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The role of modern laboratory diagnostics in supporting clinicians' decision-making

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In an age when laboratory testing has become incredibly accurate through use of advanced analyzers and highly automated using cutting-edge information technology, it is a surprise to learn that the interpretation of lab test results remains prone to human er

Clinical laboratories have been an integral part of healthcare delivery for many years, and the Centers for Disease Control and Pr states that 70% of today's medical decisions depend on laboratory test results, with more than 14 billion tests ordered every year. laboratories are equipped to perform huge volumes of tests with great accuracy and consistency in an extremely short turnaroun appropriate test selection and final interpretation of results continue to be done by clinicians using a manual cognitive process.[2] students in some institutions today spend as little as 12 hours learning about laboratory medicine over the course of a four-year c no surprise that diagnostic errors account for about 20% of all diagnoses and result in billions of dollars of malpractice claims ea

The astronomical cost of healthcare is pushing the system to the verge of collapse. Do clinical laboratories have a role in controlli healthcare costs in a post-COVID era? Can they help improve individual and population health by enabling early and accurate di identification, clinical diagnosis, and treatment?[6]

Brain-to-brain loop concept

The brain-to-brain loop concept in the laboratory testing cycle starts with the cognitive component of test ordering, followed by p analytic, and post-analytic phases, and ending in a final cognitive phase of results interpretation by clinicians.[7] The cognitive pha clinician's training, experience, and diagnostic skills to determine the right diagnosis for the patient based on history, signs, sym physical examination. After a list of provisional differential diagnoses is formulated, clinicians must tap into their knowledge of l to choose the appropriate set of tests to help rule in and rule out the diagnoses on the list. This process can be challenging. After t the pre-analytical, analytical, and post-analytical phases follow. These phases consist of sample collection, labeling, transport, qu processing, analysis, validation, and reporting. These phases are predominantly automated using high-precision instruments, ro information technology; thus, they are reasonably consistent and reproducible, even across multiple laboratories. After this thor reporting results, clinicians still face the challenge of interpreting them.

As the number of laboratory tests available for physicians to order has increased to more than 4,000, and when multiple panels c for a patient, each producing numerous individual test results, the interpretation process becomes problematic and challenging.

is poor at meta-cognition, and intuition cannot scale to solve a multidimensional data problem.[2]

Information technology today has the potential to ease some of these challenges. We have seen its impact on other industries, an laboratory diagnostics is no exception to this trend. Over the last 40 years, the laboratory has transformed from using predomina processes to automated operations. Modern laboratories can process and analyze thousands of samples per day with the utmost accuracy. In most laboratories, the result review and reporting process is semiautomated through autoverification, freeing up lab focus on exceptions, where their expertise is needed. These advances have reduced turnaround time and greatly increased the ac consistency of laboratory testing.

Even though information technology has had a positive impact on the pre-analytic, analytic, and post analytic phases, it has not progress in supporting the manual cognitive processes used by clinicians in ordering tests and interpreting results.

Shortcomings with reference intervals

Clinical laboratories report reference intervals together with laboratory test results to help distinguish health versus disease. Whi establishment and use of reference ranges has evolved in some institutions, many still rely on the traditional ranges established ago.[8] These original reference intervals were determined by establishing small groups consisting of 100 individuals drawn from and deemed as being healthy. These groups were further categorized by gender, age, and a self-declared health status determine a questionnaire. After a physical exam, group members provided blood samples for analysis, which produced individual results t demographics, ethnicity, and race. These test results were plotted using a Gaussian distribution, and the range was calculated ba that fell within two standard deviations. These reference intervals have been in use for over 50 years, but often, individual test re the edges of the reference intervals are ambiguous in determining health versus disease. Therefore, the combined indication of m must be factored in when determining the status of the patient. This process is cognitively challenging for a clinician.

