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Artificial Intelligence in Medical Laboratory Technology: A Game Changer for Quality Control and Compliance

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REVIEW ARTICLE

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ABSTRACT

The coordination of Artificial Intelligence (man-made intelligence) in clinical research facility innovation has changed the scene of Quality Control (QC) and Quality Assurance (QA). This survey article investigates the uses of man-made intelligence in improving QC and QA in clinical research centers, including prescient support, constant information examination, high level picture examination, and blockchain innovation. The advantages of computer-based intelligence fueled QC and QA, like superior exactness, accuracy, and effectiveness, as well as the difficulties and impediments of carrying out artificial intelligence in clinical research facilities will be focused accordingly. Moreover, the job of research facility experts in embracing man-made intelligence innovation and guaranteeing the respectability of lab results will also be high-lightened. This survey plans to give a complete outline of the present status of artificial intelligence in clinical lab QC and QA, featuring its capability to reform the field and work on understanding results.

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Introduction

The new era of machine learning (ML) and automation has a great impact on the laboratory sciences. The precision, accuracy, man power and at last but not least 'consistency' has also been improved and still evolving in the laboratory fields [1]. The methods or tests that are manual and semi-automated have now been evolved into new digital era that is more precise, accurate, time effective and less hectic [2]. As for the accurate diagnosis and the welfare of patient the improvement of the quality assurance (QA) and quality control (QC) is the mandatory need [3]. The incorporation of ML into QA and QC has led to the evolution of new capabilities, encompassing advance methods of identification, predictive analytics, and sophisticated data processing [4]. These enhancements have enabled effective navigation of the hurdles associated with biomedical data thorough the employment of new and advanced algorithms. Along with the advantages these cutting-edge technologies also have the disadvantages and challenges [5]. This review will elaborate the innovations in techniques of QC and QA in medical laboratory science, go through their impact, and the challenges that are the results of these innovations.

In reference to the laboratory technology, the purpose of Artificial Intelligence (AI) is to reduce the chances of errors and man power at the minimal. As the word automation itself explain the automatic system that implemented in the laboratory technology. By virtue of which the test reliability is a successful approach [6].

These advancements encompass the spectrum of the technologies broader, i.e. from basic automated machines to the advanced automated analyzers and the procedure that is done almost solely by the robotic handling systems. These advanced systems perform routine tasks that are more than hundreds of times precise and high speed with reduced man power [7].

This integration of the automation in the medical laboratory testing will enhance the precision, reduce the burden on economy, and provides the more reliable QC and QA in this field. Improved outcomes or results, safety, the reduction of the waste of the healthcare resources and the satisfaction are considered as the benefits of the implementation of the automation in the medical lab technology [8]. New clinical funding models and regulatory frameworks emphasize patient empowerment, risk management, quality assurance, and technology assessment in order to effectively handle critical clinical situations in the laboratory for the welfare of the society [9]. In order to manage the chronic diseases, the evolution of the automation in the collection of the samples and the methods for the testing, the software and the applications that are related to the health in the smartphones, computers or tablets, reporting and the patient's record keeping systems has been implemented to the maximum extent [4]. These interventions in the laboratory have enabled us to control over disease by improving the disease control patterns.

In the context of this automated loop, patient empowerment is the second most significant trend in the ML. Numerous studies have demonstrated that mobile healthcare interventions that are automated, essential to the trustworthy self-management and self-care process, that has been successful in enhancing patient health outcomes related to chronic illnesses [10]. Smart phones applications, advanced software and digital laboratories have enabled the better management and self-monitoring diseases, for example; cardiovascular diseases and diabetes by blood pressure estimation, glycemic control and oxygen level time to time [11]. Cloud computing enables us to share the data and details of the patients or other information from one case, setup or facility to the other. In rural settings these factors of the digitalization and automation will also affects the regulation and ratio and also permits the efficient, reliable and advanced monitoring [12]. The implementation of digital pathways in primary and secondary healthcare sectors will facilitate efficient and precise techniques. Safety and cost-effectiveness in relation with the AI are crucial for the reliability and credibility of the digital laboratory environments in order to give benefits to the mankind [13]. Evolution in the laboratory detection system will boost novel human-machine interfaces, although implementation depends on clear, accurate and reliable interpretation. AI is a significant factor that can influence the activation of laboratory techniques by repeat testing. ML and data analysis combined with advanced health systems may prove an efficient tool for appropriate test prescription and accuracy [14]. About 70% of the errors occurs in the pre-analytical techniques of the sample testing process. The ML multi-analytic delta checks have shown the greater dominance over the traditional single-analytic delta checks [15]. The implementation of the ML and automation in the QC and QA of the sample have proven positive feedback in order to exclude these errors. Including this the automation in the chemical chemistry reduced the wastage of the solutions [16].

