

COMMUNIQUÉ

IMPROVING PATIENT CARE THROUGH ESOTERIC LABORATORY TESTING

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Test Utilization and the Clinical Laboratory

Background

The clinical laboratory has an important and expanding role in ensuring that laboratory tests are appropriately utilized in clinical practice. Laboratories are discovering that they are well positioned to provide medical guidance and direction for clinicians who are trying to maneuver their way through the increasingly complex world of laboratory testing, including genetic-driven diagnostics and therapeutics. There are literally thousands of laboratory tests that clinicians might request as they evaluate a particular patient, but it is difficult, if not impossible, for any one individual to be proficient in all areas of medicine. Because of the number and the complexity of these tests, physicians are realizing that they have gaps in their knowledge and understanding of these assays. In addition to providing guidance to clinicians, test utilization efforts may also be driven by financial realities as laboratories try to rein in laboratory costs or in response to payer programs and policies

that reduce payments to providers. Whatever the underlying reasons, the clinical laboratory needs to take the lead in developing a successful test utilization initiative.

So, why the sudden interest and enthusiasm for test utilization? Health care costs in the United States are thought to approach \$2.5 trillion per year, and laboratory and pathology testing accounts for \$60 billion or about 4% of total health care costs. However, that percentage is increasing rapidly, with some experts estimating that laboratory costs are skyrocketing at a 15% to 25% annual increase. Molecular and genetic assays are driving this escalation, as the explosion of genomic knowledge has led to novel genetic assays for almost any common, or even rare, disease process. This financial burden will clearly become a focus for payers and health care providers alike. It will be impossible to ignore the realities associated with laboratory costs and the need for defining appropriate test utilization.

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PT1K/89464

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Test Utilization Defined

Test utilization should be defined as a strategy for performing appropriate laboratory and pathology testing with the goal of providing high-quality, cost-effective patient care. A test utilization program must be focused on patient care, ultimately leading to a more efficient and cost-effective laboratory diagnostic approach to answer the clinical questions being asked. A test utilization initiative cannot be driven as a pure cost-control process. If the primary motive is financially instead of patient care driven, then any utilization program will either be short-lived or ineffective in its outcome. High-quality medical practice must be the driving force if a test utilization program is to be successful.

Mayo Clinic has defined the clinical value equation as: $\text{Value} = \text{Quality} / \text{Cost}$ with quality defined as $\text{Outcomes} + \text{Service} + \text{Safety}$. Clinical value increases when quality (ie, outcomes, service, and safety) is improved and cost is decreased.

$$\text{Value} = \frac{\text{Quality (Outcomes, Safety, Service)}}{\text{Cost}}$$

This is as relevant for the laboratory as it is for a clinical practice. No matter how we define test utilization, the clinical laboratory needs to understand the critical role it must play in our changing health care environment.

The Clinical Laboratory's Role

Laboratory professionals need to be fully engaged with the clinical practice in any test utilization process. It is not easy and requires interactions with clinical colleagues that may not always be comfortable. We need to be able to question test requests that come from our clinical colleagues, suggest appropriate tests to answer the clinical question being asked, and cancel test orders when they are inappropriate for the question at hand. Laboratorians must become comfortable and confident in these interactions. Our clinical colleagues have few incentives to order fewer tests, and they certainly are not being trained with

that intent in mind. So it becomes the laboratory's responsibility to identify utilization issues, implement a program that will achieve more effective laboratory testing, and establish processes from the beginning to the end of the testing cycle that lead to a successful laboratory test utilization program.

Test Utilization Control Process

The biggest questions that laboratories usually encounter when trying to develop a test utilization program are simple: "How do we do it?" and "Where do we start?" That we have these very basic questions emphasizes that no simple answers exist. A successful solution requires a multipronged approach that must involve the clinician, the laboratory, and clinically engaged pathologists and laboratory directors. The key is to understand how the clinical laboratory test cycle works, the roadblocks that invariably exist, and how the laboratory can integrate into these processes and overcome the roadblocks.

A utilization control process actually starts when the clinician begins to consider what tests are needed to evaluate his or her patient—whether for diagnosis, follow-up, therapeutics, or exclusion of disease. Appropriate ordering depends on the clinician having the correct core knowledge to make that decision. The laboratory enters the process early on as it provides that clinician with the tools to order the correct test. A test-ordering process often varies. The process for ordering clinical tests may be designed to make it easy for the physician to request any and all tests, or it may include prerequisites, requirements, or permissions that the clinician must fulfill prior to placing that order.

