired pneumonia garnered a fixed payment from CMS. In the earlier version, an additional payment was added if the patient developed a urinary tract infection during the hospital stay or developed decubiti. However, now CMS does not increase the amount of payment for hospital-acquired complication. So, under this diagnosis-based reimbursement model, referred to as DRG, the payment for a given diagnosis is fixed, irrespective of how many diagnostic tests, imaging studies or antibiotics are used. Similarly, payment to physicians for their services was systematized using the amount of training, experience, and resources needed for a given service, *i.e.*, relative value-based units (RVUs). CMS periodically revises these payments, usually mandating reductions in payments.

The hospital administration generally implores the laboratory to increase its outreach to increase test volume and reduce the cost/test without focusing on appropriateness of testing. It warrants noting that reimbursement for testing, especially for tests sent to a reference laboratory, may not be fully reimbursed, and an appropriate use of laboratory tests remains relevant even when costs may be reimbursed. A notable exception to the reimbursement issue is when a test cost may not be covered fully by reimbursement, but performing the test is appropriate as the result may engender savings in other areas of the hospital. For example, when a test for fetal fibronectin was introduced, the cost of the kit exceeded the reimbursement for the test, however, laboratory implemented the test as it saved the institution far more than the cost of test by avoiding unwarranted hospital admission for women in threatened labor for childbirth. (Personal observation)

#### **Fragmented, redundant, and duplicative testing facilities**

Almost all hospitals have full-service laboratories. Even hospitals situated a stone's throw from each other have separate diagnostic facilities. It would be eminently suitable to consolidate testing not requiring a less than 4-hour turn-around time for all healthcare providers in a city, or a geographic area. However, this was not feasible even in the nationally integrated healthcare system of the Department of Veterans Affairs (VA). For example, a tertiary care VA in Western Pennsylvania offered elective testing, free of charge, to the four surrounding spoke hospitals, providing

mostly ambulatory and nursing home care, however, the hospital directors resisted the change. (Personal observation)

Regional or national issues are usually beyond the scope of authority and control for a given medical director of a clinical laboratory so most of the remainder of this communication will focus on issues that can be addressed at individual medical centers regarding optimization of laboratory usage [11]. However, national agencies, e.g., The Joint Commission (TJC), College of American Pathologists (CAP), American Medical Association and other professional associations could prescribe appropriate laboratory usage by creating standards that become a factor in the accreditation of laboratories and hospitals. At the hospital level, administration could assign the cost and responsibility for appropriate testing to the ordering services. State departments of health could use their authority for improvements in quality of healthcare to expedite consolidation of laboratory services.

#### **Causes of Overuse of Laboratory Testing**

The causes of laboratory test overutilization are multifaceted, multifactorial, and usually entrenched through generations of poor practices aggravated by less than evidence-based recommendations by organizations with apparent conflicts of interest [12-15]. Well-promoted national initiatives like "Choosing Wisely" have not significantly decreased the improper use of laboratory testing [16,17]. Even though futility of overuse has been documented in the literature, the practice continues unabated [18-20]. One notable exception to this unsatisfactory situation in laboratory usage has been a marked reduction in volume of blood and blood products used through initiatives like, "Why give two when one will do." [21,22].

**Some of the likely causes of overuse are addressed below.**

#### **Normal/reference values**

Normal values/reference ranges are usually set at the central 95% of test results in a healthy population. This results in a false positive rate of 5% in otherwise healthy people. If 20 analytes are tested on a healthy person, one of those results will likely fall outside the normal range [23,24]. "Abnormal" results prompt additional testing with the risk of additional false positives and anemia from blood loss due to phlebotomy [25,26]. Expert opinion is needed to standardize population-based results, as has been done for blood lipids, BMI and blood pressure, to provide clinically meaningful baselines. One major hinderance to developing uniform reference ranges is the lack of harmonization of laboratory tests. It strains credulity that only three analytes, Cholesterol, Creatinine, and Hemoglobin A1c have undergone international standardization, *i.e.*, harmonization. The coagulation calculated value of INR comes close to harmonization. With different laboratories using different methods for testing, references ranges would have to be developed for each method, not a feasible undertaking. For some

analytes, e.g., electrolytes, it may be easier to establish uniform reference ranges, however, that would be impossible for troponin. Despite being a critical test there is a 40-fold variation in results from different methods measuring Troponin I.