While discussing hematology department, in order to classify anemias and other hematological diseases, peripheral smear is essential technique. Moreover, in classifying the leukocytes, various ML techniques like; Bayes classifiers, multilayer preceptrons, K-nearest neighbors and supervised machine learnings (SVMs) have been implemented [17]. The dataset consist of about 17,000 cell images are used to train these models that have helped a lot in the development of the cost effective and sensitive lab systems. In classifying WBCs and myoblasts in acute myeloid leukemia convolutional neural networks (CNNs) have achieved more than 90% sensitivity and precision [18]. In order to classify RBCs, the CNNs are also used. This has offered a supplementary reclassification and improving the accuracy of the analyzers that are commercial such as Cella Vision [19].

In order to classify and identify neutrophil cytoplasmic antibodies imaging combined with immunofluorescence helps a lot in immunology. The digital imaging in the chemical analysis is limited whereas the evolved methods like mass spectrometry into the operating room has developed. In order to perform biochemical analysis in real time the tissue samples are collected from the surgical instruments. These helps a lot in the evolution of the QC and QA in the immunology and serology by automation [20].

Quality Control and Quality Assurance in Medical Laboratories using AI

Blood banks ensure a sufficient and safe supply of blood for hospitals, but managing high demand and avoiding

wastage remain challenges. Integrating ML in blood bank management can help forecast blood demand, classify donors, and optimize donation schedules. This approach can reduce blood shortages and wastage, improving the efficiency of the blood supply chain [21][22].

Applications of Artificial Intelligence in Quality Control and Quality Assurance

Computerized reasoning (simulated intelligence) is progressively changing QC and QA across different enterprises by improving productivity, exactness, and dynamic cycles.

One of the most encouraging utilizations of simulated intelligence in QC is prescient examination, which utilizes verifiable information and measurable calculations to anticipate expected imperfections or disappointments in items before they happen. By distinguishing designs underway cycles, prescient models can proactively propose changes, lessening waste and further developing item quality [23]. AI likewise assumes a crucial part in robotizing deformity identification, utilizing calculations to examine visual or sensor information from creation lines to distinguish peculiarities that might slip by everyone's notice by human monitors. Profound learning procedures, a subset of AI, further improve this capacity, empowering frameworks to perceive complex examples in pictures or sensor information with a serious level of exactness [24]. Additionally, computer-based intelligence driven Regular Language Handling (NLP) is building up forward momentum in QA, especially in regions including client criticism and item audits. NLP calculations can investigate huge measures of text-based information to distinguish arising quality issues, client feeling, and expected regions for development [25]. NLP can computerize the extraction of pertinent bits of knowledge from unstructured information, for example, online surveys or backing tickets, smoothing out the QA cycle and giving significant criticism to nonstop improvement. Man-made intelligence's capacity to screen and control creation quality stretches out past identification and input by integrating progressed dynamic frameworks that enhance store network the board, stock control, and support booking, all of which add to keeping up with steady item norms [26].

In assembling, simulated intelligence-fueled robots outfitted with machine vision frameworks lead continuous examinations, improving the speed and accuracy of value evaluations, in this way diminishing human mistake and functional expenses [27] Moreover, computer-based intelligence calculations in process control can adjust progressively to fluctuating circumstances, guaranteeing the nature of items all through the assembling system. At last, man-made intelligence's job in QA is additionally apparent in its utilization for factual cycle control (SPC), where calculations can persistently screen and change cycles to guarantee they stay inside quality boundaries [28].

Benefits of AI in Quality Control and Quality Assurance

Simulated intelligence has carried groundbreaking changes to QC and QA processes, especially in enterprises like medical services, assembling, and drugs. By utilizing AI calculations, computer-based intelligence improves the accuracy and dependability of value evaluations, lessening human blunder and giving a more elevated level of consistency. One of the essential advantages of artificial intelligence in QC and QA is its capacity to handle huge datasets rapidly and precisely, altogether further developing exactness in imperfection location and quality estimations [28]. Also, man-made intelligence frameworks can consistently learn and adjust, upgrading the capacity to recognize examples or abnormalities that might be missed by customary strategies, prompting worked on generally speaking quality and productivity [29].

