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THE ROLE OF AUTOMATION IN MODERN CLINICAL LABORATORIES

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Abstract

This essay examines the automation of laboratories that provide clinical services to hospitals, clinics, and other health-care facilities. Emphasis is placed on the automation of testing procedures during which biological specimens, such as blood, urine, and other fluids or tissue material, are analyzed for the presence of indicators of medical conditions. Laboratory automation refers to the use of mechanized equipment and computers to handle laboratory tasks that were once conducted by human technicians. Labor-intensive testing procedures performed manually can take hours or days of turn-around time, and may be more prone to errors. Automated systems dramatically shorten turn-around time, often to less than an hour, and increase testing speed and accuracy. Automation has transformed clinical laboratories from small, low-technology services into large, high-technology operations. Many larger hospitals own automated systems in-house. A growing number of smaller hospitals and health-care facilities are turning to commercial laboratory service providers that operate massive, fully automated laboratories capable of serving hundreds of health-care facilities (Avivar, 2012). In some cases, satellite systems that employ miniaturized automation are used to supplement off-site, central laboratories. The goal of laboratory automation is not only to mechanize the procedure for carrying out individual tasks, but to create a fully automated, integrated system that handles specimens automatically from the time they are received by the laboratory until results are generated, interpreted, and reported. Macrosystems are capable of handling thousands of specimens each day, providing performance far beyond what could be achieved by manual laboratories and smaller automation systems. However, the design of macrosystems is complex, and difficulties can arise with integration and control of automated components from multiple vendor companies. Most health-care facilities use either stand-alone automation systems that need human technicians to perform some tasks, or semi-integrated systems that combine automated and manual components (Archetti et al., 2017). Interest continues in new technologies that could be the basis for the next generation of systems, with an alternative

approach of employing miniaturized, integrated analysis devices performing multiple tests on a single specimen aliquot. In addition to reviewing current laboratory automation technologies and taking a look at the future, the challenges of laboratory automation are discussed.

Keywords

Automation, clinical laboratories, efficiency, turnaround time, accuracy, regulatory, quality assurance, cost, instrument, pi-control, post-analytical, metrics, virology, serology, microbiology.

Modern clinical laboratories comparatively describe automated clinical laboratory processes with a focus on viral laboratory automation in clinical laboratories. Because of the increasing patient load good laboratory practice dictates that the turnaround time (TAT) for laboratory tests should be kept as short as possible. Keeping all other factors constant, productivity will rise as TAT shortens. To achieve short TAT, batching strategies should be critically examined and avoidance of batching experiments proposed. Another way to keep TAT short is the implementation of automatic pre-analytical or post-analytical modules with conveyors. Such modules will speed up the accessioning of samples, which is important because the pre-analytical phase often takes longer than all analytical steps combined (Donald Moshen, 2010).

Originally described viral laboratory automation processes will be set against these background principles and modernization experiments introduced. This chapter will also focus upon serological testing, where the solution of cross-reactivity problems is critical in the analytical design of fully automated clinical laboratory analyzers. Fully automated serological methods, which are based on bio-chips and image analysis, have been developed in experimental laboratories. However, their introduction in clinical laboratories has been hampered because currently used methods meet almost all requirements and drawbacks of new methods, such as additional sample pretreatment, cannot be accepted (Avivar, 2012).

1. Introduction

Clinical laboratories are a key component in healthcare delivery systems playing a vital role in the prevention, diagnosis, and monitoring of diseases. They generate high volumes of data which must be processed with great accuracy and reliability in an efficient, timely, and also cost-effective manner. The adoption of highly automated systems is rapidly emerging in numerous clinical laboratory disciplines and is seen as an important means of meeting many of these requirements (Avivar, 2012). Automation in clinical laboratories refers to automated systems and robotic technologies to improve laboratory efficiency by minimizing human intervention. Over time, laboratory practices have evolved through different phases from the early stage of manual testing with glassware to the current complex automated systems. During the manual process, a number of challenges were faced like the pre-analytical errors, time-consuming testing and results generation affecting the clinical efficiency and healthcare outcome. The introduction of automation in laboratory practices drastically improved the above-said challenges and also enhanced the clinical efficiency of laboratories. Automation enhances the diagnostic accuracy and clinical efficiency in the clinical laboratories. This paper bridges the gap between theory and practical exposure with regard to automation in clinical laboratories. An overview on basics of automation is discussed followed by a detailed explanation on the application of automation in clinical laboratories highlighting the benefits, challenges, and future trends (Archetti et al., 2017).

2. Historical Perspective of Automation in Clinical Laboratories

The 1950s ushered in early attempts to automate clinical laboratory processes, beginning with the development of devices for specific tests. During the 1960s, the arrival of personal computers prompted further efforts to automate laboratory processes, leading to the advent of standalone devices linked to computers. The 1970s saw the development of comparative immunoassay analyzers, even as fully automated analyzers met with some skepticism from clinical pathologists who were wary of complexity and costs (Avivar, 2012). In the 1980s, however, as costs declined and the quality of chemistry measurements improved, clinical pathologists embraced standalone analyzers, especially for stat tests, which could quickly and accurately process a limited number of samples. As the 1980s came to a close, efforts to automate routine clinical chemistry tests gathered pace, with the emergence of large analyzers capable of performing multiple tests on samples in uninterrupted fashion. By the 1990s, it was clear that many clinical laboratories were unwilling to forgo computers and analyzers in favor of completely manual processes. Laboratory automation thus became a pressing concern, although most larger laboratories opted for a hybrid approach, combining automated and manual systems. The 2000s, meanwhile, witnessed further refinements in laboratory automation designs, as new solutions sought to combine the benefits of both totally automated and hybrid systems. Notwithstanding the resistance that existed early on regarding the complexity and cost of automation, it slowly but surely began to transform laboratory processes, and no one now expects a return to completely manual procedures (Archetti et al., 2017).

