

Laboratory Tests for Case-Finding in Ambulatory Care: Application of a Conceptual Framework

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Abstract: Recent efforts to reduce health care costs have focused attention on laboratory tests, and methods for evaluating laboratory tests for case-finding are needed. Diagnostic yield (proportion of patients with laboratory tests that resulted in a new diagnosis), therapeutic yield (proportion of patients with laboratory tests that resulted in a new therapy), cost per new diagnosis, and cost per new therapy were adapted from a published conceptual framework for evaluating laboratory tests to evaluate frequently used laboratory tests for case-finding in the ambulatory setting. The therapeutic yield of routine tests in ambulatory patients is approximately 15% for lipid tests, 3% for the chemistry profile, and less than 1% for the Complete Blood Count (CBCs), sensitive Thyroid Stimulating Hormone (TSH), and urinalysis. The cost per new diagnosis associated with treatment is approximately \$100 for lipids, \$300-\$1100 for CBC, chemistry profile and urinalysis, and \$2000 for the sensitive TSH. The application of this framework and information on the diagnostic yield, therapeutic yield, cost per new diagnosis, and cost per new therapy can be used to make informed decisions about the use of laboratory tests for case-finding in ambulatory adults in a managed care setting.

Introduction

Health care reform discussions center around the increasingly high costs of medical care. The importance of evaluating the health services provided to patients as well as the outcomes they experience is widely recognized, as payers try to reduce costs and providers strive to make informed choices about health care resources used to maintain quality of care for their patients.

Efforts to reduce costs will not spare any cost center in the new health care environment. Laboratory tests are a natural focus of efforts to reduce costs. Although the cost of individual tests is low, in aggregate substantial health care resources are devoted to laboratory tests. A likely early focus of efforts to reduce the use and therefore costs of laboratory tests is the ambulatory setting, because many of those

tests are for “screening” or “case-finding” and result in negative or normal values in most patients.

Elsewhere the author has presented a conceptual framework for evaluating laboratory tests for case-finding in ambulatory patients¹. The focus of this paper is on how to use the diagnostic yield, therapeutic yield, and costs of laboratory tests to make informed decisions about resource use in the ambulatory setting. The “diagnostic yield” is the proportion of patients tested who have a new diagnosis, and the “therapeutic yield” is the proportion of patients who have a new diagnosis associated with a change in their therapy, where change may mean initiating a new therapy, modifying an existing therapy, or stopping a therapy.

Ambulatory Testing

Tests are obtained in the ambulatory setting to search for early disease in asymptomatic patients, to evaluate presenting problems in symptomatic patients, to monitor patient responses to therapy, to watch for adverse effects of medications and other treatments, and to obtain information about the severity of disease and prognosis. The evaluation of laboratory tests in the ambulatory setting must take into account the purpose for which a test is ordered, since different criteria may be used in evaluating a test that was obtained as part of a diagnostic evaluation or for monitoring therapy. This paper focuses on tests obtained in ambulatory patients to search for a condition or disease that is not related to the reason for the patient's visit, that is, "case-finding."

"Case-finding" and "screening" often are used interchangeably, but the two terms have different meanings and implications. Ideally, "case-finding" should be reserved to describe the test ordering by the physician in the office setting to identify conditions in asymptomatic patients and "screening" should be reserved to describe programs to test the general population in other settings. Clinicians should be aware of criteria that are used to evaluate screening procedures and tests in populations, because these same criteria may be applied to evaluate the use of laboratory tests obtained for case-finding in the ambulatory setting.

Several years ago, the World Health Organization (WHO) formalized six basic criteria for screening², which have been reformulated and restated in many different ways but are still widely accepted. Screening is indicated when the condition, test, and treatment fulfill the following criteria: (1) the condition for which the screening test is performed should have a significant effect on

the quality or quantity of life; (2) the condition should have an asymptomatic period during which it can be detected; (3) the incidence of the condition should be sufficiently high to justify the costs of screening; (4) an acceptable test should be available; (5) acceptable methods of treatment should be available; and (6) treatment when the patient is asymptomatic should yield superior results to treatment when the condition would become symptomatic.