Man-made intelligence driven mechanization in QC processes additionally streamline tasks by decreasing the requirement for manual mediations, bringing about quicker navigation and diminished functional expenses [30]. The speed and exactness with which computer-based intelligence frameworks can recognize disparities or imperfections add to less item reviews, not so much waste, but rather more dependable results. Moreover, simulated intelligence's job in prescient support and observing can assist with distinguishing expected quality issues before they heighten, considering precautionary activities that lessen free time and keep up with item honesty [31].

In medical care, simulated intelligence has exhibited huge enhancements in persistent security by improving demonstrative precision, lessening the gamble of human blunder, and guaranteeing that clinical gadgets fulfill rigid quality guidelines. Artificial intelligence frameworks in clinical imaging, for example, can recognize unobtrusive peculiarities in radiographs or outputs, which may be disregarded by human clinicians,

along these lines working with prior mediation and worked on tolerant results [32]

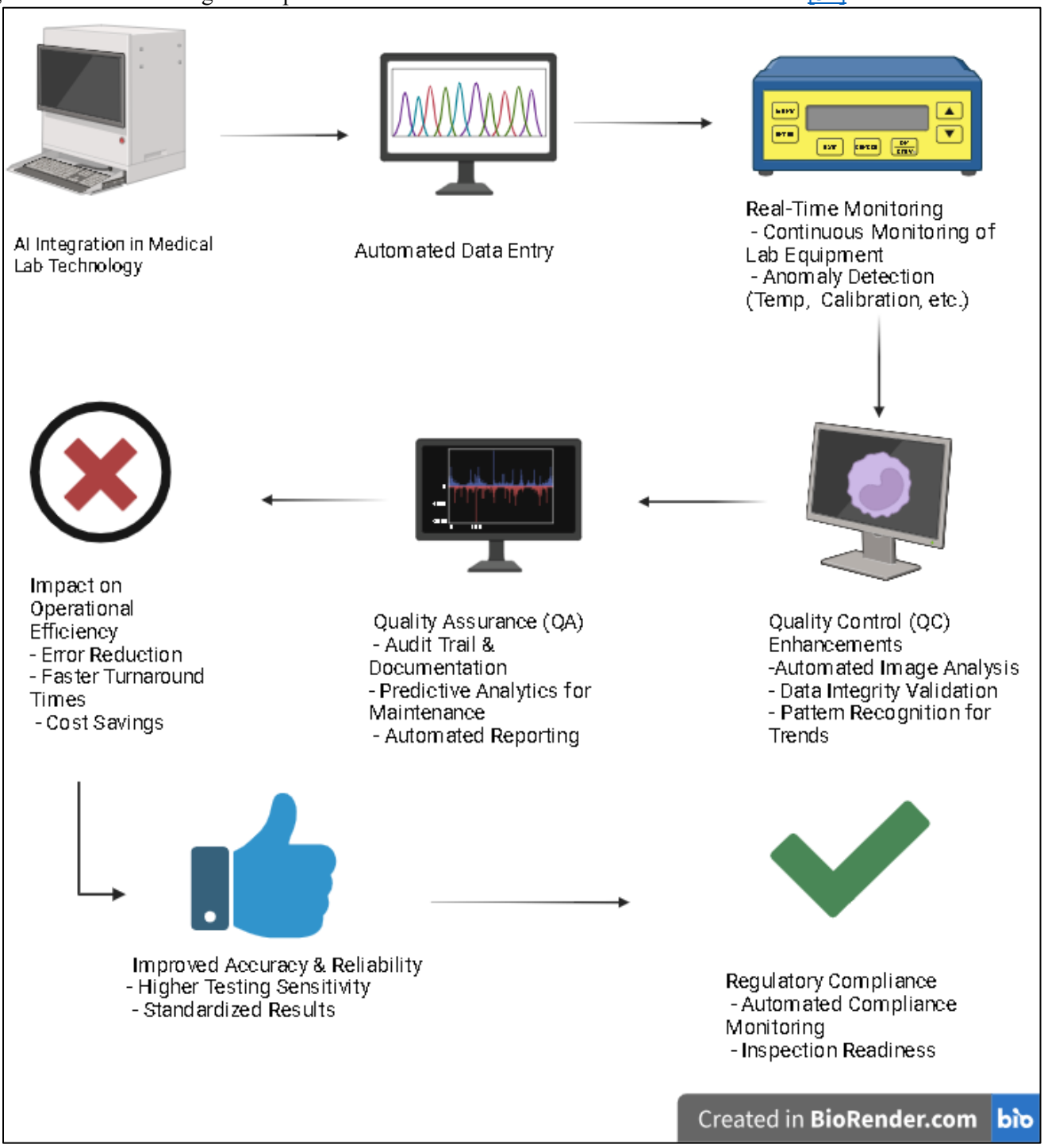

Figure 1: AI integration in Quality Control and Quality Assurance

Moreover, simulated intelligence-controlled devices can guarantee consistence with administrative guidelines by continually observing and examining clinical information continuously, which is indispensable for keeping up with elevated expectations of patient consideration [33].

Challenges and Limitations of Implementing AI

AI has emerged as a transformative technology with the functionality to revolutionize industries, beautify standard overall performance, and permit innovation. However, enforcing AI is not without its stressful conditions and boundaries. Organizations frequently come upon barriers which include information issues, regulatory constraints, and the need for the specialized frame of personnel training [34]. The regular performance and reliability of AI systems are right away counting on the exception of information used for education and operation. The foremost challenge in implementing AI is incomplete or inconsistent data quality. Unfortunately, massive records are one of the most stressful conditions confronted by the usage of groups enforcing AI [12]. AI systems require complete and correct datasets to function successfully. Incomplete or inconsistent information can bring about biased or unreliable AI outputs, undermining the hold in the mind of the generation [28]. Additionally, a big share of data, which includes emails, social media content material, and sensor records, is unstructured. Processing and standardizing these facts for AI programs is complex and useful aid-huge [24]. Another perspective is data biasness which takes place whilst datasets disproportionately constitute extraordinary demographics or viewpoints. This can result in unfair or discriminatory AI consequences, in particular in touchy regions like hiring, lending, or law enforcement [29]. Many corporations struggle with fragmented facts saved in disparate structures. Breaking down those silos to create unified datasets is a time-ingesting and expensive technique [35].

