Setbacks in Clinical Laboratory Innovations

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Abstract

Technological advancements are soaring in healthcare as a whole; however, advancements in the clinical laboratory have fallen behind. Innovation in the clinical laboratory can be complicated and comes with high risks. Consequently, new technology and its acceptance have fallen short. The slow growth of artificial intelligence (AI), machine learning (ML), and deep learning (DL) keeps laboratory technicians working harder and healthcare costs soaring. This technological lag perpetuates analysis delays, unnecessary testing, human errors, suboptimal patient care, and in an untimely fashion.

The goal of this research is to prove the significant need for innovations in laboratory medicine and establish a means to accomplish them. This paper will include analyses of articles, peer reviewed articles, websites, and journals that are no more than three years old to show how laboratory innovations can enhance turnaround times, lower healthcare costs, increase the level of patient care, and allow for greater patient outcomes.

Keywords: MACHINE LEARNING, DEEP LEARNING, ARTIFICIAL INTELLIGENCE, CLINICAL LABORATORY, LABORATORY MEDICINE, POINT OF CARE TESTING, ELECTRONIC HEALTH RECORD, CLOUD TECHNOLOGY, DATA SCIENCE, CLINICAL DECISION SUPPORT, DIGITAL IMAGING ANALYSIS, TEST RECOMMENDATION TOOLS

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Introduction

Technological advancements in the clinical laboratory have not come to a standstill, but they are constrained enough, that vast negative impacts to patient care are being realized. Historically, clinical laboratories have been structured to provide services in a silo. Each provider, hospital, nursing home, or clinic was treated as a stand-alone client—each ordering tests, billing, and receiving results separately. Today, with electronic health record (EHR) systems, laboratory results and other clinical information can be made available across all facilities and providers within a system or network.

Siloed clinical data, legacy laboratory information systems (LIS), and analytical instruments are not fully compatible with EHR systems. These, along with numerous other challenges, impede technological innovations and integrations with EHR systems. While physicians and healthcare providers are the most apprised of the consequences of technological deficits in the laboratory, patients are the ones that bear the most substantial cost. Patients not only, suffer financial burdens, but are also forced to cope with second-rate and untimely patient care. Aside from adverse effects on patients and medical care providers, there other extending impacts in healthcare. Insufficient technological advances in the clinical laboratory can also catalyze delays in medical research, clinical trials, and subsequent drug developments.

Imagine if laboratory instruments could think for themselves and could synthesize clinical data in EHR systems to predict laboratory result values. Suppose the EHR system could produce instantaneous diagnostic patient care plans by utilizing integrated laboratory data along with other clinical patient information from the EHR. It is not implausible to think that laboratory instruments could predict their own failures and unscheduled maintenance weeks before they happen. Technologically advanced laboratory instruments could even order their

own parts and reagents and schedule needed maintenance and repairs. With AI technologies in the clinical lab, these propositions could become reality.

Literature Review

Why Digital Innovation is Required

As the demand for healthcare services continues to expand, so does the clinical laboratory workload and the complexity of diagnostic testing and treatments. Advanced clinical support services must be utilized in today's clinical labs to better support patient-centric care and improved clinical decisions for optimal patient outcomes. Trends in clinical labs prove it is only through forward-thinking options and lab industry professionals that these labs will be able to overcome the challenges that exist today, as well as meet any upcoming challenges in the future (Silva, 2019).

Technology is challenged, today, by clinical information overload and the lack of analytical expertise. Most existing clinical laboratory data is unstructured and remains in closed legacy systems that are not interoperable with EHR systems. This means that clinical laboratory data has not been formatted or does not exist in such a way that it can be stored or displayed in an organized or consistent manner. As much as 80 percent of all clinical laboratory data is in this seemingly unmanageable state (Kerty, 2020). This overabundance of data is either inaccessible, or too extensive to analyze; while digital innovations in the healthcare sector demand it is controlled in a user-friendly and clinically meaningful way (Data Integration and Decision Support Along the Patient Pathway, 2021). Without a technological intervention, this data dilemma can result in prolonged and inadequate clinical decisions and have even larger downstream impacts for healthcare.