3. Types of Automation Systems in Clinical Laboratories

To understand the various automation systems in clinical laboratories, one can classify them based on the phases of laboratory testing: pre-analytical, analytical, and post-analytical automation. This classification is helpful in grasping the workflow of clinical laboratories and the purpose of each automation type. Moreover, it highlights that different automation systems are not independent and are part of the same interconnected system. Understanding their specific roles helps in comprehending how these systems work together for laboratory efficiency. Although it is possible to describe automation systems without mentioning integration, a brief emphasis on the significance of systems integration may help in better understanding laboratory automation as a whole. Integration is key to achieving seamless laboratory operations. Automation systems may be easier to understand individually, but they are most effective when fully integrated. A basic understanding of each system's function is fundamental for appreciating the complexity of modern laboratory automation (Avivar, 2012).

Laboratory testing usually comprises three main phases: pre-analytical, analytical, and post-analytical. Each type of automation system carries out one of these tasks. There are several technologies employed under each type, with some overlapping. Pre-analytical automation involves sample preparation before the analysis is performed. Tasks executed during this phase include the handling of samples, such as transportation, sorting, aliquoting, and adding reagent. Most pre-analytical automation systems utilize robotics in the form of robotic arms or pipetting machines to conduct these tasks (James Wurtz, 2014). These freestanding robotic systems are usually connected to one or more clinical analyzers using conveyor belts or tubing. This type of automation is common in clinical laboratories, particularly due to the availability of space and budget for one large automation system. Moreover, several manufacturers provide pre-

analytical automation systems compatible with various analyzers, ensuring a wide selection of equipment. Analytical automation refers to measuring and analyzing samples after preparatory steps have been conducted. Generally, this automation type is found in standalone equipment designed for a specific analysis. For instance, clinical biochemistry analyzers perform sample measurement and analysis of enzymes or proteins and are pre-programmed to conduct analysis based on user-input information such as sample type and desired test. Unlike pre-analytical automation that can be large, analytical automation systems are compact, independent, and require minimal handling. This is because clinical laboratories typically operate multiple analyzers that process different tests. Common technological platforms commercialized in analytical automation include immunoassay, chromatographic, and spectrometric systems. Post-analytical automation entails reporting results after data processing and interpretation. Different systems can run a single software, although each analyzer may come with its own data processing system. Raw data obtained from the analyzer need to be converted into interpretable results. Data produced from clinical analyzers require statistical processing to minimize the possibility of reporting erroneous results. Results are usually interpreted based on an underlying algorithm accounting for a set of rules concerning the sample, such as out-of-range values, obscure results, and interference. Interpretation is followed by data storage and reporting. With several analyzers in one laboratory, results are typically stored and reported using a single database, which could be either coupled with each analyzer or be independent of them.

3.1. Pre-analytical Automation

The pre-analytical phase is generally described as the stage before the analysis of the specimen. In clinical laboratories, this is the most important phase, as errors in this stage affect the specimen integrity and thereby the reliability of the analysis (Nordin et al., 2024). In general, there are two stages in the pre-analytical phase. The first stage includes everything outside the laboratory, such as specimen collection, transportation, sorting, and aliquoting. The second stage includes tasks performed inside the laboratory prior to analysis, such as specimen reception, checking the specimen for acceptability, sorting, and aliquoting. The majority of the tasks in the pre-analytical phase were manually performed by laboratory technicians, creating a potential source for errors. Therefore, many research studies and product developments have been conducted to automate the pre-analytical phase in clinical laboratories.

Automation in the laboratory can come in various forms. It can be a simple device that requires little human intervention and takes over one task, such as an automated timer for test tube racks, or it can be a complex robotic system that performs multiple tasks without human intervention, such as a specimen sorting and aliquoting system. However, with automation, the processes involving machines and equipment are designed to limit human intervention. Hence, the human errors associated with laboratory procedures can be eliminated or minimized. Generally, the objectives of automating sample handling systems are to improve the overall workflow efficiency of the laboratory and to maximize automation throughput by eliminating laboratory bottlenecks (Avivar, 2012). Consequently, the laboratory can run with fewer personnel, and the turnaround time in obtaining test results can be reduced. Automating specimen collection, processing, and sorting can reduce or eliminate the hazards of prolonged specimen hold times, degradation, and interference, which are related to transport delay, technological failure, or human error. This section discusses the available technologies for specimen collection, processing, and sorting automation, addressing the challenges

encountered during the automation in the pre-analytical stages and how the challenges were resolved by automation. In addition, the technologies are explored in detail regarding their impact on specimen integrity and the reliability of subsequent analyses.