Regulatory Issues: Navigating a Complex Landscape

AI implementation is a problem in an evolving regulatory environment. Governments and corporations are working to create frameworks that stabilize innovation with moral and societal issues. However, those regulatory disturbing conditions can restrict the adoption of AI. The absence of universally known downtown requirements for AI development and deployment creates ambiguity for businesses. This loss of readability makes it hard to ensure compliance with modern-day tips. Regulations similar to the General Data Protection Regulation (GDPR) in Europe impose strict necessities on how personal statistics are accrued, stored, and processed. AI systems frequently want large datasets that encompass non-public records, making compliance a big hurdle [36]. AI increases moral concerns, together with questions on transparency, obligation, and the functionality of its miss use. Organizations are ruling out to navigate the moral dilemmas at the same time to make sure the adherence to regulatory expectations [14].

Workforce Training: Bridging the Skills Gap:

The name for AI professionals, along with statistics scientists, tool-studying engineers, and AI ethicists, an extended manner exceeds the supply. This information scarcity slows down the tempo of AI adoption [17]. AI frequently adjusts device roles and workflows, requiring employees to accumulate new talents. For instance, personnel in production can also want training to feature AI-enabled tools, while entrepreneurs might also additionally want to discover ways to interpret AI-driven insights [20]. Some personnel may moreover resist adopting AI because of fears of mission displacement or skepticism about its benefits. Overcoming this resistance requires a clean communique about the rate of AI and the opportunities it creates [19]. Comprehensive AI education packages may be steeply priced, in particular for small and medium-sized agencies (SMEs) with limited budgets [28].

Overcoming the Challenges: A Holistic Approach

Implementing AI correctly calls for a holistic method that addresses statistics quality, regulatory compliance, and the body of human training desires simultaneously. Few strategies to conquer those disturbing conditions include Establish clean records governance suggestions, use a superior system for records cleaning and integration, regularly audit datasets for bias and inaccuracies [37], stay knowledgeable about the national and international AI regulations, develop inner suggestions aligned with moral AI necessities and engage in organization collaborations to form regulatory frameworks [31]. Partner with universities and education providers to grow AI curricular. Offer employees the right of entry to online AI guides and certifications. Foster a way of life that values innovation and flexibility [38].