Integrated data from other clinical sources, such as Radiology, Genetics, and Pathology, along with behavioral and social summaries, can be crucial in diagnostic decisions and treatment plans. Physicians and caregivers must be provided with complete clinical patient information to have a full and accurate picture of a patient's health; otherwise, clinical decisions, diagnoses, and treatment plans for patients can be deficient.

Pertinent but unavailable information not only renders ill effects on clinical decisions and patient care, but it also unfavorably impacts the profitability of laboratories. One of the largest hits on the clinical laboratory's profitability comes from billing claim denials. Most billing claim denials are for either missing or incorrect information. Studies have shown that over 90 percent of all denied laboratory billing claims would have been approved if these types of data errors were avoided (Patel, 2019). Integrating clinical laboratory data with an EHR system could confirm the accuracy of the provider information, diagnosis codes, insurance information, eligibility, and Advanced Beneficiary Notices (ABN) at the time orders are placed. This would ensure the accuracy of billing claims and that laboratories receive accurate and timely payments.

Order entry for laboratory testing is another area where integration of LIS with an EHR system could bridge large gaps. The lack of an interface with an EHR system allows orders to be placed with missing or erroneous information. Technical and user errors can also be introduced when testing orders are placed in external systems. The use of unintegrated systems leaves laboratories unable to perform automated data entry checks or ensure orders are complete and accurate. This technological deficit, solely, could result in testing delays and prolonged treatment times for patients.

Incorporating clinical laboratory data into an EHR system is not just an added burden to the laboratory. It is an opportunity to transform laboratories into a more profitable, precise, and efficient role within the healthcare sector by utilizing an invaluable connection between laboratory data and an EHR system. Patel claims that 25 percent of all pre-analytical errors end in increased healthcare costs due to improper care, additional testing, or investigations that were unjustified. These errors can add up to $1.2 million per year in a 650-bed hospital in the US (Patel, 2019). As many as 70 to 80 percent of clinical decisions are made exclusively based on laboratory test results (Patel, 2019). The multifaceted costs of laboratory errors add up and have quite profound and lasting effects on patients (Islam et al., 2020).

Artificial Intelligence

AI is a field of computing science that can be encompassed by data science (DS). It is committed to mimicking the human thought processes and behaviors used to make decisions or take actions (Gruson et al., 2019). Its definition is very broad and nonspecific. Any type of computer software that engages in humanlike activities, including learning, planning and problem-solving is considered artificial intelligence. AI has been around since 1956, but it has been slow to make significant progress—taking decades to become a technological reality.

AI used to be primarily associated with science fiction, especially in the movies. One of the earliest AI films released in 1968, was “2001: A Space Odyssey”. It was about a murdering, villain robot named HAL 9000. HAL stood for “**H**euristically programmed **AL**gorithmic computer”. Heuristic and algorithmic are two types of intelligence processes that were responsible for HAL’s superior level of cognition and intelligence. Presently, AI is becoming more commonplace every day. It impacts the daily lives of nearly everyone, even though many users may not realize they are using AI technology. Facial recognition on smart phones, Google search, social media apps,

smart home devices, banking apps, Netflix, and virtual assistants, Siri and Alexa, are all commonly used components of AI technology.

AI is not intended to be a replacement for human intelligence, but rather, a supporting tool to make work and life much easier. AI can process and analyze masses of data much faster than the human brain and make decisions on its own, but AI cannot process common sense tasks in real life situations. AI is most useful in analyzing mounds of data, helping humans realize possible outcomes, and smoothing out decision-making processes (Uzialko, 2019). This type of technology has existed in clinical laboratories for many years, particularly in testing and process automation, but has not sustained the growth trajectory required to keep pace with the medical data boom.