#### **Fear of malpractice**

The threat of malpractice is an oft-cited reason for over-testing as there is no penalty for over-testing but not testing may result in malpractice lawsuits due to perceived missed or delayed diagnoses. A comparison of providers engaged in over-testing vs. judicious testing did not reveal meaningful differences in outcomes [18,19,27,28].

#### **Poor training environment**

There is generally no accounting for excessive testing by trainees, but students and house staff are commonly taken to task for not getting laboratory tests [29]. Such a poor training environment also leads to more frequent and repetitive testing [30,31].

#### **Patient portal**

Release of results to patients, often before the provider has reviewed the data, is likely to lead to additional testing due to perception of abnormal test results, by patients, even when the variation from normal is not clinically meaningful. On the website, HealthTap, about 21% of the questions by users are about interpreting laboratory test results. (Personal observation)

#### **Patient satisfaction surveys**

While it is appropriate to seek client input, this has led to distortions in care. A provider with appropriately conservative use of laboratory testing and use of pharmaceuticals is likely to receive lower scores than a provider who caters to the whims of the patient, without necessarily providing optimum care [32].

#### **Vendor access to providers and bypassing the lab**

Sales personnel from companies that offer new tests often approach providers directly without involving the laboratory. This often results in providers ordering tests of doubtful usefulness that may not meet the criterion of medical necessity. Examples of overzealous marketing leading to overuse include assays for placental alpha microglobulin-1 for rupture of membranes, serum free light chain quantification, and Esoguard for esophageal lesions, without evidence of improved outcomes [33-35].

#### **Treatment protocols of questionable quality and utility:**

Many treatments become the community standards of care without undergoing rigorous testing for improvement in outcomes, e.g., endoscopic debridement of knee for osteoarthritis, and transfusion of fresh frozen plasma before endoscopic or diagnostic interventional radiology procedures for patients with questionably abnormal INR, without evidence of benefit of the unneeded treatment [36,37]. The number of endoscopic procedures at a

given facility is proportional to the number of providers with privileges for such procedures, rather than a demonstrated benefit of the procedures [38-40]. Such procedures are usually associated with biopsies that often provide little benefit. A recent example of a treatment protocol of doubtful usefulness is autologous stem cell transplantation in the treatment of multiple myeloma. The treatment not only does not improve overall survival, but it also does not improve quality of life [41,42]. All these treatments of dubious value add to the cost of laboratory testing and the overall cost of healthcare without improvement in the quality of healthcare.

#### **Misplaced incentives for providers:**

Relative value units (RVU) based compensation is partly responsible for laboratory overuse and misuse. As alluded to earlier, physician service payments are based on nationally developed standards for the relative value of a given service. Procedure-based services generally command higher payments and thus promote procedure-based care. Endoscopy is reimbursed at a higher value than interpreting an imaging study. Another example of wasteful use due to this incentive is hematologists using bone marrow examination when urine examination would be better for settling the diagnosis and monitoring of multiple myeloma. As mentioned above and addressed here, the RVU incentive is likely responsible for the vast overuse of endoscopies and endoscopic biopsies [38-40]. This applies to hospital-based physicians as well, for example doing more special stains increases RVU for the histopathologic interpretation service. Performing more immunofixation procedures adds revenue to the hospital and raises the RVUs generated for the physician. Many institutions base part of the compensation of a hospital-based physician on RVUs generated by the provider thus promoting excessive and inappropriate use of services. Medical centers should consider value-based compensation rather than favoring volume of service and procedures.

#### **Lab tests of questionable usefulness**

Overuse of laboratory tests of limited usefulness may be driven by reference laboratories with financial incentives for promoting such use. Two examples of such tests are serum free light chain assays and MASS-FIX MALDI for diagnosis of monoclonal gammopathy and ostensible detection of minimal residual disease without demonstrated superiority over gel-based assays or any improvement in outcomes [43,44]. Additional tests of limited usefulness that have been recommended for removal from the lab test menu include RBC folate, CK-MB, AST, free PSA, procalcitonin, and ova and parasite examination of stool. Several analytes are also suitable for minimum testing intervals such as Vitamin D, Vitamin B12, A1c, tumor markers, D-dimer, and gamma glutamyl transferase [45-56].

### **Lack of incentive for pathologists to enforce medical necessity criteria**

CMS ostensibly does not pay for medical tests that do not meet the requirement of medical necessity and, in theory, a laboratory medical director can refuse to honor such test requests [43]. A similar issue applies to repetitive testing [18,45,47]. Such actions are perceived by the providers as infringing on their prerogative of ordering diagnostic testing and creating an adversarial relationship with the laboratory medical director.

