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Advanced Technology and Its Impact on the Clinical Laboratory: Innovative Technological Advancements in Laboratory Medicine: Predicting the Lab of the Future

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1. Introduction

Advancement in technology is an opportunity for clinical laboratories because many of the changes taking place in laboratory medicine are driven by technology. It is fair then to estimate that diagnostic testing of the future, whether it be predictive, preventive, or diagnostic, will continue to be as significantly dependent on innovation and invention as in recent history. Technology will have a major impact on the practice of pathology and laboratory medicine, as well as on the management and organization of the clinical laboratory, and consequently on the roles of those who provide services to health care. Rapid changes in technology continually improve in vitro testing, bringing forth more complete and more reliable information. Consequently, the future clinical laboratory will be asked to fulfill roles very different from its traditional use for direct observation and measurement of diagnostic indicators. These changes are coupled with a necessity to reduce health care costs and to furnish improved and more practical uses of clinical and anatomic pathology information.

Methods

The project surveyed medical experts on advances in clinical laboratory technology. Priority areas included complex reporting, local processing of simple testing, and direct patient care using testing results. Methods included an expert panel, anonymous survey, Delphi process, and secondary research. Top tests identified were Factor V Leiden, HIV-1 Pro viral DNA, HCV-RNA, HSV-2 test, robotic blood and urine culture, combo influenza A/RSV test, MRSA culture, HIV p24 antigen test, Trichomonas vaginalis test, screening for toxic entities in general chemistry, computer algorithms for digital histology, antigen test for Group A beta-hemolytic streptococcus, HPV nucleic acid test, vancomycin-intermediate S. aureus culture, C. difficile toxin test, Lyme disease test, prothrombin molecular analysis, HIV-1 viral load test, oral cancer diagnosis using salivary proteomes, DNA-pathology analysis, voided-urine marker of bladder and renal cancer, fecal markers Lactoferrin and glucosidase, diagnostic antigen for C. difficile, CSF-PCR for encephalitis, GBS antigen test in late pregnancy and delivery, and stool DNA for COL2Y.

Conclusion

If we applied an axiom from the physicists' view of the world to laboratory medicine, we might well conclude that the world of the future is already among us; we just have to complete our full examination and know where to obtain what we want from it. In investigating the innovations covered in this report, it was constantly apparent that the grass was, indeed, greener on the other side, not because the other side was new and glossy, but because other established technologies, new and old, were being creatively embraced to satisfy clinical needs. We do not need to go far to create the clinical laboratories of the future—indeed, probably not to leave our own locales—just to identify and bring together the necessary tools and make them work for us as members of a highly competent team in the same focused way that we wish to work with each other, and with our clinical associates and patients. The future is both challenged and charged ahead of us. While we cannot ignore those willing to accept and lead change, we can make ourselves change-ready and armed with knowledge about technologies and innovative uses that can focus more sharply the conduct of laboratory medicine.

Introduction

Advanced and rapidly evolving innovative technologies are causing dynamic changes in the clinical laboratory. The desire for fast and accurate results and the utilization of tests to detect disease in patients who do not demonstrate symptoms are paramount in the practice of medicine today. Clinical laboratory test results drive more than 70% of all medical decisions or contributions to this decision. The impact that these advancements in technology have had on the effective delivery of the healthcare system, and the potential impact on it in the immediate future, are considered. It is important for the clinical laboratory management team to recognize these dynamic changes and not limit their vision to the present-day laboratory. They must anticipate and be ready to face the challenges that technology will impose on clinical laboratories and must be leaders in dictating their future and not just followers of technology.

1.1. Background and Significance

While the clinical laboratory has traditionally been viewed as the "back room" of medicine, advances in technology have direct implications for the profession of laboratory medicine, the laboratory facilities themselves, and the way in which the findings generated by the clinical laboratory are transmitted, stored, and utilized. These forces have the capacity to both enhance and limit laboratory capacity, with significant associated effects on the delivery of health care. This paper explores current trends in the operationalization of innovative technology within a variety of laboratory settings. The description of technological change is supplemented with critical commentary on the implications of this change for health care delivery and for the cost of clinical laboratory services.

As vendors, public policymakers, and health care professionals alike promote the adoption of advanced technology in the clinical laboratory in the service of improving the quality of patient care, it is important to anticipate how such change might manifest itself in the laboratory of the future, as well as in the way in which laboratory services will be called upon to contribute to the provision of health care within a rapidly evolving health care delivery system. As a discipline with clinical governance rooted in both the production of objective data and interpretative services, the practice of medical technology is particularly sensitive to technical change. However, advances in automation, computerization, and clinical information systems have implications far beyond the world of the medical technologist.

