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The Role of Artificial Intelligence in Enhancing Quality Management Systems Within Clinical Laboratories: Implications for Diagnostic Accuracy and Patient Safety

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Abstract

Background: The integration of artificial intelligence (AI) into clinical laboratories has emerged as a pivotal advancement aimed at improving diagnostic accuracy and patient safety. As healthcare systems grapple with increasing demands for precision medicine and efficient resource allocation, AI technologies offer innovative solutions to enhance quality management systems (QMS). This study systematically reviews the existing literature on AI applications in clinical laboratories, focusing on their impact on diagnostic processes, error reduction, and overall patient outcomes.

Methods: A comprehensive search was conducted across multiple databases, including PubMed, Scopus, and Web of Science, yielding studies published up to 2023.

Results: The analysis revealed that AI-driven algorithms significantly enhance the interpretation of laboratory results, optimize workflow efficiencies, and reduce diagnostic errors. Key findings indicate that AI applications, such as machine learning and predictive analytics, markedly improve the accuracy of test interpretations and facilitate timely decision-making in clinical settings.

Conclusions: In conclusion, the adoption of AI technologies within quality management systems in clinical laboratories is crucial for advancing diagnostic accuracy and ensuring patient safety. This study underscores the need for healthcare policymakers and laboratory administrators to invest in AI-driven solutions that can streamline operations and enhance the quality of laboratory services. Future research should focus on developing standardized protocols for AI implementation and assessing long-term impacts on patient care and safety.

Keywords: artificial intelligence, clinical laboratories, quality management systems, diagnostic accuracy, patient safety.

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1. Introduction

In laboratory medicine, artificial intelligence (AI) has emerged as a transformative technology capable of fundamentally altering several aspects of healthcare delivery. Artificial Intelligence denotes the capacity of a computer system to learn, reason, and make decisions—functions that conventionally need human intellect. This technology allows computers to replicate human cognitive abilities, including information comprehension, complicated reasoning, and conclusion formulation. Artificial intelligence is employed in laboratory medicine to enhance precision and efficiency, optimize diagnostic procedures, and assist in clinical decision-making [1]. The significance of AI advancements in this field lies in its ability to analyze vast datasets, identify trends, and generate valuable insights rapidly and accurately. Artificial intelligence can facilitate the interpretation of laboratory test results, predict patient outcomes, and aid in the early diagnosis of diseases through the application of machine learning algorithms. This technology can enhance patient outcomes, reduce diagnostic errors, and optimize treatment strategies [2].

Artificial intelligence is profoundly influencing medical imaging, transforming diagnoses and patient care. AI algorithms possess the ability to attain a high degree of accuracy in identifying pathologies in radiological images such as X-rays, computed tomography scans, and magnetic resonance imaging scans. Consequently, diseases like cancer can be diagnosed earlier, facilitating prompt and effective treatment. Pathologists may use AI to enhance the accuracy and efficacy of diagnoses by analyzing histological images. Predictive analytics is a significant application of AI in laboratory medicine. AI algorithms can identify risk factors, predict disease progression, and inform decisions regarding personalized treatment by analyzing extensive datasets that include patient information, laboratory results, and clinical outcomes. This has the potential to enhance patient care, refine treatment strategies, and facilitate the advancement of precision medicine methodologies [3,4].

Artificial intelligence technology can support healthcare systems in low- and middle-income countries (LMICs). The phrase "low- and middle-income countries" categorizes nations based on their developmental and economic status. The World Bank categorizes countries into various income groups, including low-income, lower-middle-income, and upper-middle-income, based on their Gross National Income per capita [3]'. Numerous socioeconomic factors, such as income levels, poverty rates, healthcare system quality, and access to resources and services, characterize lower-middle-income countries. Low- and middle-income countries (LMICs) are crucial for the advancement of AI in laboratory medicine. These countries often have challenges in health care, including limited resources, inadequate infrastructure, and a significant illness load. AI technologies have the potential to address these issues and improve healthcare delivery in LMICs. AI can facilitate clinical decision-making in resource-limited settings, enhance the precision of disease identification, and streamline diagnostic procedures. Low- and middle-income countries (LMICs) can mitigate healthcare disparities, enhance patient outcomes, and surmount access limitations through the implementation of AI algorithms. The demand for accessible and cost-effective healthcare solutions is closely linked to the advancement of AI in laboratory medicine within LMICs [5].