Randomized controlled trials of multiphasic screening have produced information to test these criteria. Perhaps the best known study of routine tests for case-finding is the Kaiser Permanente study of the multiphasic health checkup, which used a randomized design to compare a comprehensive, multiphasic checkup to usual care. The study compared the outcomes of 5156 plan participants who were urged to have yearly multiphasic health checkups with the outcomes of a control group of 5557 who had access to the multiphasic checkup but were not actively encouraged to complete a yearly checkup. The cost of this multiphasic health checkup was approximately 10% of the annual per capita health care costs in 1967 and 1968. Follow-up reports of the outcomes of this trial were published in 1978³ and 1986⁴. There were no differences in all-cause mortality or disability in the group that received yearly multiphasic examinations compared to the usual care group. There was 30% reduction in "postponable" causes of death, predominantly those due to colorectal cancer, hypertension, hypertensive heart disease, and stroke. No difference in any outcomes was noted that could be attributed to a routine laboratory test.

Another randomized controlled trial of

multiphasic screening was performed in 574 families from three socioeconomic groups in the Salt Lake City area in the 1970's. The use of health services, morbidity, health status, and attitudes were measured over one year. There were no significant differences in morbidity or attitudes; an increase in hospitalization was observed in the multiphasic health checkup group compared with the usual care group⁵.

Although routine laboratory tests can identify early manifestations of several conditions, the WHO criteria for screening are not met for most conditions that could be detected by routine laboratory tests in the ambulatory setting. The Canadian Task Force on the Periodic Health Examination, the American College of Physicians, and the U.S. Preventive Services Task Force have used similar methods to review available evidence and make recommendations about the use of the CBC, chemistry profile, lipid tests, sensitive TSH, and urinalysis as case-finding tests in ambulatory adults. The table summarizes the recommendations from these expert panels (Table 1).

Perhaps the most striking fact is the general agreement that routine CBC, chemistry panel, and thyroid disease screening tests are *not* routinely indicated in the otherwise generally health adult. Also of note is the recommendation that the interval for obtaining a serum cholesterol level should be every 5 years. The expert panels differ in their recommendations for routine urinalysis for case finding. The urinalysis has been recommended for pregnant women and in patients with diabetes by the U.S. Preventive Services Task Force, which also has stated that it may be "prudent" to obtain a urinalysis in preschool children and in older adults.

These recommendations are important

because they have implications for laboratories. The data from a Mayo Clinic prospective study of 531 ambulatory adults suggests that if these or similar recommendations were followed, the number of laboratory tests ordered would be substantially reduced. The reduction would be 65% for CBC, 57% for chemistry profile, 50% for lipids, 65% for sensitive TSH, and 38% for urinalysis. Clearly, if these guidelines were used in a managed care environment for routine case-finding in ambulatory adults, there would be significant impact on laboratory test volumes⁶.

Although these expert panels have recommended against using routine laboratory tests for case-finding in otherwise healthy adults, patient expectations for the tests remain high, and physicians still frequently obtain these tests in the ambulatory setting. As insurers raise barriers to use of tests and treatments to try to reduce health care costs, it is imperative that clinicians and laboratories make informed decisions about test use. Obstacles exist that make this process difficult. The condition, test, or treatment may not meet WHO criteria for screening, and the test may be judged as unnecessary or inappropriate. The needed information may not be available: Patient outcomes may occur days, weeks, or even years after the laboratory test has been obtained and treatment initiated. Laboratory tests alone may not be sufficient to produce good patient outcomes. Laboratories have no control over the treatment decisions, quality of treatment provided, or patient compliance with provider orders. Therefore, the relationship between the diagnostic test and the therapeutic outcome must be evaluated.

Test	American College of Physicians	Canadian Task Force on the Periodic Health Examination	US Preventive Services Task Force
CBC	Not Recommended	Not Recommended	Not Recommended
Chemistry	Not Recommended	Not Recommended	Not Recommended
Lipids	Males & females, age 18 or older, every 5 years	Males ages 30-59, every 5 years	Males & females, age 18 or older, at least every 5 years
Thyroid	Not Recommended	Not Recommended	Not Recommended
Urinalysis	Pregnancy	Not Recommended	Pregnancy, Diabetes Mellitus & possibly children < age 5 & adults >age 60

Table 1. Recommendations of Expert Panels for Laboratory Tests for Case-Finding in Ambulatory Patients

Diagnostic Yield and Therapeutic Yield

Recent studies from Basel, Switzerland, evaluated the use of routine CBC and chemistry for case-finding. The CBC was studied in a university clinic in an unselected cohort of 595 adults, predominantly young men (mean age 40; 62% male). The CBC was analyzed as consisting of four components (hemoglobin, mean cell volume, leukocyte count, and platelets). 65% of tests were obtained for screening or case-finding. Abnormal values were noted in 6%. Five patients had new diagnoses as a result of the laboratory test, and three patients were treated. Thus, the diagnostic and therapeutic yield of the CBC in this population was less than 1%⁷.