2. Technological Advancements in Laboratory Medicine

Newer and more advanced technologies are increasingly manifesting themselves in medicine at a seemingly exponential pace. Medicine has always been guided by the concurrent advances in technology. The prevailing environments, political climate, and economics have always had moderating or hastening effects on such manifestations. Indeed, the limitations of current technologies are generally encountered as the reasons for the completion of clinical laboratory tests within the current time frames in which they exist. The definitions that cleanly divide soil from highly complex technologies, or conventional from high technology, are tenuous at best.

The introduction of new computational technologies by the clinical laboratory was guided by the needs of the diagnosticians who were proponents of its initiation, and it has existed as needed. Interdisciplinary mixing was present when computational technologies were introduced to the clinical laboratory. Its introduction was accomplished by microbiologists, chemists, computer scientists, and electrical engineers, as well as hematology specialists.

2.1. Automation and Robotics

In recent years, the clinical laboratory has been profoundly impacted by the introduction of advanced automation and robotics, most prominently in the area of chemistry and, to a lesser extent, hematology. Several companies have now introduced advanced automation lines that can process hundreds of chemistry specimens per hour. These systems combine robotics with both large and small analyzers in a dynamic, computer-controlled environment that automatically sorts specimens and determines which tests should be conducted. Additionally, robots can now be programmed to add diluent to blood, pipette for both large and small samples, and cap and decap samples. Robotic technology is also employed to conduct colony counts for urine specimens. Equally important is the interface of automated systems with the laboratory information system. In a perfect setup, a clinician can thus send a patient to the laboratory with an electronic lab order into which he has embedded clinical decision criteria. This order would trigger the automated chemistry line to analyze the critical tests for that particular patient. On initiation of the test by the automatic line, the system would measure and produce results in adequate numbers of milliseconds and seconds. In the future, the clinician could also review these results electronically in the office as soon as they are available. Such a system has helped to maximize the cost efficiency of chemistry testing.

Automated instrumentation for urine analysis is also available. Once again, the forward-thinking clinician can design the urine test request to cause the automatic line to determine automatically the number of urine parameters needed for each specific patient, and the automated system would then scan the urine specimen, delivering results several seconds later, again providing the clinician with timely test results. Summarily, the introduction of automation and robotic technology has significantly raised the productivity of the clinical laboratory in the areas of chemistry, hematology, and urine testing, while reducing labor costs and improving the turnaround time for result reports. However, these areas collectively contain less than 50% of the volume of tests performed in the lab. To keep pace with the continued workload demand, robotics and/or automation would have to be adapted to the remainder of lab testing areas, including but not limited to bacteriology, virology, parasitology, mycology, histology, cytology, genetic testing, serology, endocrinology, coagulation, immunology, and molecular diagnostics.

2.2. Artificial Intelligence and Machine Learning

The concept of artificial intelligence (AI) and machine learning (ML) is something that most of us have heard about. AI is a computer program or machine that is capable of learning from and adapting to real-time data, seeking distinct and accurate patterns within the data. The goal of these algorithms is to have predictions or recommendations learned from the data without human intervention. AI is the major umbrella term. Jobs of AI include automation, artificial intelligence, cognitive computing, machine learning, robotics, etc. ML is a subset of AI and is the technology that allows our computers and machines to learn from the data sets that we give them; data includes text, engineering plans, pictures, patient information, and even genetic data.

AI is a group of programmed behaviors based on patterns of activity discovered or predicted, and action outcomes are based on predictions with a high probability of occurrence. Examples of the uses of AI-based algorithms include predicting organ transplant rejection possibility; the use of clinical rules and learned patterns of physician/nurse practice data in order to identify at-risk patients with progressive heart failure for the creation of a tool for physicians to use in treating them; the use of microbiomic or genetic data in order to develop a method to discover bacteria or viral content of a patient that are identified in construction site dust; elucidate mixture and specific identification of an unusual blue-green soil bacterium found in RA patients and normal non-RA controls, and even to describe patterns of endosomal gene expression due to the age of RA-treated mice and predict potential drug interactions and adverse effects of these drugs over time.