Machine Learning

ML is a subfield of AI. It is built upon statistical and optimization concepts. It can be described as the development of computer programs that learn from experience with respect to task and performance measures, (Gruson et al., 2019). ML programs have the ability to adjust themselves, or "learn" without being explicitly programmed when they are exposed to new datasets (Gruson et al., 2019). ML is a common type of AI that is being used today, for business purposes, due to its ability to solve many kinds of problems. Using algorithms, ML can analyze data to gain predictive insights and make replicated decisions at scale. Its primary use is to process large amounts of data, quickly. ML is useful for putting extensive collections of data—increasingly captured by connected devices and the internet of things (IoT)—into a digestible context for humans (Uzialko, 2019). Since algorithms are trained and continue to "learn" progressively, they can continue to get better and better in time, with practice.

Deep Learning

Deep learning (DL) is a subfield of ML. Living up to its name, it is literally a “deeper” learning. It is a type of AI that is concerned with algorithms and mimics how the human brain works to process data, create patterns, and facilitate decision making. It is also known as deep neural learning or deep neural network (Brownlee, 2019). DL can be a powerful tool for pattern recognitions in large datasets. This technology currently excels in image recognition and can perform this task much faster than a human can.

Employing DL, along with other clinical information from an EHR system, can serve as a test recommendation tool. Optimal laboratory test selection for patients can advance clinical practice and increase patient safety. The cost effectiveness of this technology has not yet been determined. Future studies have been recommended to ascertain its feasibility in real-world clinical settings (Islam et al., 2020).

Technological Solutions for the Lab

Predictive Methods

IT solutions present an opportunity to achieve consistent and accurate test results that are industry-standardized and reproducible (Silva, 2019). In a recent interview with CAP TODAY, Dr. Anand Dighe, director of clinical informatics and director of the core laboratory at Massachusetts General Hospital, and Dr. Jason Baron, a pathologist and clinical informatician in the MGH laboratory and assistant professor of pathology at Harvard Medical School, elaborated on one of these solutions. The doctors discussed how they, along with two computer scientists from Massachusetts Institute of Technology, were able to make their vision become actuality. They revealed how they were already using ML at MGH, and in another phase, would begin a

trial for predicting laboratory result values using ML and existing result values found in a patient's medical record (Albert, 2020).

Dr. Dighe declared that ML techniques are the new paradigm for cost-effective laboratory medicine and an important way laboratories can change how they do business (Albert, 2020). Although there were many mature machine learning methods accessible, they were not very adaptable with clinical data. The doctors and their colleagues were pressed to decipher novel algorithms that were accommodating to clinical data and could work well with sometimes missing data—a common occurrence with clinical laboratory information. Although their algorithm was successful and produced promising results, it was placed on hold and not implemented, as they could not identify a straightforward path for implementing this program into an already existing information system (Albert, 2020).

Digital Decision Support

Predictive methods are not the only solution to improving overall patient care. Advanced clinical decision support (CDS) systems are not only capable of assisting operational and clinical decision-making, but they can also improve clinical workflows, quality, efficiency, and patient safety. When other essential clinical elements harmonize with existing workflows, processes, and systems, a superior level of patient-centered care can be achieved. The end result is a complete patient record that can contain demographic information, clinical history, laboratory results, x-rays, pathology reports, vital signs, medication history, allergies, and progress notes—everything a provider needs for a whole picture of a patient's health. Decision support systems can ensure patients receive a superior level of care (Raymond et al., 2020).

Studies have provided substantial clinical evidence that reveals the significance of using advanced CDS systems. In a study of children with head injuries researchers using ML algorithms

were able to identify children that were at a much lower risk of traumatic brain injury, while not missing other children that had traumatic brain injuries. The children with only minor head injuries were able to forego unwarranted CT scans that are both costly, and needlessly expose children to ionizing radiation (Bertsimas et al., 2019). In another large cancer study, researchers were able to prove that using an advanced CDS system promoted compliance with clinical guidelines, decreased treatment costs, and lightened the physician workload (Klarenbeek et al., 2020).