In addition to improving disease surveillance and facilitating earlier disease detection and management, AI algorithms can also assist in the interpretation of laboratory test data. It is important to recognize that overcoming various challenges is essential for the successful integration of AI in laboratory medicine in low- and middle-income countries (LMICs) [4]. The challenges encompass data scarcity, the necessity for contextually and locally suitable algorithms, ethical concerns, capacity enhancement, and infrastructure advancement. Collaboration is vital for knowledge exchange, resource allocation, and capacity development in the domain of AI in laboratory medicine between low- and middle-income countries and high-income nations, international organizations, and research institutions [6].

This study intends to examine the history, relevance, and consequences of AI breakthroughs in laboratory medicine, with an emphasis on low- and middle-income countries (LMICs). A comprehensive study will be undertaken to examine the history and importance of AI breakthroughs in laboratory medicine, specifically on their implications for LMICs. This study will provide possible ways to address difficulties and improve healthcare outcomes in resource-constrained environments via the use of AI. Evaluating the present condition of laboratory medicine in LMICs and pinpointing common challenges will provide essential insights to policymakers, healthcare practitioners, and researchers, facilitating informed decision-making and the progression of knowledge in the discipline.

2. Summary Of Laboratory Medicine in Low-and-Middle-Income Countries

Laboratory medicine is crucial for sickness detection, surveillance, control, and management. Nevertheless, low- and middle-income countries (LMICs) continue to encounter significant obstacles in obtaining quality-assured laboratory diagnostics, potentially resulting in delayed or erroneous diagnoses and ineffective treatments [7]. These challenges stem from various factors, including deficient supply chain management, absence of governmental standards for laboratory testing, inadequate infrastructure, and limited laboratory supplies and equipment. Recent initiatives have been implemented to tackle these issues and enhance laboratory medicine in LMICs [8]. The Lancet Series on Pathology and Laboratory Medicine (PALM) in low- and middle-income countries (LMICs) conducts thorough examinations of the challenges and inadequacies within PALM services while proposing strategies for the enhancement of laboratory medicine. The suggested solutions include improving infrastructure, ensuring the availability of essential laboratory supplies and equipment, strengthening the workforce through mentoring and training initiatives, establishing quality management systems, and implementing government standards for laboratory testing [9].

Furthermore, initiatives such as the Lancet Commission on Diagnostics emphasize the imperative of improving LMICs' access to diagnostics, especially laboratory testing. The commission endorses advancements in technology and evidence-based essential diagnostics lists, emphasizing COVID-19, antimicrobial resistance, and global health security. Strengthening laboratory medicine in low- and middle-income countries (LMICs) necessitates enhancing mentorship programs, investing in infrastructure development, expanding educational and training opportunities, and implementing effective quality assurance mechanisms. Collaboration among LMICs, high-income countries, international organizations, and research institutions is vital for information exchange, resource sharing, and capacity building [10].

The advancement of AI in laboratory medicine presents both opportunities and obstacles for LMICs. Access to comprehensive and high-quality data in LMICs may be constrained by inadequate infrastructure, insufficient digitalization, and a disordered healthcare system. Furthermore, there exists a deficiency of knowledge, resources, and specialists necessary for the implementation of AI. Preserving patient trust and safeguarding sensitive data necessitate the assurance of data privacy, security, and confidentiality, which can present challenges associated with ethical and legal issues [11].