3.2. Analytical Automation

Automated systems in analytical laboratories are responsible for the testing and analysis of samples. These analytical automation systems comprise sophisticated technologies that enable high-throughput testing and real-time analysis. Throughout clinical laboratories, various automated instruments, such as analyzers and robotics, have been deployed for clinical testing. Such instruments measure certain attributes of samples in an automated fashion. Measurements can be made on blood or its components for a wide variety of medical conditions. Automated systems have significantly enhanced the accuracy and precision of the measurements during laboratory diagnostics. Interestingly, one of the goals of automation in analytical laboratories is to minimize human intervention. Human activities such as sample handling and equipment maintenance can affect the consistency of results. The automation systems can, therefore, improve consistency via their pre-programmed functions. However, certain functions of analytical systems such as calibration and maintenance have to be performed by humans. Otherwise, the performance of the systems would degrade, resulting in unacceptable measurement errors (Donald Moshen, 2010). To aid laboratory personnel, vendors provide guidelines on the frequency at which these critical functions ought to be performed. Each measurement type on an analytical system is accompanied by certain pre-defined activities on the system. When these activities are performed, the system is said to be in a state analytical automation considered desired for that measurement type. If such activities are not carried out, the system is in a non-desired state. A system non-desired state can lead to unexpected measurement errors.

Equipment malfunctions are the major cause of non-desired states in analytical automation systems. A laboratory that uses modular analytical systems experiences non-desired states on the equipment from time to time. These non-desired states can prevent the laboratory from performing critical measurements for long durations, thereby affecting the quality of its services. Several examples are described to illustrate how automation has revolutionized particular testing methods and processes in analytical laboratories. The advances in laboratory automation have been critical in the development of high-throughput screening biotechnological applications. Progress in molecular biology and genomics has accelerated the ongoing interest in technology-forwarding laboratory applications. Analytical automation is a significant step toward excellence in laboratory diagnostics (Avivar, 2012). Most modern analytical systems are now automated, with all essential functions, including sample introduction, in a robotic configuration, and analytical measurements performed with little or no operator involvement.

3.3. Post-analytical Automation

The post-analytical phase represents the final phase in the laboratory workflow, during which the results are handled and disseminated. Although different disciplines may use different equipment and methods, the core technologies that automate the result reporting and data management processes are similar (Lenicek Krleza et al., 2019). These technologies facilitate the communication and accessibility of results through various channels, such as printed reports, computer networks, and Internet-based access. As a result, healthcare providers can

receive laboratory data in a timely manner, which is crucial for clinical decision-making. However, the time between specimen processing and result reporting is even more important because the criticality of test results determines their significance to patient management (Avivar, 2012). Consequently, services that provide laboratory data to clinicians must be able to deliver results quickly and accurately, especially when the laboratory analytical workload is high.

There are also integrated systems incorporating laboratory information systems (LIS) with the automation of laboratory equipment for pre-analytical, analytical, and post-analytical phases. In these scenarios, results are automatically transmitted from the analytical devices to the LIS, which generates reports and transmits the results to healthcare providers. These integrated systems reduce the time needed to transmit results from the laboratory to the healthcare providers, thus enhancing laboratory productivity. On the other hand, non-integrated systems require laboratory technicians to manually enter results from the analytical devices into the LIS. Consequently, the automated transmission of laboratory results is contingent upon the prior manual data entry into the LIS, which creates a risk for the workflow through errors or delays in the manual process. The post-analytical phase represents a significant portion of laboratory workflows; so, to better illustrate the potential improvements in laboratory efficiency brought by automation, two successful implementations will be presented as case studies.

4. Benefits of Automation in Clinical Laboratories

Clinical Laboratories are a fundamental piece of the healthcare system, and the analytical tests they perform play a crucial role in the clinical decision-making process. By quantifying biomolecules related to pathologies, laboratories provide healthcare personnel with data for diagnosis, prognostic evaluation, and treatment monitoring. As a result, more than 70% of medical interventions are directly related to information produced by analytical data. In this context, laboratory human resource management is a complex task best approached with mathematical optimization methods. The evolution of clinical laboratories over the last two decades has been characterized by biotechnological breakthroughs that greatly improved laboratory efficiency and led to the widespread implementation of automated systems (Avivar, 2012).

The new clinical laboratory equipment drastically enhances the accuracy and precision of the test results, minimizing one of the main outside sources of error: the human. An automated clinical laboratory can process a greater volume of samples in a shorter time frame. This is possible because most of the operations involved in the analytical tests are automated. A good automation system comprises an integrated set of equipment wherein the sample workflow is automatic from the moment a sample enters the lab until the final results are delivered to the healthcare personnel. Automation also allows the implementation of enhanced quality control systems, which are crucial to the reliability of the diagnostic procedures (Archetti et al., 2017).

The expenses associated with the automated equipment are high; however, a good automation system results in savings in the laboratory operational costs. The automated systems necessitate fewer human resources than manual systems. Furthermore, automation eliminates the tedious and time-consuming operations, allowing laboratory personnel to devote their time to better activities such as method development or maintenance of the equipment. The implemented

automation systems in clinical laboratories are continuously under pressure from the laboratory management to improve performance or minimize costs. By understanding how automation impacts the laboratory service level, human resources can be allocated more effectively, and the advantages and drawbacks of the implemented automation can be demonstrated. Overall, automation has positively impacted laboratory performance, and in healthcare settings, it has a crucial role in improving patient outcomes.