After the test order or specimen is received in the laboratory, the laboratory professional can play a more active role in the test decision process. Clinical laboratories are beginning to explore how to use algorithms, test guidelines, and test formularies to put appropriate medical and utilization reviews in place. Instead of taking the easier and passive role, "if the doctor orders it, we do it," clinical laboratories are beginning to explore how to use algorithms, test guidelines, and test formularies to put appropriate medical and utilization reviews in place.

An overall test utilization control process might look something like this:

1. Important test information (clinical indications, overall value of that test, test indications, etc) that is readily available is the first step for the laboratory engaging the clinician in a test utilization effort. This information should be available in an easy electronic format—whether it is linked to the electronic medical record, the electronic ordering system, other available electronic tools, or via smart phone applications. If that is not possible, a current laboratory test catalog may substitute. Electronic information is preferable as it is current and accurately represents recent changes.
2. Algorithms and test-ordering guidelines are the next step necessary to guide the clinician through a utilization process (Figure). While they are a small piece of the puzzle, testing algorithms and guidelines are essential tools in guiding both the clinician and laboratory toward appropriate test selection. The success of test-ordering algorithms and guidelines, however, depends on the clinician making the effort to seek out that information, and a busy clinician may lack the time or willingness to do so. It may be necessary to actively engage the clinician in discussions surrounding the use of algorithms using educational tools such as recorded videos, Grand Round presentations, publications, etc.
3. Other tools are available to assist in a utilization process. Some laboratories have implemented a test formulary patterned after the pharmaceutical model. The laboratory test formulary is used to limit access to certain tests and often requires authorization from a pathologist, subspecialist, or laboratory committee before a particular test can be ordered. Laboratories may use a tiered approach, with some tests available to all physicians, some complex tests available to only a subspecialty group of physicians, and other complex tests requiring written justification and committee authorization. Another approach that has been used to control test utilization is mandating that some tests can only be ordered after discussion with the laboratory pathologist. Whatever the process, test formulary restrictions may be driven by cost and reimbursement issues, known situations of test misutilization, or whether the test is performed in-house versus sent to a reference laboratory. Regardless of the underlying rationale, a test formulary by itself will have little impact, but appropriate test utilization requires active engagement with the clinical practice by the laboratory to ensure that the most effective testing strategy is being used to answer the clinical question.
4. Sometimes it may be necessary to use a “send and hold” process where a test may be sent to a testing laboratory (or even held within the ordering laboratory), but testing is not performed by the receiving laboratory until the sender notifies the receiving laboratory to perform or cancel the test. This strategy is utilized when an initial laboratory result is required to determine the need for the follow-up test, but delaying the shipment could impact specimen integrity. In this manner, the specimen is available for testing as soon as the initial result is released. For example, it is very appropriate that flow cytometry, molecular-based studies, and cytogenetic studies in hematologic disease be held until the bone marrow aspirate and biopsy are reviewed by the pathologist or until the initial round of testing is complete. A decision can then be made regarding if or what subsequent testing is necessary.
5. Reports must be clear and should integrate all the findings associated with an episode of care. Unfortunately, laboratory information systems do not always effectively transmit the intended information to the clinician. Laboratory reports are often just lists of results with no or minimal correlative interpretation. This can make it difficult, if not impossible, for the clinician to get the information he or she needs. The pathologist in particular needs to be engaged in this process to ensure that the reporting system is working as intended.
6. Finally, auditing results is a critical step in the utilization process. The laboratory generates a tremendous amount of data. When analyzed, these data can tell you how a test is being used, whether the intended outcome of a utilization process is being achieved, and where problems exist. The audit process can also identify which guidelines are not working as planned or need modifications or revisions.

Where Can The Laboratory Influence Test Utilization?

At several points along the test-ordering continuum laboratories can influence and change the ordering process.