Future Directions and Recommendations: AI-powered Predictive Maintenance

In the laboratory, routine predictive maintenance (PM) is essential to the overall effectiveness of your safety, much like changing the oil or flushing the coolant system in your car. Laboratory employees depend unconsciously on systems that operate as intended and on emergency systems that are reliable the first time. To ensure the dependability of the equipment that employees use on a daily basis for their well-being, a system of operability checks must be established and maintained. Almost every mechanical and electrical device, as well as every safety and emergency system, needs to have some routine maintenance and inspection performed. Even for a tiny laboratory, that is a lot of equipment [7].

By analyzing equipment performance data, AI-powered predictive maintenance algorithms can anticipate potential failures, minimizing downtime and improving maintenance schedules. Inaccurate results can be avoided and patient safety can be guaranteed with early detection of instrument malfunctions [32].

The goal of predictive maintenance is to prolong the life of equipment and minimize downtime for fixing malfunctioning parts. Systems for preventative maintenance also aid in averting catastrophic equipment failure. To prevent failure and guarantee that systems function when they need to, we should apply good preventative maintenance principles to many of the things we typically find in the laboratory, even though PM systems typically concentrate on cleaning, lubricating, and making small adjustments to equipment [39].

Real-time Data Analysis

Real-time data analysis powered by AI can spot irregularities and departures from anticipated QC ranges, allowing for prompt remedial action. Accuracy and precision in laboratory operations can be enhanced by ongoing monitoring. Laboratory employees can make better decisions and streamline processes with the help of real-time feedback [24]

One noteworthy and recent example is the use of Accelerate PhenoVR to quickly provide antimicrobial susceptibility test results from digital image analysis of bacterial cell growth in real time. The use of AI to measure protein biomarkers in a micro bubbling digital assay format using bright-field smartphone microscopy was also recently reported by Chen et al. [40] Additionally, scientists are still looking into whether AI can make it possible to measure non-traditional analytes like breath, the pupillary light reflex, or vocal patterns [25][28].

Advanced Image Analysis

AI-powered image analysis can increase the precision and effectiveness of diagnosis by automating the interpretation of microscopic images, such as tissue samples and blood smears. Pathologists' workload can be decreased and diagnostic consistency increased with automated anomaly detection. Additionally, sophisticated image analysis can be applied to reagent and consumable QC [41].

AI is being used in the new field of computational pathology, which goes beyond whole-slide imaging and digital pathology. A diagnostic method led by pathologists, computational pathology integrates and analyzes raw clinical data from various sources, such as imaging, EHRs, and laboratory information systems. Luo et al. recently published a simple example of this, which involved predicting disease or future laboratory results by combining routinely available laboratory measurements with patient demographic data. They emphasized the potential worth of multianalyte analyses and showed excellent accuracy with their approach. Despite the encouraging outcomes of early computational pathology efforts, there are numerous issues to take into account when working with real-world data. When implementing prediction models in real-world settings, one of the biggest obstacles is dealing with data sparsity. The problems with sparse matrices have been studied from a technical standpoint, and ML techniques for imputed missing data have demonstrated potential for increasing the precision of predictions based on laboratory data [42]. Computational pathologists, pathologists, and clinicians must surely work closely together to ensure high-quality and clinically useful results as computational pathology advances.

Blockchain Technology

This technology can guarantee the integrity and security of data collected in laboratories. The traceability and transparency of lab results can be enhanced by immutable records. Platforms built on blockchain technology can help healthcare providers collaborate and share data securely [29]. Various scientific works have examined the role of blockchain technology in the healthcare industry. Blockchain has the potential to significantly increase hospital information systems' security, as discussed in. Nevertheless, the majority of scientific endeavors to date have been theoretical or in their infancy, and it is not always evident which protocols and framework components should be employed to carry out system implementations that can be implemented in actual healthcare settings [42].

Blockchain is becoming more and more acknowledged as a tool that can solve current problems with open information access [16]. It is actually feasible to increase transparency, security and privacy, traceability, and efficiency in health services by utilizing blockchain technology. Regarding this, discusses a solution that uses Blockchain technology to ensure that patients' medical information is accessed appropriately. Specifically, methods that maintain the patient's identity and the accuracy of their medical history are suggested.