4.1. Improved Accuracy and Precision

Automation in clinical laboratories has resulted in significant enhancement of accuracy and precision. Automated systems used in laboratories greatly minimize human error prevalent in manual tasks (Avivar, 2012). A variety of automated systems and technologies today facilitate precise measurements. Most test procedures are composed of a series of time-sensitive events such as sampling, dilution, mixing, incubation, measurement and cleaning. Any delay in this sequence can alter the test result. Automation minimizes this situation as they are composed of mechanical devices that can perform these tasks in a consistent manner. Automation also allows greater control over temperature, pressure and other environmental factors, which can have a significant impact on test results. Additionally, it is easier to standardize and calibrate the equipment involved in automated procedures than manual ones (Nordin et al., 2024). For clinical laboratories that engage in similar testing, automation is an advantage as it allows the establishment of uniform procedures across laboratories. It is also possible to pre-program standard procedures into machinery, preventing operators from deviating from them. These benefits have made the pharmaceutical industry heavily reliant on automated systems to ensure that their products can be accurately and reliably analyzed. A popular example of automation systems in laboratories is the continuous-flow analysis (CFA) system. CFA pioneered the introduction of automation systems that conducted sample processing, addition of reagents and measurements. CFA is now widely considered a first generation of analyzers, as the basic mechanism behind CFA systems is still the focus of modern analyzers today. Since accuracy and precision are fundamental for ensuring that test results are valid bases for making diagnoses and treatment plans, the wide adoption of automation systems has impacted patient care in a positive manner. Growing efforts are made to highlight specific research scenarios where automation has greatly improved accuracy. An example would be the automated imaging-based colony counting system deployed to assist in analyzing the performance of bacterial growth inhibition experiments. Automated systems are not entirely free from inaccuracies though, and there are documented cases where poorly designed automation compromised data integrity. High accuracy in laboratory results often implies compliance with good laboratory practices, which increase the costs of maintaining the laboratories. Compliance with these regulations becomes increasingly complicated with the introduction of automation, as most procedures need to be revalidated. Nevertheless, improved accuracy and precision would emerge as fundamental benefits of automated systems in laboratories.

4.2. Increased Efficiency and Throughput

A significant role of automation is its capability for increased efficiency and throughput. Modern laboratories need to process a higher sample load in a reduced timeframe. Within laboratory informatics, process automation is essential and forms the basis for increased efficiency and throughput. Automated systems can be implemented to optimize almost every laboratory workflow. In addition, the automation of systems frees staff to engage in more critical tasks that can only be performed by humans. With automation, routine processes can

be operated faster, more reliably, and free up staff to engage in other tasks (Avivar, 2012). Metrics, examples, and experiences will be provided to illustrate how laboratory automation can increase throughput and workflow efficiency. Healthcare establishments face the challenge of providing efficient healthcare delivery in consideration of available financial and human resources. Efficiency is generally understood as the ratio of the output of a process to its input. In this context, output translates broadly to the performance or the result of a service provided to a patient. Therefore, efficiency is closely related to an overall description of healthcare delivery performance.

Healthcare processes are commonly subdivided into five steps: patient engagement, diagnosis, treatment, patient monitoring and follow-up, and discharge. The diagnostic step is crucial to determine the nature of a medical condition and requires considerable time and resource investment. With the growing number of patients seeking treatment from healthcare establishments, there is increasing emphasis on the need to provide rapid diagnostic services (Archetti et al., 2017). Consequently, laboratory processes need to be re-engineered to ensure an increase in overall efficiency. Generally, throughput is defined as the number of units processed in a certain time period. Relating throughput to the healthcare context refers to the number of patients that can be serviced in a certain time frame. An increase in throughput translates to an increase in patient turnover, hence improved overall patient satisfaction and outcome. With the growing number of tests prescribed per patient, an increase in laboratory throughput is essential in ensuring timely provision of test results to clinicians. The improved efficiency and throughput explain the critical role of laboratory automation in modern laboratories.

4.3. Enhanced Quality Control

A critical advantage of laboratory automation is enhanced quality control. Automated systems continuously monitor processes and results, comparing them to predefined parameters and standards. Out-of-specification results trigger immediate corrective actions, such as retesting or notifying personnel (Avivar, 2012). Sophisticated software tools track and analyze data from automated processes, providing overviews of performance and quality assurance. Software can also generate reports necessary for maintaining compliance with regulatory standards. Adhering to these standards is crucial for the operation of clinical laboratories. Automated systems help ensure compliance with good manufacturing or laboratory practices (GMP or GLP), good clinical practices (GCP), and international standards (ISO). Automated equipment can run independent quality control processes on tests, as seen in some immunoassay analyzers. Procedures for monitoring the quality of the equipment itself are also automated.

Quality control processes typically detect defects or out-of-specification conditions for individual tests and result batches. By automating these processes, the variability and defects inherent to manual operations are reduced. Properly implemented automated quality control can enhance performance and quality beyond the capability of exclusively manual operations. The importance of quality control is paramount in ensuring patient safety and care directly. Too many deviations or defects in test results can result in a misdiagnosis, inappropriate treatment, or no treatment at all. On the other hand, situations in which laboratory results are unavailable can delay clinical decisions and adversely affect patient care. Therefore, enhanced quality control is a crucial benefit driven by the automation of clinical laboratories. Illustrated

examples of how an automation design ensures accuracy in test results via automated quality controls may be included in this section.