Even though clinical laboratories have transformed over the years in terms of efficiency, accuracy, and consistency, their role in support to physicians has not expanded much beyond providing the reference intervals and highlighting the results that fall outs intervals.[9] This certainly has helped clinicians in quickly scanning a large number of results and picking the abnormal ones for fu biochemical process of any disease is a complex mechanism, and the early signs of a majority of diseases are evident by changes i parameters that occur way before the first symptoms appear. Changes in the parameters of commonly ordered routine blood pan underlying disease processes and provide an opportunity to order specific tests to further confirm or rule out potential diseases.

Some other common capabilities of laboratory-enabled clinical decision support include functions such as reflex testing to autom additional relevant tests based on abnormal lab results. Delta-checks are also commonly used to help identify a potential change health based on a percentage or absolute-value change in specific lab values for blood work done over a period of time. For exam hemoglobin value of 12 mg/dL may be considered normal for an adult female. But a trend of 15 mg/dL down to 12 mg/dL could i bleeding. Such trends can be more useful than a snapshot, where an abnormal test result may still be regarded as normal as long in a desirable direction. Potential problems can be flagged by the laboratory through use of delta-checks.

Although these capabilities offer definitive value to clinicians, they are basic compared to those that laboratories potentially can times, and especially with the advent of molecular and genetic testing, the number of choices for laboratory testing has skyrocket Wisely initiative started by the American Board of Internal Medicine (ABIM) to help clinicians order the appropriate tests is end 70 medical specialties. The goal of this initiative is to improve the safety and quality of patient care and reduce harm.[10] With the electronic medical records (EMR), institutional laboratories have access to the initial, provisional diagnoses documented by clini logical that a future service provided by the laboratory would include recommendation of an optimal test battery that could be us in the most probable diagnosis and rule out the unlikely ones. In addition, it may be possible to rank-order tests that are less-exp by the patient's insurance.

AI's value in disease diagnosis

There are also opportunities for labs to support clinicians during the final phase of the brain-to-brain loop, when the test results to the physician for interpretation. Artificial intelligence and machine learning (AI/ML) technology can be used in this phase to h multidimensional test results. Based on the patient's age, gender, comorbidities, and current presentation, AI/ML technology ha compare the results of the various analytes and provide probability scores that can be used to help rule in or rule out the potentia diagnosis. Another approach may include providing a list of the most likely diseases the patient may have based on the combined patient's lab test results compared to a large population of confirmed diagnosed cases.[11] These opportunities could expand the va laboratories currently provide to physicians to improve clinical decision support and help rule in or rule out diagnoses with much confidence.

Another important role of laboratory medicine is providing clinicians with information to choose the appropriate therapy based o status of the patient. A prime example includes testing to assess kidney and liver function, then monitor therapy for effectiveness Clinical decision support (CDS) can play a crucial role in tracking blood results and trends to monitor organ functions, thereby en appropriate dosing to maintain patients within the most effective therapeutic spectrum. Thus, CDS creates the opportunity to pu multiple modalities, IVD, imaging, and the EMR, integrate that data, and present it visually to the multispecialty care team to en comprehensive assessment of patients for optimal management decisions.

As we enter the post-COVID era, it is imperative to expand the traditional role of the clinical laboratory beyond its four walls to fi hospital units and clinics. In addition to the decision-support information and services the laboratory can provide, there is also o more-direct engagement by laboratory specialists. Laboratory directors who are trained physicians specializing in laboratory me unique role in working with other clinical specialists on care teams to evaluate, diagnose, and treat patients. With the advent of th and data interchange standards, laboratory directors can access complete medical data of patients and have the expertise to help ordering appropriate tests, interpreting results, and guiding further investigations.

In closing, the laboratory is very well positioned to expand the value it offers to clinicians. Advanced information technology and such as AI/ML, have a tremendous potential to help identify disease processes at the very early stages of routine blood examinati have a tremendous impact on population health and disease prevention. It could also support improved use of appropriate testin diagnosis, treatment, and therapeutic monitoring. AI/ML-enabled clinical decision support has the potential to propel the model laboratory to the forefront of diagnostic modalities and, thus, support appropriate intervention to keep the population at larger h the crucial role of the clinical laboratory in reducing healthcare costs and preventing the system from eventual collapse cannot be

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