An additional area where CDS tools can create a high value within healthcare systems is monitoring prescription drug orders. Laboratory and medication information in EHR systems provide opportunities for CDS tools to improve medication dosing, laboratory monitoring, and possible detection of medication side-effects. With a regular and systematic review, these tools could detect and flag inappropriate medications or dosages and keep physicians informed of drug levels, treatment response, or abnormal test results that may be medication related. Further research is needed to determine the ability of CDS tools to reduce adverse drug events (Whitehead et al., 2019). Despite the clinical justification and requisiteness of CDS tools, just as with AI and ML, there is currently no straightforward and easy path to integration of CDS technology into legacy information systems. More research and development in this domain are needed (Albert, 2020).

Point of Care Testing

With AI and ML becoming more widespread in healthcare, the cost savings from these technologies are proposed to be as much as $150 billion by the year 2026 (Miller, 2021). AI and ML growth continue to expand into point-of-care testing (POCT). POCT is a means of moving simple, non-complex testing outside clinical labs to be more conveniently performed, usually on

handheld devices, by other healthcare (non-lab) professionals. It is not a new technology, in fact, it has been around for many years. It started with glucose monitoring, and later came coagulation therapy monitoring. These types of devices are widely used by physician offices, clinics, home health care providers, and patients, themselves. The goal of POCT is to make analysis more expedient and economical while providing trouble-free quality control checks (Miller, 2021).

In recent studies, AI and ML have been employed to foresee acute kidney injury in burn patients to determine C-reactive protein concentrations, and in a separate study, to identify positive Lyme disease tests. Historically, these were considered specialized testing and could only be performed in certain laboratories. According to Miller, patients may soon be able to purchase many new POC tests, like these, at local drugstores and perform their own testing at home—possibly within the next decade (Miller, 2021).

However new and cutting edge this technology may be, it does not ensure that it will be successful or worthwhile. Neither does it guarantee its acceptance. POCT is also regulated and must be validated just like any other laboratory testing, which takes time. Even though POCT is taking testing outside the clinical lab, it should not be viewed as a threat to the central laboratory. It should be embraced as a useful tool working in conjunction with the lab and a way to optimize valuable human resources (Miller, 2021).

Automated Imaging Technology

Laboratory automation can offer relief from the staffing shortage in routine, repetitive, and high-volume testing areas, leaving the high-skilled work for the trained and skilled technicians. The microbiology department is one of the key areas where AI can produce exceptional gains in efficiency and quality in the clinical lab. Automated imaging software is

being utilized to screen urine cultures for further workup if their total colony forming units (CFU) meet the requirement for further testing. Urine cultures are one of the highest volume tests performed in laboratories and one of the least fascinating. This technology delivers a very high degree of consistency in colony quantification, that cannot be achieved with human screeners. It can also free up an already shortened clinical staff to perform more technical or complex work (Ford & McElvania, 2020).

There are currently only two of these automated microbiology platforms in the United States that are approved by the Food and Drug Administration (FDA). The first is the WASPLab, by Copan Diagnostics Inc. The second is Kiestra, by Becton Dickinson. These high-tech instruments' abilities go far beyond automated image technology. Each one offers "smart" incubation, plate imaging, application of patient identification information, barcodes for tracking, and medium selection and inoculation. This automation covers numerous steps, that if done manually, would not only take much longer to perform, but could also introduce errors and inconsistency. These platforms reduce preanalytical errors and lost or mislabeled plates, and they bring consistency to a process that is highly variable when performed by humans (Ford & McElvania, 2020). The plate imaging technology used by these two platforms is trained to detect growth and to quantify CFUs. It also allows laboratory technicians to view large images on screen for reading and interpreting cultures. The smart incubation feature speeds the culture growth and enhances the turnaround times for cultures (Ford & McElvania, 2020).