2.3. Big Data and Analytics

When one hears the term "big data," it is often in the context of information technology or established corporations. In recent years, big data has taken hold of even more industries and people. The clinical laboratory, specifically, has seen firsthand how big data dreams are shared across vast segments of our healthcare system. With the push toward population health management and the desire to finally realize the potential of the electronic medical record and associated electronic health record systems, big data analytics have become necessary for those organizations that are charged with providing care, such as hospitals and their associated laboratory test facilities.

Big data, as the name suggests, is predominantly about growth. It has moved from an era of terabytes to exabytes. And while it was very clear about what exactly "big data" constitutes, it becomes quite prevalent. Big data is not very big—huge. Having just data is not meaningful by itself. The questions are always there—tacked onto the very next moments—of what to do with it and how to advance understanding that supports better decisions. Making decisions with no knowledge of the outcome can be disastrous, which is why the study of big data in healthcare analytics has taken such a boom.

3. Impact of Advanced Technology on Clinical Laboratory Practices

The continuing evolution of advanced technology will have a significant impact upon the clinical laboratory. A portion of this report will therefore be directed at the clinical laboratory, regarding what to expect both in the near and distant future, and how we will have to respond to those advances in a responsible and perhaps even visionary manner. The laboratory has become the centerpiece for patient management. No longer just a "supportive" function, the results of laboratory testing guide the medical decision-making process on the part of the physician. Will that situation always be the case? What should be expected of laboratory medicine as we look ahead, toward the anticipated improvements in health care? (Gagnon et al.2020)(Khatri & Aronowitz, 2021)(Garg, 2023)

First, there are those who believe that although the practice of laboratory medicine will continue to be important, it will not continue to be as greatly involved in the study of human disease as it is at present. Many feel that the future medical emphasis will shift away from therapeutic intervention at a later stage of disease, after it has become established and manifest, into serious interest in detecting abnormalities much earlier in the course of a disease, even at an asymptomatic state. For many illnesses, therapeutic interventions should then actually be effective in preventing the occurrence of disease, and will therefore mobilize a largely different collection of health care providers: those practicing the science of health care rather than disease care.

3.1. Efficiency and Accuracy

This section describes how advanced technology will improve the accuracy, efficiency, and quality of laboratory analyses. Key features of the lab of the future will be digital, bar-coded specimens, high-efficiency analytical instruments, decreased manual intervention by laboratory operators, advanced capabilities in laboratory middleware, and high-quality internal and external peer review. With new technology, pre-analytic processing area turnaround time goals will be in time frames of less than 40 minutes with nearly zero error potential. Laboratory result reporting time frames will be separated into routine stat and regular stat categories. Results for routine stat will be reported back to the ordering health care team in less than one hour. Results for regular stat will be reported by the end of the patient's stay in the hospital. World-class education and training programs will also define the laboratory of the future.

By using advanced technology in the lab of the future, laboratories can make significant contributions to patient safety and can positively impact patient care and clinical outcomes. In the clinical laboratory, the mission of leveraging technology is efficiency, accuracy, and high analytical quality for laboratory testing. With advanced technology, the right results are communicated to the right patient at the right time. The future that will become the "new benchmarks" for the lab of the future. Harsh words you might think? No, only words from a lab customer.

3.2. Cost-Effectiveness

It must be emphasized that the purchase of prices comes at a very high price, thus justifying the shorter fee schedules for clinical laboratory testing. There are still few studies on the cost-effectiveness of AT in clinical laboratory testing. The analysis showed that the results of these studies were more accurate and cost-effective than those obtained using automatic devices. It was reported that the method was superior for evaluation of depressed serum IgE levels in patients with low values.

Rather than trying to show that the results obtained with AT methods are equivalent to those obtained with non-AT, the concept of cost-effectiveness should be used as a decision-making tool to determine whether AT methods should be implemented in the laboratory. The concept of cost-effectiveness is used to evaluate potential risk: that is, the least costs associated with errors of commission and errors of omission. The decision related to a sequence will be based on considerations as to whether the consequence of commission, omission, or uncertainty is greater than the cost of each of the alternative decisions. The cost aspect is evaluated in terms of the necessary technology and resources to implement the procedure, and the quality control systems required to ensure good performance; the consequence aspect is evaluated in terms of the costs of an adverse decision by the clinician, such as costs associated with hospitalization, further tests, or litigation.

3.3. Quality Improvement

The ISO 9000 series of quality system standards, beginning with the ISO 9001 requirements document, have revolutionized corporate thinking about quality.