Preanalytic: Clinician test ordering

1. Modify test order requisition forms, whether electronic or paper, and keep them current. Remove obsolete tests and limit the inclusion of esoteric tests on the general requisition. Establish a process to destroy old forms, remembering to remove hard copies from outlying areas.
2. Organize tests by disease state or by ordering patterns, rather than the more typical alphabetical approach.
3. Review and minimize the process where tests are bundled together for ease of physician ordering.
4. Review standing orders and how they are used in the clinical practice.
5. Establish a process to review any new tests that are requested.
6. Include necessary educational material—algorithms, practice guidelines, publications, etc—to help close the knowledge gap.

Laboratory processing

1. Establish an approval and cancel process for certain tests. If it is a low-volume test, this process can be undertaken by knowledgeable individuals and reviewed manually. For higher-volume tests, an information system-based process and intervention may need to be developed.
2. Review those tests the laboratory sends to reference laboratory partners using a test formulary-like or a utilization review process. Some requests may need laboratory director approval before processing.

Postanalytic

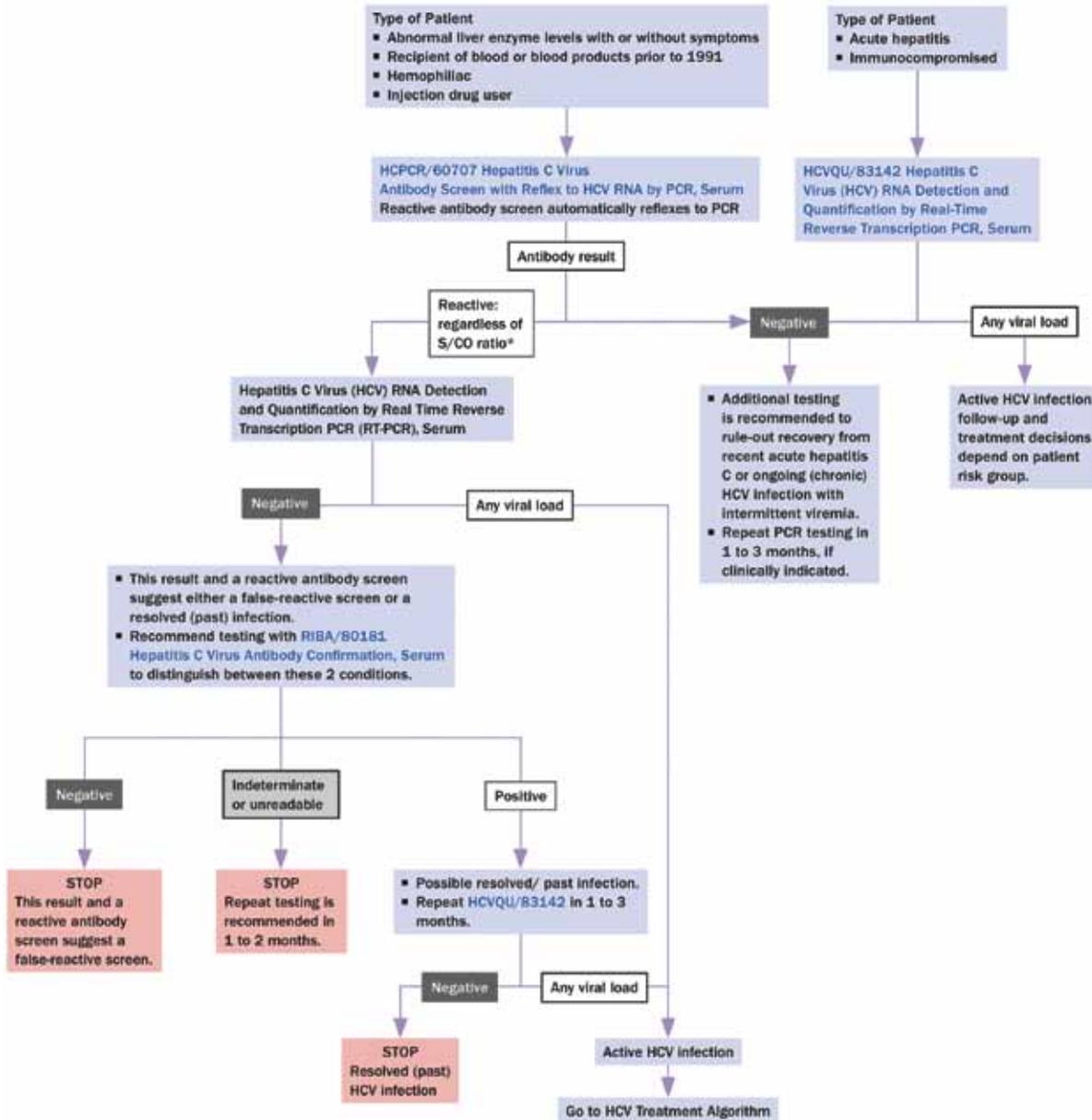
Laboratory reports may not be easy to read or understand, leaving the clinician with more questions than answers. While there will be differences in format and presentation, all laboratory reports must contain certain elements as mandated by the Clinical Laboratory Improvement Amendments (CLIA). The report may also need to contain additional items not specifically required, but that can assist the clinician in the interpretation of laboratory test results.