The WASPLab and Kiestra platforms make use of extraordinary technology in the clinical laboratory, but their capabilities expand even further. Their digital imaging technology coupled with ML can offer additional "analysis" to quantify microorganisms and distinguish cultures with significant growth from cultures with insignificant growth. Urine cultures with no growth make up a large part of the microbiology workload. The image analysis technology can quantify

culture growth and auto-verify certain classes of plates that have no growth or insignificant growth and do not require technologist intervention. Expert humans are left to perform Gram stains, reading and interpreting cultures, and identification and susceptibility testing (Ford & McElvania, 2020).

This imaging analysis technology was tested and "trained" in various microbiology laboratories. The discrepancies seen between manual plate readings and automated plate readings were generally very low. However, when mixed cultures were deemed "insignificant" by a manual reading, the total colony count was over the threshold and was deemed as "significant" by the imaging analysis technology. Digital image analysis in a microbiology lab is highly complex and leaves questions as to how this technology can be accurately validated and implemented into practice. This type of imaging analysis technology has not yet been approved by the FDA but is still evolving to make its way into microbiology labs of the future (Ford & McElvania, 2020).

Pre-analytic Specimen Checks

AI also has the potential to be used for pre-analytic specimen checks to determine if specimens are acceptable for testing. Pre-analytical errors have seen drastic reductions in recent years, but there continues to be needed improvement. Up to 70 percent of all laboratory errors can be attributed to variables in the pre-analytical phase (Meng, 2020). Hemolysis, icterus, and lipemia are three of the most common specimen integrity interferences. Hemolysis occurs when red blood cells become lysed or ruptured. It can cause falsely decreased RBC counts, Hematocrit, and PTT results. It can also cause falsely elevated Potassium, Ammonia, Magnesium, Phosphorus, AST, ALT, LDH, and PT results. Icterus occurs because of an overproduction of Bilirubin and causes a serum or plasma sample to be yellow in color. It can cause falsely

increased Magnesium levels and decreased Cholesterol, Triglycerides, Creatinine, Lipase, Bile Acids, Total Protein, Uric Acid, and GGT levels. Lipemic samples have large fat or lipid particles that can make serum or plasma samples cloudy or even turbid. It can increase coagulation results and interfere with other analytical results that are measured by optical methods or instrumentation (Meng, 2020).

Manual detection is inconsistent and labor intensive. This method requires specimens to be visually inspected by a technician and still allows for human errors and inconsistency. There are also certain interferences that cannot be visually detected by a human. A specimen diluted with IV fluids may not be detectable at visual inspection but would yield highly inaccurate test results. Most laboratory tests have specific collection requirements. Depending on the test ordered, a specific tube type and additive or anticoagulant is required. Samples can arrive in the laboratory outside of the original tubes they were collected in. Lab technicians would not be able to visually discern if the sample was collected in the correct tube or if it was the appropriate sample type, both of which are crucial for accurate analysis.

Automating these checks with analytical instruments or laboratory information management systems (LIMS) could deliver greater efficiencies in clinical labs and higher accuracy in detecting preanalytical errors (Meng, 2020). By utilizing AI, unacceptable samples could be detected prior to testing and automatically rejected. Testing orders would then be cancelled and notifications sent to the ordering physicians. Another notable gain from this innovation is the accuracy of test results is directly boosted by analyzing more suitable specimens.

Cloud Technology

Cloud hosting is another alternative to storage and data integration woes being faced by clinical laboratories. The cloud offers many storage options for the laboratory's legacy data and can provide ways to structure, format, and mine the data to produce more useful and manageable information. Software-as-a-service (SaaS) can remove infrastructure costs and security concerns for the clinical laboratory. It can also provide unlimited space for the data growth that is expected to persist. Additionally, SaaS models can provide reliable connections, ease of accessibility, and required flexibility, when it comes to communications between systems. SaaS models can also provide the financial benefits of not having to purchase or replace expensive systems or infrastructures (Borgenicht, 2019).