4.4. Cost Savings

Cost savings: The reliance on manual, labor-intensive processes increases the likelihood of errors and leads to longer turnaround times for test results. Automation can improve overall efficiency in the laboratory by cutting down on the time it takes to complete tasks while minimizing the chance for human error. As a result, labor costs will be significantly decreased because there will be a reduced dependency on staff to perform tasks that can be automated (Archetti et al., 2017). While staffing might need to be scaled back comparing pre-automation to post-automation analysis of cost structure reveals that there is a remarkable reduction in operational expenses as a result of the technology investments. Overall, for laboratory management it is important to note that automation brings long term financial gains and investment in technology that streamlines workflow will more than pay for itself. Cost effectiveness: Clinical laboratories typically allocate most of their resources to testing so it is important to maximize the return on these investments. For this reason, it is prudent to identify as many free as possible to more effectively manage remaining resources. Many activities performed in the laboratory today are repetitive in nature which could be easily taken over by an automated system. Reallocation of effort away from low level tasks and towards functions which require more advanced training is another method to optimize staff utilization. The automatic system takes care of transferring samples to and from analytical instruments and performing simple operations, such as adding reagents or changing cuvettes. Employees are therefore free to devote their time to troubleshooting difficult tests or evaluating and preventing issues with equipment. Cost savings specify that for all the reasons mentioned above, bringing automation into the laboratory is not only desirable but in many cases essential. In addition to increasing throughput and productivity, savings on one set of tests can be directed to lower price tests, thus ultimately reducing patient costs for services rendered. Impact on healthcare affordability: It is widely acknowledged that in order to improve quality and maintain their current breadth of services, clinical laboratories will need to invest heavily in new technology systems and infrastructure. However these fixed costs will be difficult for some laboratories to bear particularly smaller ones in rural or underserved areas. In this respect adding services to existing systems and operating them more broadly presents what may be the best option for organizations with multiple laboratories.

5. Challenges and Limitations of Automation in Clinical Laboratories

Like any new technology, introducing automation can bring numerous challenges and limitations. Some initial costs can be prohibitively high for certain facilities, even if financial support is available elsewhere for budget deficits (Archetti et al., 2017). Equipment maintenance, calibration, and any required technical repairs require further investment and manpower, which can be more of a concern as resources are taken away from laboratory instruments and technical staff. Furthermore, without the appropriate technical staff, laboratories may struggle to cope with software and hardware issues that directly impact productivity. Added to this are the issues of incorporating automated systems into existing laboratory workflows, where even minor compatibility issues can cause widespread disruption. Consideration also needs to be given to the laboratory's future growth and test menu increases. Automated systems can take many shapes and forms, and if existing arrangements haven't been thoroughly investigated, the wrong decisions can be made that incur unwanted

consequences during development (L. Rutherford, 1995). It's also important to consider staffing, as underestimating how much staff training is required can lead to staff resistance and a difficult transition. A failure to engage all parties in the planning stages can also leave staff feeling less secure in their roles, and as a result, automation may be viewed as a negative thing rather than an opportunity for improvement. Change management strategies should always be utilized to ease the transition of introducing an automated system, not only for staff training but also to assist in decision-making processes when developing workflows and future growth. Other challenges and limitations still remain, but attempts have been made to provide potential solutions. With this in mind, it is important to maintain a realistic understanding of what automation can achieve while also appreciating the complexities that come with it.

5.1. Implementation Costs

As laboratories contemplate the integration of automation, they must navigate a web of significant implementation costs that could otherwise be allocated to enhancing health services. Hence, laboratories exploring automation options provide insights into budget allocation strategies and discuss recent laboratory experiences in the context of financial challenges faced. A clear grasp of the costs and how to approach them is pivotal to a laboratory's transition towards partially or fully automated settings. Since the 1990s, clinical laboratories have rapidly evolved, primarily driven by technological advances focusing on automation. Sample throughput augmentation, improved data integrity, shortened method development time, and reduced sample data turnaround time (TAT) are benefits that automation can furnish clinical and other laboratories (Archetti et al., 2017). Automation pervades various health sectors, including clinical, pathology, blood banks, and infection laboratories.

Considering a wider public health perspective, a laboratory engaging in automation should exhibit a satisfactory service quality and an even degree of accuracy in routine tests. Automation in a clinical laboratory significantly enhances the service by minimizing the time taken for sample analysis and test results delivery to concerned doctors. However, there is an economic burden linked to automated laboratory analysis systems, particularly involving upgrading legacy systems with additional configurations to import automation. In addition to overheads in space, equipment, and infrastructure, the automated laboratory necess acquisitions of essential software packages to run the systems efficiently, along with employee training to operate them. Moreover, operating an automated laboratory involves ongoing maintenance costs of automated systems, equipment, and software. Generally, the costs incurred while upgrading a legacy health sector laboratory into an automated experimental setting must be clearly understood in terms of initial investments, ongoing costs, and how to ensure that costs remain within budget limits.