Conclusion

Test utilization management is not a new concept to most laboratories, but few have taken the steps necessary to truly initiate a utilization control process. Every laboratory needs to design its own strategy for test utilization and find what best fits the structure and culture of its institution. Laboratory professionals can position themselves as utilization experts who can assist clinicians with test ordering and ultimately improve the quality and efficiency of patient care. The task is not easy. Conversations with clinical colleagues to gain information, cancel a test, or suggest ordering a different test can be uncomfortable, but these interactions are necessary to build a successful laboratory utilization program that leads to high-quality, cost-effective patient care.

Authored by: Dr. Curtis Hanson and Elizabeth Plumhoff

Recommended Approach to the Diagnosis of Hepatitis C



*S/CO ratio = signal-to-cutoff ratio

Figure. This is an example of an algorithm that was developed by Mayo Clinic Department of Laboratory Medicine and Pathology, Division of Clinical Microbiology and Mayo Medical Laboratories to guide the diagnosis of hepatitis C. Algorithms are available online at www.mayomedicallaboratories.com

Test Utilization and Appropriate Test Orders:

The Role of the Genetic Counselor

The science of genetic testing and its application in clinical practice has evolved rapidly over the last 20 years. As a result, today's clinical laboratory can offer a wide expanse of various genetic tests that can be requested by a clinician. A recent study by the UnitedHealth Group's Center for Health Reform and Modernization states that, as a nation, we spent over \$5 billion on genetic testing in 2010 with that total potentially growing to somewhere between \$15 billion and \$25 billion by 2021. Not only are these tests growing in volume, but these tests are often the most expensive assays on a laboratory menu.

Ordering the appropriate genetic test for a patient can be complex, but is important from both a cost-savings and a patient-care standpoint. The Mayo Clinic Department of Laboratory Medicine and Pathology and Mayo Medical Laboratories employ genetic counselors to help clients navigate through the genetic testing ordering process. Genetic counselors are health care professionals who are educated in human medical genetics and trained in communicating genetic information. They are also skilled in interpreting family history information and identifying potential implications of genetic testing.

Genetic counselors at Mayo Clinic specialize in many areas of laboratory genetics, including Molecular Genetics, Cytogenetics, and Biochemical Genetics. A critical role for genetic counselors in each clinical laboratory is to evaluate the appropriateness of genetic testing. Mayo Clinic genetic counselors review many of the genetic test orders and reduce health care costs by ensuring the most appropriate test has been ordered. On average, the genetic counselors change or cancel approximately 8% of all reviewed genetic test orders. In addition, they help identify those patients who may need additional testing or who would benefit from time-sensitive therapies.

Genetic tests are misordered for a variety of reasons.

1. One of the most common is the similarity of names among several genetic diseases. This

is especially challenging in the Biochemical Genetics Laboratory where enzyme names are complex, as well as similar to each other.

For example:

Uroporphyrinogen I synthase versus uroporphyrinogen III synthase

Diminished uroporphyrinogen I synthase activity can cause acute intermittent porphyria (AIP). AIP presents *after puberty* with pain crises and psychiatric symptoms.

Reduced uroporphyrinogen III synthase activity results in congenital erythropoietic porphyria (CEP). CEP typically presents *in infancy* with cutaneous findings, hemolytic anemia, and hepatosplenomegaly.

While these 2 conditions have a very different clinical presentation, the similarity of the enzyme names leads to frequent test misorders. By reviewing the patient's age and the clinical information provided, the genetic counselors can identify most of these types of order mistakes. Performing the correct test ensures a more meaningful result for the patient and saves the patient, the health system, and the insurance provider time and money.