Obstacles in the Way

With technological advances, comes many challenges for clinical laboratories. Clinical laboratories have been isolated in hospital basements for years. It is not surprising that laboratory leaders are not fully aware of the major responses that healthcare innovation demands of the lab (McBride, 2020). This problem is all too common for clinical laboratories. They are overworked and understaffed, and their focus tends to be on getting the work done and not what is going on in other areas of healthcare.

Additionally, there are two conflicting agendas plaguing the clinical lab's integration with EHR systems: privacy and security, as opposed to interoperability (Electronic Health Records and the Lab, 2020). The challenge is to share patients' health information across an entire network of organizations, while adhering to strict privacy and security regulations. It is entirely possible to overcome this challenge, but EHR software developers have not made these clinical lab requirements a priority, and laboratories are not interested in incomplete software.

Financial obstacles are also impeding technological advances in laboratory medicine. Healthcare providers, especially in the United States, have been offered financial incentives to take on the implementation of EHR systems, while laboratories were not as fortunate and were somehow left out of financial assistance payouts (Electronic Health Records and the Lab, 2020). The steep costs of replacing outdated infrastructures or information systems places another financial burden on laboratories. The age and size of the lab's existing infrastructure can be one of the largest obstacles in LIS and EHR integration. Small, low volume labs may not be able to meet the expense of replacing infrastructures and systems. Larger labs are ideal candidates for the integration, because their demands are greater, and staff and resources are sizeable. This positions larger laboratories for a much more successful return on investment (Silva, 2019).

As the demand for healthcare and the volume of laboratory testing are growing exponentially, there are technological setbacks with integrating existing LIS, health information systems (HIS), infrastructures, and workflows with new technology. It was previously discussed that clinical laboratory data is inadequately structured. This means it can have missing ICD-10 diagnosis codes (10th revision International Classification of Disease), insufficiently labeled datasets, incomplete data, or altogether missing information—making it incompatible with AI technology (Durant, 2019).

It was previously established that a mass of bad data already exists in LIMS, and the healthcare boom continues to grow it aggressively. POC devices, smart devices, smart apps, and cloud services are also contributing to the multiplying medical data (Borgenicht, 2019). In 2019 the amount of health information was said to be doubling every three years. It was estimated that by the following year (2020), health information would be doubling every 73 days (Borgenicht, 2019). This presents the LIS with an overwhelming call for digital innovations. The

LIS must not only organize, manage, and store this mountain of data, but it must also be able to utilize and synthesize it for clinical decision support (Borgenicht, 2019).

Issues and Barriers

Prior research on this topic has been limited. Studies related to AI in the clinical laboratory that revealed promising results were stopped or put on hold due to the inability to test in real life systems. This limitation identifies the need for future research. This research includes self-reported data from an interview that must be taken at face value. It could contain biases or exaggeration. This research does not investigate whether the financial incentives for technological innovations in healthcare were given or to whom.

Methodology

This research was performed to prove the need for innovations in laboratory medicine and establish a means to accomplish them. The topics of “clinical laboratory innovations” and “technological advances in the clinical laboratory” were the two main search points. Peer reviewed articles, websites, and journals that were no more than three years old were studied and analyzed for this research. This method used pre-existing research and data that included prior studies and surveys. All sources cited support this research. There was a common consensus that clinical laboratory innovations are an absolute must to enhance turnaround times, lower healthcare costs, increase level of care, and allow for greater patient outcomes. Another common agreement is, there is currently no clear path forward for integrating legacy LIS with advanced EHR systems and tools.

Proposed Solutions

As clinical laboratories struggle to implement new and relevant technologies, numerous hurdles stand in the way, but there are just as many good and valid reasons for digital innovation, as there are hurdles. Clinical laboratories have been left behind and counted out. As the rest of the healthcare sector was incentivized to promote digital innovations, the clinical laboratory was overlooked. One solution is to provide a champion and advocate for clinical laboratories to boost innovations. If Laboratory and organizational leaders, government agencies, and regulating bodies would form an alliance to make this technological shortfall known and the voice of the clinical laboratory heard, changes would soon be forthcoming. This united front could also assist with bargaining for any missed or upcoming financial incentives that may be available. Along with this union comes a higher level of accountability that can naturally drive initiatives to catch the clinical laboratory up to speed in tech savviness. Agencies such as, College of American Pathologists (CAP), Clinical Laboratory Improvement Amendments (CLIA), and the Federal Government are also necessary partnerships to ransom clinical laboratories from an innovation impasse.

