Diagnostic algorithms: guiding optimal test utilization management

Abstract

Optimizing laboratory test utilization requires that healthcare providers simultaneously ensure needed tests are performed while suboptimal tests are avoided. In each clinical encounter, the physician must apply clinical judgement to determine whether the patient requires testing. Then, from many possible interventions, the physician must select tests that are both clinically advantageous and economically prudent. For multiple reasons discussed, physicians report finding it challenging to stay abreast of changes to swelling test menus and methods of interpretation. Numerous interventions exist to help guide appropriate utilization management. Among them, the use of diagnostic algorithms during order entry and result interpretation has proven effective in both improving patient health and reducing waste in an era of increasing financial pressure. This paper describes the need for and successful application of diagnostic algorithms in utilization management.

Introduction

More than thirteen billion tests[1] are performed in certified clinical laboratories each year in the U.S. These tests have an immeasurable impact on diagnostic and treatment decisions made by healthcare providers. Until relatively recently, healthcare providers pulled from a manageable list of tried and true lab tests to diagnose the common conditions they encountered routinely in their patient population. Technological advances, especially as they relate to the genomic revolution, have exponentially increased the size of test menus that are available to physicians, challenging them to discern which novel test is the optimal choice in each situation. With this plethora of choices, doctors require access to resources that help in selecting the right test for their patients. Laboratory professionals are being called on to create tools which guide optimal diagnostic test utilization.

> Over the past 20 years, the number of laboratory tests available to clinicians has more than doubled to at least 3,500 tests.
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Assessing the problem

More than 30 years ago, George Lundberg defined the concept of the "Brain-to-Brain Loop" to illustrate the complexity of the clinical laboratory testing process.[2] The model was later refined in 2011 to include nine distinct steps. (See figure 1.) The loop begins with the physician posing a clinical question, followed by diagnostic test selection, sample collection, transport to the lab, analysis of the sample, reporting and interpretation of the test result. The loop closes with decisions by the clinician regarding patient care planning. This last step is essential. Without using the test results to take appropriate action, the loop has no clinical value. Indeed, Lundberg's concept has evolved over time to elevate the goal of the process beyond merely achieving a patient diagnosis. Rather, a successful process is "concerned about the effects of that laboratory test and whether the performance of it was useful for the patient or for the public's health."[3]

Two areas of the Brain-to-Brain Loop that are made especially difficult by this complex process are the initial phase of test selection by the physician and the later interpretation effort. These steps are vulnerable to error[4] and may result in suboptimal test utilization management and patient care.[5]

Figure 1. Lundberg's 'Brain-to-Brain' Loop illustrates the complexity of the laboratory diagnostic testing process. (Reproduced from Epner, et al.)

Suboptimal utilization

In today's fast-paced and rapidly advancing healthcare environment, the optimal ordering and results interpretation of ever-expanding test menus is a challenge for physicians. In a 2011 CDC survey of primary care and general practice physicians across the U.S., 14.7% of respondents reported being uncertain about which test to order.[6] Since then, significant growth in genomic medicine has led to more than 1,500 genetic tests being available for clinical use, further complicating test selection. What's more, that number is expected to increase 25% annually.[7] Without guidance around new and more clinically significant tests, clinicians may tend to order a familiar test or, when in doubt, all tests that may be appropriate. Such ordering may lead to suboptimal test utilization, a known source of waste in our healthcare system.[8,9]

Patient care impact

The ramifications of inappropriate test ordering extends beyond the financial burden placed on healthcare resources to include downstream effects such as incorrect diagnoses, unnecessary drug therapy, increased length of hospital stays, and additional medical or surgical interventions.[10] Traditional ordering patterns reflect a focus on selecting the "right test" for a patient to confirm the most likely diagnosis but do little to return an unexpected diagnosis. In fact, in 55% of U.S. malpractice claims involving a missed diagnosis, there was a failure to order the correct diagnostic test.[11]

Likewise, errors in the post analytical phase, i.e., test interpretation and communication to the patient, are the second highest in frequency, comprising 25-46% of all errors throughout the process. These errors may include delayed/missed reaction to test results, incorrect interpretation, inappropriate/inadequate follow-up plan, and/or failure to order appropriate consultation.[12] The previously mentioned 2011 CDC survey revealed that 8.4% of PCP respondents were uncertain about interpretation of the test results.[13] Furthermore, the breakdown in test results communication among caregivers is the most common root cause of delayed treatment or failure to follow up.