5.2. Maintenance and Technical Issues

Automated systems need extensive maintenance and tend to technical issues throughout their lifetime. Maintenance is the most time consuming task in running clinical laboratory automations. Regular upkeep is necessary to avoid breakdowns, as other critical technical concerns can arise with any automated system (Avivar, 2012). All automated systems consist of technical hardware and software, which sometimes run into issues that affect functionality. Systems require updates to their software, which often results in compatibility issues with the hardware and the need for IT help (L. Rutherford, 1995). Strategic improvements to software

are sometimes overlooked, but fixing these bugs can take up extensive time and resources if systems require a third party to intervene. Similarly, hardware can fail, causing systems to become inoperable. When this occurs, hardware may need to be replaced which often requires the manufacturer to be involved. Having competent in-house staff to carry out modifications to software or install replacement hardware is critical to ensuring automated systems run smoothly. Technical issues can seriously affect laboratory operations. Automated systems generally run hundreds of experiments per day, meaning a technical issue can delay these results. Delays can lead to a backlog of work and slow turnaround times; a particularly problematic situation for time-sensitive samples. Beasts of automation often come with robust technical support, and comprehensive maintenance contracts should be put in place with the manufacturers to alleviate the stresses of technical issues. Compliance to maintenance contracts is critical; whilst the contractual obligations for both parties may be thoroughly defined, good faith must also be extended in keeping as close terms to the spirit of the contracts as possible. Technically complex equipment is only as good as the maintenance and support applied to it. Without proper upkeep, systems will become more vulnerable to technical issues, and the necessary skilled support to solve such issues may become limited. Automated systems are not a quick fix solution to improving laboratory efficiency; rather, they are significant commitments that need constant consideration to maximize their benefits.

5.3. Integration with Existing Systems

Integration with existing laboratory systems presents numerous challenges when adopting automation solutions. As laboratories modernize their workflows by bringing in automated technologies, they often discover unexpected compatibility issues with existing systems. Therefore, it is crucial to thoroughly assess current systems before embarking on the introduction of new automation technologies. While new automation systems may elevate workflow efficiency, potential disruptions caused by the integration process can affect laboratory efficiency overall (Zimmermann, 2021). Compatibility concerns often extend to laboratory information management systems (LIMS). Careful planning and consideration are required to ensure that integration is as smooth as possible. Failing to account for integration issues may render new automation systems useless, despite the initial investment. Part of the planning process is understanding the limitations of legacy systems (L. Rutherford, 1995). In some cases, legacy systems may need to be replaced altogether with more modern versions that accommodate the new automated technologies. This analysis can include case studies that showcase both successful integrations and common pitfalls. Ultimately, integration is critical in ensuring that laboratories fully enjoy the benefits automation brings.

5.4. Staff Training and Resistance

With the initial costs of the purchase and installation of the equipment incurred, care staff for the automated equipment must also be considered. Staff must be trained in the correct operation of the systems and the laboratory processes involved; if this does not occur, the laboratory may find itself repeatedly requesting the same service from the vendor because the equipment is being used inefficiently (L. Rutherford, 1995). Consequently, in some situations, it may be appropriate to train staff on the operation of the systems before the systems are installed in the laboratory. A balance must also be reached between how much operation and maintenance training a vendor provides and how much is considered essential from experience with other systems. Depending on staff levels and how critical a system is to a laboratory, it may also be essential to train at least two staff in each area that is automated to ensure a single staff member

moving to another laboratory does not leave a system incapable of being operated or maintained.

As much as the correctly trained staff will ensure that automated systems are being operated as efficiently as possible, there are potential resistances to automation that will need to be overcome. There is a natural resistance to change that has been noted with nearly every laboratory that has transitioned to automation. Staff concerns for job displacement are generally at the forefront of this resistance, especially in laboratories with high sample throughput where it is clear that fewer staff will be needed to run an automated system than were needed to conduct the same processes manually. While it is true that some staff positions will be lost in a laboratory with automation, it should be noted that employment numbers in the discipline have generally increased as business growth has generally outpaced employment cuts with the introduction of automation and data analysis systems. In addition to fears over job losses, there is often a discomfort with the technology being introduced, particularly with older staff who may not feel adequately equipped to operate new computer-based systems. There is also the problem of laboratory personnel not being involved in the transition before the installation of the automated systems; this is a crucial stage as the acceptance of the new systems will be easily fostered if staff are involved and consulted on how the new automated systems will integrate into the laboratory.

6. Future Trends in Automation for Clinical Laboratories

This section explores anticipated future trends in the field of automation for clinical laboratories. The introduction outlines the rapid advancements in technology and their integration into laboratory environments. It discusses emerging technologies expected to influence laboratory automation, including robotics, artificial intelligence (AI), machine learning, and the Internet of Things (IoT). The sections also touch upon changing perceptions of automation, with the workforce increasingly viewing robots and automation as allies rather than threats. This section highlights how automation technologies will likely improve laboratory processes through efficiency, accuracy, and overall management.

Robots, especially collaborative robots (cobots), are discussed in laboratory environments. Recent advancements in cobot technology, including affordability, ease of use, dexterity, and sensitivity, are mentioned. Prioritizing ergonomic design in cobot development is expected to prevent musculoskeletal disorders among laboratory personnel. Cobots also have the potential to address labor shortages, particularly in tasks such as plating, streaking, and inoculation. The potential impact of AI and machine learning on laboratory processes is emphasized, focusing on the need for proactive adaptation to these technologies. Laboratory leaders play a crucial role in developing AI models that enhance laboratory efficiency. Machine learning algorithms are viewed as valuable tools for interpreting laboratory data and enhancing quality control measures.

The Internet of Things (IoT) is examined, along with its role in creating interconnected laboratory environments. Considerations for careful implementation are highlighted, including network vulnerabilities and data privacy concerns. Lab sensors can monitor temperature, humidity, light exposure, and equipment status, sending alerts when predetermined parameters are exceeded. An AI approach combined with IoT is proposed for a smart laboratory monitoring system addressing various laboratory environments. Laboratory automation trends

are summarized, focusing on how technologies can benefit laboratory professionals and improve overall performance.