### **Optimization at Each Individual Health Center: Recommended Interventions**

The medical director of a given laboratory can try to promote measures to optimize laboratory utilization. A partial list of the various measures that have been employed at different centers is given in Table 1. All of these techniques are effective, depending on the commitment and persistence of the person implementing them [47]. Almost all the measures for optimization of laboratory utilization require support from the medical and administrative leadership of the hospital, which may not be an easy task for an introverted pathologist [57]. It is recommended that pathologists and laboratory scientists establish their bona fide with the hospital authorities by first focusing on non-controversial changes, e.g. reducing the frequency of panel testing, to demonstrate savings to the institution and gradually add changes to promote optimum use of laboratory. Suggesting new, scientifically valid tests in lieu of traditional ones would be useful in establishing the expertise of the laboratory. Similarly promoting measures that would improve the CMS ranking of the hospital would be welcomed. The techniques used with some success by the authors are presented first, followed by other suggestions.

#### **Testing panels**

Testing panels, including CMS approved panels, promote wasteful over testing. For example, including AST in liver panels adds little value [58,59]. Well-meaning panels created by individual laboratories also promote excessive, non-productive testing, e.g., anemia panels, and hypercoagulation panels [60,61]. Further duplication is added when providers add tests for individual analytes included in the panels. Panels tend to be repeated rather than testing only for those analytes specific to a patient's needs. Curtailment of panels, including CMS approved panels, can be implemented by limiting the frequency of panel orders. At this institution, Comprehensive Metabolic Panel (CMP), Basic Metabolic Panel (BMP) and Complete Blood Cell Count (CBC) with differential cell count are limited to once a day for in-patients, except in critically ill patients [62]. Data has been presented for removing AST, uric acid and calcium from chemistry panels [58-64]. The limited usefulness of eclampsia panel testing has been recommended for curtailment [65]. Hypercoagulation profile is

not suitable for use in hospitalized patients and is not available for ordering for in-patients [66,67]. Panels for auto-antibody testing are screened and testing narrowed to the medically necessary analytes [68,69]. Use of clinical decision support software may be beneficial in controlling overuse and costs [62].

#### **Tests with limited utility**

Several tests have limited usefulness and can/should be removed from the laboratory test menu, e.g., RBC folate, 1, 25 hydroxy vitamin D, total T4, insulin levels, CK-MB, thrombophilia testing, cancer screening tests, and procalcitonin [51-56,58-70]. If one of these tests is needed by a particular specialist, it could be ordered as a miscellaneous test. Pre-operative and post-operative testing without known risk factors are also suitable for curtailment because most such testing does not add value [71-73].

#### **Algorithmic testing and diagnostic management teams**

Stepwise testing is a more prudent use of laboratory resources and can be promoted by clinical laboratories. Examples of clinical situations suitable for algorithmic testing include the work-up of anemia, celiac disease, autoimmune disorders, monoclonal gammopathy, bleeding diathesis, and hypercoagulation [7,74-76]. Development of Diagnostic Management Teams, as promoted by Laposata, should be considered by institutions with appropriate expertise and resources [77]. Diagnostic management Team (DMT) consists of a multidisciplinary group that operates in a manner similar to that of a tumor board. The DMTs have emphasis on diagnosis and monitoring of hard to diagnose issues and are dependent on a high level of expertise by a laboratory physician. The DMT produces an expert-driven, patient-specific narrative not only for cases in which one is requested, but for all cases in multiple areas of laboratory medicine and anatomic pathology. This value-added activity considers clinical information and laboratory data, meets on a regular schedule, includes their diagnostic conclusions in the medical record, and provides information not known to non-expert physicians. The success of such teams depends on the contribution of a person with outstanding expertise recognized by providers outside the laboratory. Diagnosis and monitoring of coagulation disorders are a common condition where DMTs have reduced errors.

#### **Change from culture to molecular testing in microbiology**

Most laboratories have embraced the shift from culture to molecular testing for microbiologic testing. The change has improved sensitivity and reduced turn-around time for results [78]. Such testing is suitable for consolidation within a town or geographic area.