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Applying clinically-proven solutions

Survey results from 2012 illustrate the factors contributing to suboptimal ordering practices. The single most important issue respondents identified was limited curriculum related to laboratory medicine in medical school, followed by a failure to collectively organize best practices around lab test selection[14] and result interpretation, a lack of valuable clinical decision support tools, and limited use of diagnostic algorithms to direct appropriate test selection. Two promising resources available to physicians to more easily, confidently, and effectively order appropriate tests include increased consultation with laboratory professionals and the application of diagnostic algorithms.

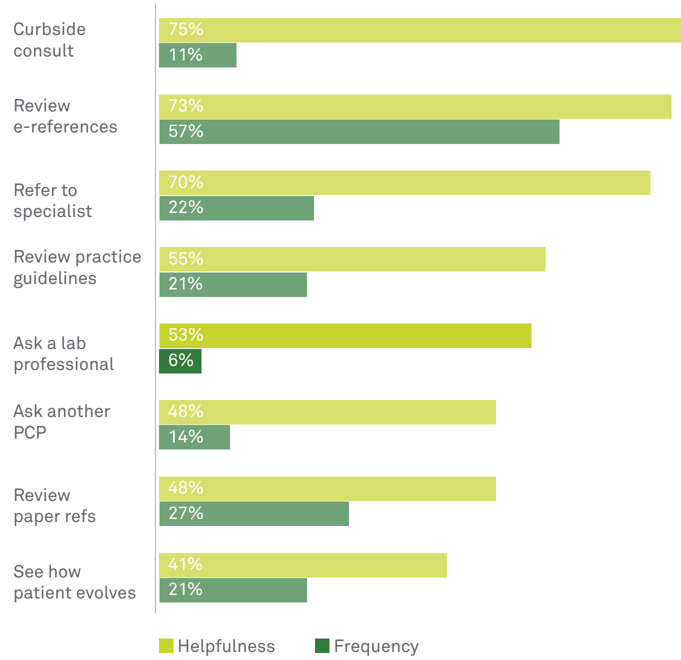
Laboratory consultation

Consultation with pathologists and laboratory personnel could also be a rapid and cost-effective method for reducing uncertainty about test ordering and interpretation.[15] Recognizing the complexity of test selection, leaders in laboratory medicine are increasingly focused beyond the traditional expectation of merely providing timely, accurate test results. Their mission has expanded to rapidly and efficiently enable the accurate diagnosis of conditions, the selection of appropriate treatments and the effective monitoring of health status.[16]

Utilization optimization relies on the ability to expertly assess the diagnostic accuracy and predictive value of each test.[17] To fully understand the relative diagnostic performance of a test, clinicians must understand specific test characteristics such as prevalence, sensitivity, specificity, efficiency, and predictive value, a complex matter by all accounts. With an understanding of the latest research in the fields of laboratory and pathology, laboratorians are uniquely qualified to help narrow the diagnostic choices for physicians, direct optimal test utilization and aid in results interpretation.

However, according to the aforementioned national survey of primary care physicians, common tactics to optimize test selection do not often include consultation with the laboratory. Rather, to overcome uncertainty in test selection, physicians reported using a variety of tactics as summarized in Figure 2. The most helpful tactics for overcoming these uncertainties were curbside consultation, E-references, and referral to specialists. Only 6% of respondents regularly consulted with laboratory professionals, even though 53% of respondents reported laboratory consultation to be useful. Although there is presently no clearly described policy within the profession to structure and emphasize the role of consultation, efforts to do so have the potential to positively impact physician test utilization and effective results interpretation.

Figure 2. Decision support tactics employed by primary care physicians in ordering clinical laboratory test and interpreting results.



Source: Hickner J, et al. Primary Care Physicians' Challenges in Ordering Clinical Laboratory Tests and Interpreting Results. J Am Board Fam Med March-April 2014 vol. 27 no. 2 268-274

Diagnostic algorithms

One-time educational efforts such as emails, memos, calls for enhanced vigilance, educational pamphlets, and continuing medical education lectures have little sustained impact on physician ordering patterns and habits. However, combining general education efforts with easily available information in the form of diagnostic algorithms can facilitate consistent and optimal utilization management.