Notwithstanding these challenges, efforts are underway to eliminate the barriers to the integration of AI in laboratory medicine inside low- and middle-income countries. Leveraging AI's potential necessitates investment in digital infrastructure, the creation of data-sharing networks, and the standardization of data. Furthermore, innovative financial frameworks and public-private partnerships might facilitate the accessibility and affordability of AI technology in low- and middle-income countries (LMICs) [7].

Initially, the availability of accessible and affordable diagnostic tools enables the timely and precise detection and monitoring of diseases, which is crucial for healthcare management in LMICs [5]. These innovations facilitate early-stage disease diagnosis, thereby aiding in the prevention of disease progression, minimizing complications, and enhancing patient outcomes. Furthermore, by facilitating personalized and tailored therapies, these advancements enhance the effective use of resources. Maximizing the efficiency of scarce healthcare resources is essential. Accessible and cheap diagnostic technologies in low- and middle-income countries enable healthcare practitioners to make educated decisions, resulting in successful treatments, decreased needless interventions, and cost-efficient strategies [12].

Moreover, these technologies facilitate the integration of machine learning models and artificial intelligence algorithms into laboratory medical practices. Artificial intelligence necessitates precise and comprehensive data for training and validation, which can be produced by readily available diagnostic technologies [13]. This amalgamation facilitates the development of AI-driven diagnostic instruments that improve accuracy, speed, and efficiency in diagnoses, including automated image analysis systems and predictive models. Prioritizing the development of accessible and cheap diagnostic tools is essential for maximizing the promise of AI in laboratory medicine in low- and middle-income countries (LMICs). This necessitates the allocation of resources for research and development focused on producing economical solutions customized for the specific requirements of LMICs. The implementation of these technologies may be rendered more economical, accessible, and sustainable via partnerships among governmental bodies, healthcare organizations, and technology providers [14].

3. The function of laboratory medicine in healthcare provision

In low- and middle-income countries, laboratory medicine is essential to healthcare delivery. It assists healthcare systems in several capacities, including laboratory medicine provides essential diagnostic services that facilitate the early identification, diagnosis, and monitoring of illnesses. Accurate and prompt laboratory testing is crucial for guiding clinical decision-making, therapy selection, and patient care [9]. These assessments include several domains, including cellular pathology, microbiology, clinical chemistry, and hematology. The results of these tests provide medical practitioners with insights into a patient's health state and guide the optimal course of action [16].

Moreover, laboratory medicine is essential for the surveillance and management of diseases. The information it offers on illness prevalence, outbreaks, and trends allows public health officials to efficiently monitor and mitigate health hazards. Laboratory medicine aids in the detection and surveillance of infectious illnesses, hence facilitating the execution of preventative measures, including vaccination programs and infection control methods [17].

Furthermore, laboratory medicine underpins research investigations, clinical trials, and the development of novel diagnostic tools and technologies. Research conducted in low- and middle-income countries (LMICs) may address regional healthcare challenges and enhance global understanding of laboratory medicine. The significance of laboratory medicine in healthcare delivery within LMICs is crucial for mitigating disease effects, assuring precise diagnoses, and enhancing patient outcomes [18,19].

4. Advancements in Artificial Intelligence in Laboratory Medicine

Despite the high level of automation in all modern clinical chemistry and hematology analyzers, only a limited number of total laboratory automation (TLA) systems have been developed. The Cobas®, an essential automated laboratory tool from Roche Diagnostics, autonomously processes, analyzes, and stores samples. This equipment is capable of performing sample sorting, decapping, quality control, aliquoting, and recapping of in vitro diagnostic specimen tubes when used with one or more connection modules on a track system. The Accelerator is a highly automated system intended for preanalytical processes, which may be integrated with a multi-instrument core laboratory system, recently launched by Abbott Diagnostics. The Accelerator is advantageous due to its "open" nature, which allows for interaction with other systems, hence enhancing the consolidation of testing across several laboratory specializations. The Power Express Clinical Automation system, TCAutomationTM, Aptio® Automation, and VITROS® Automation Solutions provide more instances of commercially available TLA systems. Centralized techniques have shown improvements in analyzer performance and reductions in human error [20-24].