#### **Shifting the cost of diagnostic tests to the ordering service**

Under the current system of fee for service, providers have little



incentive for curtailing laboratory tests. For in-patient testing a hospital could assign budgets for laboratory tests to each service. A more practical method, as a first step, may be billing the ordering service for reference laboratory testing costs. This was a short-lived experiment, seen by one of the authors, at one institution. Department of Medicine that generated the bulk of test requests requiring use of reference laboratories objected to this model and given the usual status of Chief of Medicine in the hierarchy, the hospital discontinued the practice with resulting increase in reference laboratory use that was then the responsibility of the laboratory. (Personal experience)

#### Cost controls of questionable ethical practice

Laboratory tests done during the three days prior and 14 days following discharge are considered part of the in-patient stay and are not reimbursed. Laboratories may engage in unethical behavior by postponing testing for follow-up care, e.g., genetic testing for tumors, to more than 14 days after discharge [79].

#### Provider education

Educating the providers about appropriate utilization of laboratory tests is essential, time consuming and requires on-going effort, which provides little return to the pathologist or laboratory scientist. A new category of laboratory professional, namely, Doctor in Clinical Laboratory Sciences (DCLS) could be deployed

to round with providers and advise about laboratory tests in the same vein as Pharm Ds do for stewardship of pharmaceuticals, especially antibiotics [80].

#### Anatomic pathology optimization of diagnosis through consolidation at centers of excellence

While not exactly appropriateness of use, digital pathology is eminently suited for facilitating consultation with experts in each area [81]. If it could be paired with centralized tissue processing facilities and slide imaging at large centers in a given geographic area, it has the potential to shorten the time to diagnosis and ease of consultation. Remote experts could be engaged to review representative samples as a quality assurance/improvement measure.

#### Conclusion

Controlling laboratory testing overuse and diagnostic stewardship have gained national attention and this may be an opportune time for a concerted effort by individual laboratory directors and national laboratory medicine, and healthcare organizations to bring about change [82]. Radical changes based on market economy should be considered, e.g., assigning budgets to clinical services for laboratory and imaging testing based on the DRG reimbursement model.

**Table 1:** Partial list of various measures that have been tried to reduce lab costs [47].

Stop recurrent orders, e.g., daily CBC in nonbleeding patient [83].
Stop extra work, e.g., (a) manual diff on routine CBCs, (b) Urine culture on negative dipsticks [84], (c) IFE on normal SPEPs and specimens with known monoclonal Ig [7].
Pathologist approval for expensive tests, e.g., genetic testing [85]
Limit the frequency of testing, e.g., viral load assays, Hep B surface antigen testing, Hb A1c [86,87].
Pathologist approval for frequently mis-ordered tests, e.g., hypercoagulable state work-up [88].
Substitute tests for low yield methods, e.g., Giardia and Cryptosporidium antigen testing for stool ova and parasites [89,90].
Limit panels, e.g., anemia work up; hypercoagulation panel; must order individual tests [91].
Shift blood drawing to requesting party/site
Offer/facilitate add-on tests and reflex tests [92].
Pop-up information for, or stopping, frequently mis-ordered tests, e.g., Protein C, Protein S and Anti-thrombin III, frequent repeats [93,94].
Reveal cost of tests with test menu
Provide data on laboratory costs incurred by each provider, peer group comparison, and best practice data [95].

Report inappropriate test utilization to credentialing and privileging committee, similar to inappropriate blood utilization [96].
Bring high volume reference lab tests in-house [97].
Discontinue outdated/obsolete tests, e.g. LE prep, bleeding time, stool O&P, RBC folate, Urine hemosiderin cells [70,98].
Issue vouchers for Lab tests or establish quota for lab tests/house staff [47].
Limit ordering privileges to specialists, e.g., IGRA TB testing and HIV genotyping to Infectious Disease and Pulmonary Medicine [99].
Promote use of diagnostic algorithms with reflex testing, e.g., work up of Celiac disease, protein electrophoresis [7,100].
Educate users about tests of limited usefulness, e.g., stool culture in children with non-bloody diarrhea [101].
Reduce the volume of blood collected [102].
Shift testing from hospitalized patients to out-patient status [103].
Cancel duplicate orders, e.g., Magnesium and CMP [104].
Present objective data specific to your setting, e.g., overuse of SPEP with IFE, Serum free light chains [7,44].
Limit tests of dubious value, e.g., tumor markers for screening, CMP and CBC for annual physicals, PSA in an 85-year-old, ANA for joint pain, influenza screen during off-season [105].
Reduce false positive blood cultures [106].
Reduce/eliminate stat tests [107].
Consolidate services within a geographic area [108].
Join buying consortia, e.g. Novation [109].
Shift costs, e.g., Activated prothrombin complex in-lieu of FFP [110].
Do not repeat critical value [111].
Remove analyte of dubious utility from panels, e.g., AST and calcium in panels [58].
Charge the lab cost to the ordering service [112].

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