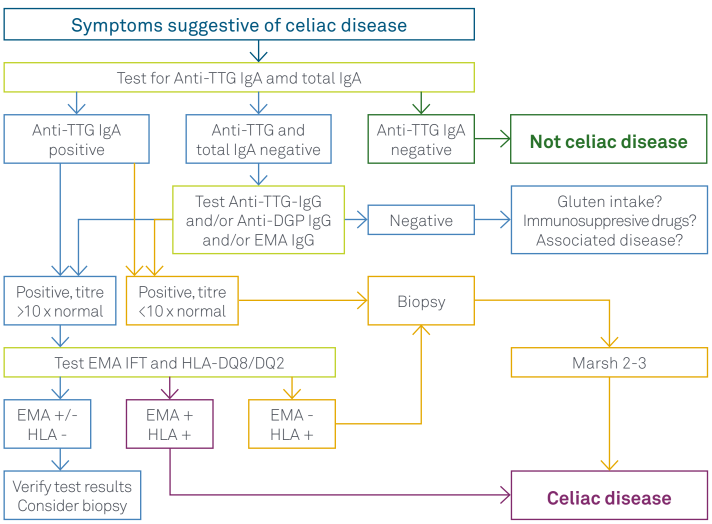
Diagnostic algorithms provide a road map for appropriate test ordering in the work-up of a suspected condition and can help reduce the uncertainty which might lead physicians toward misutilization and inefficiencies in the Brain-to-Brain Loop. The use of an algorithm enables appropriate sequencing of tests with screening tests preceding more expensive and extensive testing. For example, a simple computer algorithm can identify a negative test for Epstein Barr Virus (EBV) on a child under 4 years of age and then automatically order subsequent tests for EBV IgM and IgG, since the utility of the initial test is unclear in that age group. This sort of "reflex" or "cascade" testing requires no physician intervention and reduces the steps required to arrive at a diagnosis.

Use case: celiac disease algorithm

Celiac disease (CD) is the only treatable autoimmune disease, if it is diagnosed and the patient adheres to a strict, lifelong gluten-free diet. The long-standing protocol for celiac disease diagnosis includes initial screening serological tests, followed by a confirmatory small intestinal biopsy. In 2012, the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) published new guidelines for a revised algorithm.[18] This new guidance was built on accumulating evidence that disease-specific antibodies against tTG, EMA, and DGP have diagnostic value, thus challenging the earlier reliance on invasive biopsy. Researchers reported that, in well-defined cases, serologic testing may replace histology. Specifically, the new algorithm presented requirements for diagnosing CD without a biopsy for children with high anti-TTG titers due to the high likelihood for villous atrophy. In these cases, the pediatric gastroenterologist may exercise the option of performing further laboratory testing (EMA, HLA) to make the diagnosis of CD without biopsies. If EMA testing confirms specific CD antibody positivity in this second blood sample, then the diagnosis can be made and the child can be started on a gluten-free diet.

Likewise, to avoid unnecessary biopsies in asymptomatic patients with low CD-specific antibody levels, the algorithm directs the clinician toward the more specific test for EMA. If the EMA test is positive, it is then recommended that the child be referred for biopsy. If the EMA test is negative, then repeated serological testing on a normal gluten-containing diet in 3 to 6 monthly intervals is recommended.

Figure 3. Diagnostic algorithm for patients with symptoms suggestive for celiac disease. (Reproduced from Hammar F.[19])



While following the iterative testing approach specified by a diagnostic algorithm is clearly preferred to a scattershot approach, sequential testing requires the clinician to place an initial order, wait for the results, then place additional orders as indicated. Ultimately, the process can become time consuming for both the physician and patient. This inconvenience may be avoided by allowing physicians to order cascade testing in which the informatics system allows the ordering of an algorithm and enables the laboratory to perform the initial testing and, following the algorithm, automatically stop testing or order additional pre-approved appropriate testing. The lab is responsible for the sequential testing as defined within the algorithm. The approach has led to significant cost savings. In one health system, it was estimated that the average cost of the algorithmic testing was one-seventh the cost of the whole panel previously ordered for celiac disease.[20] In addition to cost savings, benefits of employing algorithms include avoidance of misdiagnoses, reducing the number of laboratory tests needed, reducing the number of procedures and hospital admissions, shortening the time-to-diagnosis, reducing errors in test ordering, and providing valuable information about how the laboratory results might affect other aspects of a patient's care.[21]

Conclusion

The process of optimally leveraging the clinical benefits of diagnostic testing is highly complex. This complexity may contribute to errors which may negatively impact patient outcomes and create waste. With an immense number of laboratory tests available, doctors require resources that support them in selecting the right test for their patients and interpreting the results properly. The laboratory is a valuable resource in the creation of tools that can guide optimal diagnostic test utilization. Diagnostic algorithms are an essential tool in meeting this important objective. Computerized algorithms can provide a welcome resource for physicians to access evidence-based guidelines when selecting tests and interpreting test results. Furthermore, cascade algorithms can reduce the inconvenience and turnaround time of sequential testing and yield cost savings and improved patient outcomes.

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