Businesses that used to feel that they "could not afford quality" now recognize that "you cannot afford the lack of quality." It is certain that hospital management in the 1990s will recognize that, to effectively utilize the clinical laboratory, they will have to integrate it into the overall hospital quality improvement plan and invest in its necessary staffing, equipment, training, education, and management to do so. As this integration materializes, the laboratory departments of the future will evolve from "quality control" laboratories to actual "quality management" centers. (Colquhoun et al.2020)(Alowais et al.2023)(Alrawahi et al.2020)

Good quality improvement has as much or more to do with prevention as it does with detecting and correcting errors. Attaining and maintaining a high standard of care is an everyday effort that must permeate every activity of the laboratory. While blood samples are on the decline, the clinical laboratory's work in areas such as therapeutic drug monitoring, hemoglobin A1c, and other tests that reflect chronic disease states and wellness rather than acute disease states and "illness" is on the increase. Bloodborne pathogens and chemical hazards in the workplace have made the clinical laboratory a workplace risk and have increased the need for quality improvement and appropriate cleaning and infection control procedures.

4. Predicting the Lab of the Future

Important thoughts for predicting concepts and issues associated with the development, design, and use of the lab of the future and different visions of the future role of the clinical laboratory are discussed. New radar systems, the search for new raw materials, the development of energy systems, and the consequences of new technologies in the biomedical field were considered. A paradigm was suggested: the transfer of laboratory tests and patient monitoring to the physician's office. No laboratory would be required. It seemed that technological development could imply a reduction in the number of clinical laboratories. Institutes and hospitals would have their own resources, or suitable personal equipment would be obtained, while community laboratories would disappear. More recently, the total elimination of the laboratory has been suggested, including the protective diagnosis of certain causes of human death, traditional and new technologies, the incorporation of that information into the comprehensive network responsible for monitoring health, and the implementation of innovations in telemedicine. The bioinformatics sector, the chapters, and mathematical models developed at the time of that diagnosis would indicate the formulated treatment. The laboratory result may come from miniaturized and portable systems, a technology that may open room for the use of office and home-based miniaturized laboratory tests, with tests ordered from a distant location. The total automation technology of the diagnostic process, the access of the equipment operator to knowledgeable support, as well as to the control of the procedure, was not neglected. Any possible malfunction would require maintenance. It seems that patients may request laboratory tests from product sellers or pharmacies.

4.1. Emerging Technologies

New technologies have been introduced to facilitate many processes in the clinical laboratory, including testing developed for point-of-care use by non-laboratorians. Emerging technologies to monitor patient health may revolutionize the role of the clinical laboratory in health care. For more than two centuries, the U.S. clinical laboratory has offered national and international healthcare services that are supportive in nature. Currently, technological advances for those who seek protection, together with a knowledge-based worldwide community, are enabling the laboratory to explore, understand, and help to shape health, life/work, and career planning decisions in a meaningful manner. This remarkable change was initially set in motion about 20 years ago; the united global scientific and technological team continued its momentum, achieving significant advances. The following section describes some of the emerging technologies that could be adapted toward the laboratory of the future. Many of the newer technologies require that non-laboratorians perform tests having potential clinical significance, especially when performed at the point-of-care. These tests include continuous glucose monitoring, direct eye measurement of the tear glucose sensing, home testing for white blood cell counts or bleeding disorders, and preoperative tests in cardiology or other sensing tests. In the U.S., mandated safety-locking products have been developed and are available for blood glucose meters. Some of the rapid tests are available, but rapid home tests that include reading a mini-device are in development.

5. Conclusion

In conclusion, the advance of modern technology, in addition to enabling earlier diagnosis of various diseases and conditions, and developing more cost-effective tailored therapies, provides laboratory professionals with opportunities to work in a setting that is more complex and changing more rapidly than ever before. The continued study of the basic technologies—chemistry, immunoassay, toxicology, blood gas, etc.—in terms of how they can be improved, combined with a greater involvement in the pre- and post-analytical phases, is essential in order to assure the central role of the clinical laboratory as the major tool for supplying an increasing amount of information required for the planning, management, and execution of the diverse activities carried out in the area of health.

Today's laboratory professionals must understand, eventually, how to generate lab results and information from tests performed on a variety of analyzers and other devices, totally independent of size, that will be developed specifically for use in non-laboratory settings. This represents an enormous change in the philosophy and practice of laboratory medicine as we know it and involves new initiatives for the education of new health care workers. The technology of the present and future will provide many new opportunities to laboratory medicine, but its correct use in the health field depends on a good understanding of the value of the proper integration of existing and new technologies into the networks of health-related activities, within the context of modern society.

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