An additional method to resolve data integration issues that was not found in research is the abandonment of attempting to integrate legacy information with an EHR system. Laboratories could make a fresh start with new EHR compatible LIMS. Only clean data from the new laboratory systems would become part of the EHR system. Unstructured data is not being utilized by EHR systems, currently. Nothing would be lost by not utilizing this information going forward. It would not take long to build complete and accurate patient records with fresh data. Legacy data may be devalued, anyway. The type of demographic and medical information that is currently captured may be much different than what was historically collected or required. Additionally, limitations could be set on how long to retain old and unstructured data. For

instance, data that is more than five years old would be archived and not integrated into new systems. This could ease integration efforts tremendously and free up a great deal of storage space. Systems could be built, or cloud technology could be utilized to mine old data, determining which information should be archived and which should be integrated.

Conclusion

The role of the clinical lab can conceivably be the most important element of a patient's treatment team. As long as there are humans, the demand for healthcare and clinical laboratory services will continue to exist. Increasingly digitalized healthcare processes and multiplying health information indicates that data integration is no longer a “nice to have” in the clinical laboratory setting. Artificial intelligence components have become vital amid a healthcare evolution and to the long-term success of the clinical laboratory. The EHR system is considered a mission-critical application that clinical laboratories must integrate with to become a key player in this digital revolution. This prescribed, fundamental collaboration would bring about increased productivity, efficiency gains, leveraged costs, reduced errors, and decision support tools to attain the highest level of patient care and safety.

As important as it is, AI cannot do it all. It is merely a tool and cannot replace or take away the value of skilled laboratory professionals. Artificial intelligence components exist to optimize the most valuable resources in the clinical laboratory—humans.

Future Research

There are several areas where further research is warranted. A large gap still exists in integrating legacy systems and data with EHR systems and artificial intelligence elements. This area admittedly has not been made a priority by software developers. Cloud technology is

another vast expanse that needs to be explored to push clinical labs into the next level of innovation. In previous discussions about CDS tools and their potential ability to prevent adverse drug events, it was mentioned that current evidence was inconclusive and further research is warranted. Assessments have not been completed to determine the feasibility and cost-effectiveness of test recommendation tools. This is another area that requires further research.

Currently, there are only a few FDA-cleared ML products on the market for clinical labs, and these technologically advanced instruments have capabilities that cannot be implemented They require further testing and validation. Integration of laboratory data is also critically important in CDS tools and calls for further research and development. As these tools proliferate, the role of the clinical lab in development, testing, and maintenance of these models still has not been clearly defined. Governing bodies and accrediting agencies may influence the approval process of some ML models that deliver calculated laboratory results, as there is a need to ensure their reliability and safety. These areas are all still unknown and no formal guidelines have been established. Although the fields of ML, DL, and AI are expected to change the way clinical medicine is practiced, their use is still limited.

Finally, future research for a globally shared EHR system could have great and wide-reaching impacts. Picture a secure EHR in the cloud where health information from around the world would be available to select credentialed providers. Private or identifiable patient information would be redacted for privacy and regulatory reasons. This global system could be a searchable, virtual, treasure trove of conditions, symptoms, associated lab values, x-rays, pathology reports, and geographical information. This technology could present physicians with a wealth of knowledge about disease states and assist with identifying potential, new, or rare diseases and diagnoses. This information could potentially be used to determine if some disease states or diagnoses had geographical or environmental implications. This global, searchable EHR

system could change the way the world practices medicine and could save lives by accelerating patient diagnoses and treatment plans from months or years to weeks, or even days.

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