Finally, the implications of trends on workforce dynamics and skill requirements are discussed. While some repetitive tasks may become obsolete, advanced technologies will also create jobs focused on programming, maintenance, and good laboratory practices. Awareness and on-the-job training need to keep pace with technological advancements to mitigate employee anxiety. The analysis concludes by emphasizing the importance of laboratory automation future trends for understanding new opportunities and challenges. Ultimately, this understanding is crucial for laboratories striving to remain at the forefront of automation development (Cadamuro, 2021).

6.1. Artificial Intelligence and Machine Learning

Artificial intelligence (AI) and machine learning (ML) will have a transformative impact on clinical laboratories as they improve decision-making and analysis through data. AI and ML take datasets, learn from them, and automatically improve without human intervention, transforming predictive analytics through insights from data. Enhanced predictive analytics lead to improved diagnostics and the potential for personalized medicine. An overview presents a vision for the next decade of progress, concentrating on the role of AI and ML in laboratory automation. Current applications of AI in automation are discussed, including screening techniques for anomaly detection, outlier analysis, and the foundational use of AI in laboratory quality control. The focus is on laboratory analysis, where AI and ML are employed to analyze spectra, chromatograms, and images. AI and ML have the potential to significantly change the way clinical laboratories operate, shaping the laboratory of the future.

Innovative algorithms could aid in the rapid development of low-cost laboratory analysis systems in many locales around the globe. However, the use of AI in healthcare raises important challenges, such as the potential propagation of bias and ethical concerns regarding automated decision-making. These issues are explicitly acknowledged but will require discussion and deliberation on the part of society, regulators, and the healthcare industry as a whole. AI systems are increasingly deployed across numerous sectors of the economy, often with unforeseen consequences. A robust framework and set of principles are necessary to help industry stakeholders navigate implementation choices. Simultaneously, it is imperative that human oversight is institutionalized alongside automated AI systems given the stakes involved (Cadamuro, 2021). AI and ML represent a new frontier for laboratory automation as the technologies become deeply embedded in laboratory processes.

6.2. Robotics and Cobots

Recent advancements in robotics have allowed for an increase in laboratory efficiency through robotic technology. Collaborative robots, or cobots, are robots that are designed to work beside human staff, which fosters a synergistic relationship between the technology and the human staff, allowing for a remarkable increase in productivity (Zimmermann, 2021). Robotic technology comes in many forms with a variety of applications in the lab—from large robotic arms that can process hundreds of samples in a single run to small, table-top instruments that can perform a single assay. As clinical laboratories continue to grow and the demand for testing is ever-increasing, robotic technology offers a solution that allows labs to maintain high standards of data quality and turnaround time. There are currently many advantages seen from robotic integration, including consistency, speed, reduction of manual labor, and freeing the

human staff for more valuable tasks. With the advancements made in robotic systems, these instruments are quite flexible and can be reconfigured for a variety of processes and applications.

Although robotic technology is becoming more commonplace in laboratories, there are still hurdles to overcome for technology adoption. One of the major hurdles is cost, as most robotic systems can be quite expensive to acquire and maintain. Additionally, robotic systems often require considerable time investment with staff training and programming. However, there have been numerous laboratories that have successfully adopted robotic technology, and with increasing demand, lab cobotics may become inevitable. Examples may include fully automated tube-processing systems, where batches of samples can be analyzed and interpreted without any human intervention, or instruments that utilize machine-learning algorithms to validate test results independently. The evolution of robotic systems will fundamentally change how laboratories operate. With the increased demand for laboratory testing after the COVID-19 pandemic, the lab has adopted two new instruments that employ robotic technology, which have proven to benefit the laboratory greatly. First, a fully integrated, random-access batch-sample-processing analyzer for immunoassays will be presented. Second, a high-throughput, fully integrated device for the processing of nucleic-acid-based assays will be discussed. These advancements in robotics and cobots will impact laboratory operations.

6.3. Internet of Things (IoT)

Internet of Things (IoT) is another notable trend in laboratory automation. Clinical laboratory devices can connect with each other and form a network with the help of IoT. This network enables a high level of monitoring and collection of data of connected devices (Kong et al., 2022). Cohesive and various data can be analysed right away, which allow insights into data to be gathered. Faster insights on data can lead to faster and improved decision-making which enhances efficiency (Kang et al., 2018). However, privacy and security of data collected through IoT devices have also emerged as important concerns. Implementation of IoT into healthcare systems requires careful consideration of data security. Although there are concerns with the implementation of IoT devices, this technology can streamline laboratory operations and allow improved management of resources. Automating construction processes consumes less time and fewer resources in laboratories. Unattended IoT devices can also help researchers to focus on important tasks rather than monitoring these devices. As trends of the IoT devices grow, laboratory operations can be more automated and streamlined. Laboratory productivity is highly dependent on the staff managing the laboratory. Lab staff juggle several tasks at once, including running experiments, planning, lab book keeping, data analysis, maintenance of equipment, and troubleshooting. It can be very challenging for the staff to keep up with the pace of one's experiments considering all the above tasks. Laboratory automation allows scientists to progress on experiments while the automated device manages others. Devices such as automated liquid handlers can perform sampling and reagent addition steps in experiments. These devices also allow data to be gathered on experiments while in progress. A growing trend of implementing IoT devices into laboratories enables scientists to better manage their time and resources. IoT devices can perform unattended experiments, and laboratory scientists can focus on other tasks. While unattended, these devices can generate data on experiments which can be used for predicting useful outcomes from given inputs and allow scientists to explore new regions of parameters. These trends of IoT would pave the way for laboratory automation to be further innovated and implemented.