The routine chemistry profile was evaluated in an unselected cohort of 493 adults (likely a subset of the same patients in the previous study). The chemistry profile

consisted of 23 individual tests. 89% of the chemistry profiles were obtained for screening or case-finding. Abnormal results were noted in 11% of patients tested. 35 new diagnoses were made, 25 of which were associated with therapy. The diagnostic yield was approximately 7% and the therapeutic yield was approximately 5%, with most of the yield due to lipid tests⁸.

A Mayo Clinic retrospective study of 100 adult patients from Olmsted County or the surrounding area who had a comprehensive general medical evaluation reported the diagnostic yield and therapeutic yield of the CBC, chemistry profile, a thyroid test (usually sensitive TSH, but less often thyroxine), and urinalysis. The patients' mean age was 59 years, and approximately 60% were females. The patients had an average of 2.3 serious medical conditions, and the mean interval between the current

examination and their last comprehensive medical evaluation was just under 3 years. Approximately 70-90% of patients had routine tests for case-finding, and the majority of test results, as expected, were normal. The diagnostic yield of the lipid tests was greatest (12.3%), followed by thyroid (2.8%), CBC and chemistry (2.2% each), and urinalysis (1.1%). The highest therapeutic yield also came from the serum lipid tests, 9.2%. The therapeutic yield of the chemistry profile was 2.2%, and the therapeutic yield of the CBC, thyroid disease screening test, and the urinalysis were all less than 2%⁹. Similar results were found in a Mayo Clinic prospective study of 531 patients, although the contrast was greater: Therapeutic yield of lipid tests was 16.5%, chemistry profile 2.8%, and the others less than 1%⁶.

Cost Per New Diagnosis and Cost Per New Therapy

In a managed care environment, profit centers such as laboratories become cost centers. Providers of care are responsible for the costs of providing services for the patients in their care. Costs of routine laboratory tests for case-finding were estimated using the methodology recommended by the College of American Pathologists and standard accounting practices and estimates of diagnostic yield and therapeutic yield in ambulatory adults. The cost per new diagnosis associated with treatment is approximately \$100 for lipid tests, \$300-1100 for CBC, chemistry profile, and urinalysis, and \$2000 for sensitive TSH.

Charges to payers are, of course, higher than laboratories' costs of performing the tests. When estimates of the actual medical charges are used, charges (in a fee for service system) per new diagnosis and per

new therapy from the use of these laboratory tests for case-finding in ambulatory adults can be calculated. The charges per new diagnosis associated with initiating therapy are lowest for serum lipid tests at approximately \$325; between approximately \$2000 and \$3000 for the CBC, chemistry profile, and urinalysis; and almost \$11,000 for the sensitive TSH. Within managed care systems or other integrated health systems, a corresponding relationship of costs per new diagnosis associated with initiating therapy can be assumed.

Unfortunately, data are not directly available on patients' outcomes resulting from treatment initiated as a result of using the laboratory test for case-finding. Until such data are available, decisions about the use of laboratory tests for case-finding in ambulatory patients must be based on information on diagnostic yield and therapeutic yield, as defined in this paper.

Conclusions

More than half of "routine" laboratory tests in the ambulatory setting are now obtained for case-finding. Decisions about the use of laboratory tests for case-finding in ambulatory patients reasonably could be based on costs per new diagnosis or cost per new therapy. The therapeutic yield of routine tests in ambulatory patients is approximately 15% for lipid tests, 3% for chemistry profile, and less than 1% for CBCs, sTSH, and urinalysis. Actual costs per new diagnosis or new diagnosis associated with treatment are modest in light of other health care costs (\$100-\$2000 per new diagnosis treated). More information on patient outcomes resulting from laboratory tests for case-finding is needed to improve the decision-making process. Especially needed is information on

outcomes of case-finding for hypercholesterolemia, diabetes mellitus, and other conditions for which case-finding is potentially indicated. Laboratorians and clinicians must work together to control costs and to measure outcomes to ensure that we are actually achieving the benefits of effective treatments that are initiated for conditions detected by the use laboratory tests for case-finding.

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