2. Another group of commonly misordered tests involves "mutation screens" versus "known mutation tests".

A mutation screening test is designed to identify a genetic mutation in a patient with clinical features of a disease.

A known mutation test is a targeted test for a specific mutation that has already been identified in an affected family member. Known mutation tests cannot be performed unless the familial mutation is provided to the laboratory. When a familial mutation is known, the known mutation test is a far less expensive and is a more direct

approach to testing than performing a full mutation screen.

To illustrate, if an individual with colon cancer is suspected of having a *MLH1* germline mutation (causative of Lynch syndrome), the mutation screen for the gene should be ordered. However, if a familial mutation in *MLH1* has already been identified in a relative, then the known mutation test for *MLH1* should be ordered, which costs approximately one-half that of a full mutation screening test.

3. In addition to assessing the appropriateness of testing, genetic counselors monitor duplicate testing requests. Because a person's DNA and chromosomes in the majority of his or her cells remain the same throughout the lifetime, it is seldom necessary to repeat a molecular genetic or congenital cytogenetic test. A common situation that leads to duplicate testing is when a new provider orders genetic testing unaware that the same test was previously ordered by a different provider.

Consider this situation: A congenital chromosome analysis is requested by a child's pediatrician. Two years later the child is referred to a geneticist who orders another congenital chromosome study, as the geneticist had no knowledge that it was performed previously. In this case, the genetic counselor would identify this second, repeated, test as unnecessary and contact the clinician or client lab to determine if the previous result can be shared with this new request submitter. This effort improves patient care by providing important results to the provider currently caring for the patient and also reduces unnecessary health care spending.

Another situation that leads to duplicate testing is that some genetic tests are part of panels or other testing techniques, but are also orderable as separate tests. In the case of an infant presenting with cleft palate, a clinician may want to rule-out DiGeorge syndrome by fluorescence in situ hybridization (FISH) analysis of the 22q11.2 region. Given the nonspecific clinical findings, the clinician may also order an Array Comparative Genomic Hybridization (aCGH). The aCGH analysis covers the 22q11.2 region, rendering the FISH testing unnecessary. In these

situations, if the stand-alone test and the panel or other testing method are both ordered, analysis of the same genetic region would be performed and charged twice. Genetic counselors attempt to identify these cases prior to analysis to avoid duplicate testing.

Each genetic laboratory has a slightly different approach to evaluating the appropriateness of testing but, in general, a thorough review of clinical history provided, patient's age and gender, and previous genetic testing are used when assessing whether the order is appropriate. Based on this review, if the genetic counselors believe that a different test may be more appropriate for the patient, they will contact the client laboratory or ordering physician to discuss the clinical symptoms of the patient, the differential diagnosis, and what testing the ordering physician intended to order. The genetic counselors take all this information into consideration when they recommend what test or tests would be most appropriate for the patient.

The large repertoire of genetic testing services offered by Mayo Medical Laboratories can make selecting the appropriate test complicated. With the rapid growth of genomic medicine, testing options will only increase, further increasing this complexity. This multifarious nature has amplified the need for laboratory genetic counselors to assist clients with complex testing algorithms and the review of ordered tests for appropriateness to optimize patient care. Mayo Clinic's laboratory genetic counselors are available to help physicians select the most appropriate tests for their patients and reduce unnecessary testing.

Authored by:

Claire Anderson, CGC

McKinsey Goodenberger, CGC

Katrina Kotzer, CGC

Kimberly Schahl, CGC

2012 Education Calendar

Upcoming Education Conferences . . .

19th International Surgical Pathology Symposium

May 1–4, 2012
The Westin Zagreb
Zagreb, Croatia

Coagulation Testing Quality Conference and Wet Workshop

August 7–10, 2012
The Kahler Grand Hotel
Rochester, Minnesota

Conceptual Selling

September 24–25, 2012
The Kahler Grand Hotel
Rochester, Minnesota

Leveraging the Laboratory: Mining Your Hidden Revenue Source

September 26–28, 2012
The Kahler Grand Hotel
Rochester, Minnesota

Phlebotomy 2012

October 4–5, 2012
The Kahler Grand Hotel
Rochester, Minnesota

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MayoMedicalLaboratories.com | 800-533-1710

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