7. Regulatory Considerations for Automated Systems in Clinical Laboratories

With the growing role of automation in clinical laboratories, regulatory considerations must also be taken into account when developing and implementing automated systems. Patient safety is paramount, and with automation comes a change in the system used to gather and analyze data, which opens new avenues for system failure. Because of this, regulations surrounding laboratory automation were enacted almost as soon as laboratory automation was developed. Compliance with regulations set forth by governing bodies is critical to ensure the safety of patients, the integrity of data, and the credibility of the laboratory (L. Rutherford, 1995).

The precise regulations and standards that are applicable to laboratory automation depend on the current locale and accreditation of the laboratory. However, most regulatory environments have very similar regulations regarding the quality management systems in place in laboratories. Relevant regulations include Title 21 of the Code of Federal Regulations (CFR) Parts 11 and 820; CFR Part 11 deals with electronic records and signatures, and CFR Part 820 details the requirements for medical device Good Manufacturing Practices (GMP). Also relevant are the FDA guidance documents. For laboratories accredited by The Joint Commission, their standards on “Information Management” and “Record Management” are also applicable.

In general, the implementation of automated systems may lead to compliance challenges due to the change in the laboratory workflow. Most compliance challenges can be rectified through adding capabilities to existing documentation or controlling compliance through different means. Thorough documentation is essential for compliance with any regulations, but this is especially true for automated systems. Consideration must be given to ensuring that all aspects of the system’s compliance are well documented. Failure to meet regulatory standards can cause laboratories to operate out of compliance, which incurs the risk of significant penalties. This can include the laboratory’s accreditation being suspended or revoked, which would cause a halt to all laboratory operations until a successful audit could be conducted. Other penalties include civil or criminal prosecution of laboratory staff, which is often accompanied by monetary fines, and the laboratory’s reputation could be irreversibly damaged.

8. Case Studies of Successful Automation Implementation in Clinical Laboratories

This section presents a variety of case studies that illustrate exemplary automation in action within clinical laboratories. Each laboratory is unique in the automation technologies utilized; some focus on pre-analytical automation while others highlight post-analytical or even fully-integrated systems. These laboratories range widely in size and scope, from regional hospitals providing a limited range of testing to massive reference laboratories performing high volumes of complicated assays. Despite the differences in approach and design, every lab profited from the changes brought on by automation. Some improvements are more difficult to quantify than others, but in nearly every instance the interviewees noted enhanced efficiency, reduced turnaround times, and improved accuracy as a result of the automation efforts.

Beyond the specific improvements achieved, the analysis of the case studies stresses one consistent theme: Every laboratory faced challenges during the implementation process, but they were largely overcome through careful planning and good communication. In fact,

interviewees from four laboratories stressed the importance of having both pre-analytical and post-analytical equipment from the same vendor. These experiences should provide valuable lessons for laboratories looking to automate some or all of their processes. These case studies illustrate how a number of clinical laboratories took the plunge into automation, and the successes they have achieved as a result. The details of each case study provide a window into the practical aspects of automation and how it can benefit laboratories, as well as potential hurdles to be overcome (Archetti et al., 2017).

For laboratories contemplating automation, these case studies can serve as valuable learning tools. Each laboratory tackles similar issues, but the solutions can differ dramatically. Some lab directors interviewed for these case studies note that their teams learned as much from other laboratories' mistakes as from their successes. Thus, one precious benefit of these case studies is the opportunity to examine in detail the decisions and processes that led either to successful implementation or to failure. Although each case study highlights the accomplishments of one laboratory, it also seeks to outline the steps taken to achieve success and some hurdles that had to be overcome along the way. The final point to be emphasized is that no laboratory is ever finished with automation; there must be periodic reviews of the process to ensure that it is delivering the intended benefits. Several interviewees noted that automation is never truly "on cruise control;" careful monitoring of the system is essential to take full advantage of the initial investment.

9. Conclusion and Future Directions

The significant findings and discussions on the role of automation in clinical laboratories have been summarized. Firstly, the major benefits automation can bring to clinical laboratories, such as efficiency, accuracy, cost-effectiveness, and quality, have been evaluated. In addition, the challenges and limitations of implementing laboratory automation have been discussed. Issues such as the cost of equipment, space, maintenance, and the need for staff retraining were identified as the obstacles laboratories face when considering the implementation of automation. However, it has been highlighted that these barriers can potentially be overcome through careful planning and consideration (Avivar, 2012). Finally, thoughts about the future of laboratory automation practices have been shared. As new technologies and trends continue to emerge, the laboratory environment will have to adapt and be proactive in integrating new solutions. Whether it be advanced robotics systems, artificial intelligence, machine learning, or high-throughput methodologies, these will have an impact on laboratory processes and workflows. Moving forward, clinical laboratories should welcome and perform further research into innovative automation techniques and strategies, as successful implementation can significantly improve patient care and overall workflow efficiency (Archetti et al., 2017). It is clear that laboratory automation is becoming a major driving force in contemporary laboratory practices and needs to be embraced in order to take advantage of the many opportunities it can provide.

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