Numerous blood tests, such as the CBC, Basic Metabolic Panel, Complete Metabolic Panel, Lipid Panel, Thyroid Panel, Enzyme Markers, Sexually Transmitted Disease Tests, Coagulation Panel, and DHEA-Sulfate Serum Test, can be performed by a medical laboratory device. The market is currently filled with a wide variety of medical laboratory equipment. Considering "connected" and "not connected" devices, a classification can be made. We envision medical laboratory equipment with network (wired and/or wireless) and USB interfaces for connected devices, as well as the ability to export and transmit results to other devices; for unconnected devices, we envision medical laboratory equipment without any data transmission interface [42].

Based on upcoming tele-medical laboratory services, we present a summary of the main connected medical laboratory devices below. A medical device called the Telemedcare Clinical Monitoring Unit (CMU) [22] can conduct blood pressure, pulse oximetry, and blood glucose tests. One gadget that can monitor blood sugar levels continuously is called Enverse [23]. It entails implanting a chip beneath the patient's skin and connecting it to a smartphone app. An integrated solution for glycemia auto-monitoring, Med-Care [24] can send alerts by SMS or email and is compatible with both web and mobile systems. With a local web interface, the inexpensive portable hematology analyzer HemoScreen conducts a complete blood count at the point of care.

The Samsung Labgeo PT10S [26] is a portable clinical chemistry analyzer that reduces time spent by patients and clinicians by providing quick, simple, and precise blood analysis. For exporting exam results to an external Personal Computer (PC), it has an Ethernet interface. To conduct tests, all of the aforementioned devices need a blood sample. Alternative non-invasive experimental tools that can conduct blood tests are currently being researched by the academic and commercial healthcare communities [42]. In departments spread across various hospitals, telemedical laboratories enable the execution of blood tests, results validation, diagnosis, and therapy assignment tasks. The establishment of a virtual healthcare team made up of physicians and biomedical laboratory health technicians from various federated hospitals makes this feasible. A quarter of laboratory professionals surveyed recently expressed concern about possible job loss and quality problems with AI implementation. Furthermore, 72% of respondents said they had never encountered an AI application in their day-to-day activities or were unsure. According to these findings, it may be necessary to encourage training on ML literacy, technological awareness, and the scope and purpose of AI for laboratory workers as its use grows in the workplace. In the past, clinical medicine has not advanced as quickly as computer science and artificial intelligence [40].

Implementing recently developed AI technologies as they become available is seen to have advantages, but it is still necessary to address the disparity in pace between the two domains and stress the necessity of evidence-based applications of AI/ML-based models. Finally, because many of the models being used, both inside and outside the lab, depend on data produced by the lab, laboratory professionals are uniquely suited to serve as stewards of these technologies, providing a possible avenue for professional advancement [38]. Although laboratory services have traditionally been paid for on a fee-for-service basis, value-driven healthcare initiatives have the potential to alter how laboratory resources are used and managed. The Laboratory 2.0 concept was recently introduced to promote the use of laboratory practice guidelines and laboratory data analysis to improve clinical care procedures that are typically outside the purview of the laboratory [37].

Conclusion

In conclusion, the integration of artificial intelligence and ML into clinical laboratory science holds immense potential to transform diagnostic accuracy, efficiency, and patient care. By automating routine tasks, improving QC, minimizing errors, and enhancing workflow, AI significantly boosts lab productivity across disciplines such as hematology, immunology, and clinical chemistry. However, to fully realize these benefits, critical challenges must be addressed including data quality issues, ethical concerns, lack of standardized guidelines, and a shortage of trained professionals. Investing in workforce development and establishing robust regulatory frameworks are essential steps toward responsible AI adoption. As predictive analytics and automation continue to evolve, their strategic implementation can further reduce operational costs, enhance reliability, and support precision diagnostics. Ultimately, a balanced, thoughtful approach is key to unlocking the full potential of AI in modern clinical laboratories.

Authors' contributions

ICMJE criteria	Details	Author(s)
1. Substantial contributions	Conception, OR Design of the work, OR Data acquisition, analysis, or interpretation	1,6 2,3 4,5
2. Drafting or reviewing	Draft the work, OR Review critically for important intellectual content	1,2,3,5 4,6
3. Final approval	Approve the version to be published	1,2,3,4,5,6
4. Accountable	Agree to be accountable for all aspects of the work	1,2,3,4,5,6

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Availability of data and materials

Not applicable.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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