The incorporation of TLA into microbiology and the subsequent transformation of this discipline was facilitated by recent advancements in the digitalization of culture plate images and the ability to electronically scan incubated plates. Clinical laboratories currently utilize two commercially available microbiological automation systems: WASPLab® and KiestraTM. Various degrees of automation are achievable with both systems, extending from front-end processing only (automated plating) to TLA [20]. Traditionally, the microbiology sector of clinical laboratories has necessitated substantial manual work. To enhance productivity and mitigate the persistent national shortage of medical laboratory scientists, automated workflows have garnered increased attention in recent years. Consequently, opportunities for the integration of machine learning-based technologies in these novel procedures have emerged [25].

Enhanced automation is beneficial as it lowers expenses, allows technicians to engage in more specialized activities (such as microscopy, plate interpretation, and antimicrobial susceptibility testing), boosts efficiency (as assessed by LEAN or other metrics), shortens turnaround time, elevates performance, and streamlines various manual and labor-intensive clinical microbiology procedures [20, 24, 26].

The domain of molecular diagnostics has seen a profound transformation due to the advent of high-throughput and high-multiplexity nucleic acid technologies. These strategies have been facilitated in part by developments in machine learning. Many next-generation sequencing (NGS) approaches analyze millions of tiny clusters of labeled nucleic acids over thousands of images at their core. These approaches generate substantial volumes of data, necessitating resilient big data management pipelines, since individuals are unable to evaluate such extensive datasets independently [27-29].

High-dimensional, structured data sets generated by contemporary NGS tests may provide significant diagnostic and prognostic insights. The magnitude and intricacy of these data sets make the processing of NGS data laborious and time-consuming. Consequently, many software solutions use machine learning to expedite multiple stages in the next-generation sequencing data processing pipeline. This technique, like other machine learning technologies, may enhance human interpretations or unveil new diagnostic opportunities. These technologies facilitate variant calls, curation, and clinical interpretations [30].

5. The Influence of AI Progress in Laboratory Medicine In LMICS

A prevailing belief exists that laboratory test results substantially impact around 70% of decisions concerning diagnosis, treatment, and patient discharge. Increasing workloads, escalating healthcare costs, and the demand for enhanced precision necessitate the ongoing improvement of laboratory operations [31-33]. The capacity to deliver accurate, readily accessible, and contextualized data has gained paramount importance in healthcare and laboratory medicine, particularly with the emergence of big data and artificial intelligence. The application of AI in laboratory medicine holds the potential to yield significant advancements, especially for individuals living in low- and middle-income countries [34]. These breakthroughs include the refinement of laboratory procedures, application, and analysis, alongside the augmentation of accuracy and efficiency in the provision of individualized patient care [35]. The domain of artificial intelligence in healthcare focuses on the analysis of vast amounts of medical data produced by diagnostics, medical records, claims, clinical trials, and analogous sources. This assessment employs sophisticated algorithms and software intended to emulate human cognitive functions. For AI algorithms to operate well, the laboratory data used must be both precise and dependable [36,37].

Artificial intelligence has emerged as a very promising instrument in laboratory medicine, presenting several current and prospective uses. A significant application involves predicting laboratory test values utilizing clinical and demographic data, thereby improving efficiency and personalizing patient care [38]. Additionally, AI has shown considerable promise in optimizing laboratory utilization by refining test ordering processes and decreasing superfluous testing. Consequently, this technology can conserve resources and reduce healthcare costs. The domain of laboratory processes is now seeing a substantial revolution driven by the incorporation of AI. This connection has resulted in the automation of several processes inside labs, including sample preparation, analysis, and reporting. This enhances accuracy and efficiency while allowing laboratory professionals to focus on more complex tasks. Recently, there has been an increasing tendency to employ automated workflows to improve efficiency and mitigate the ongoing shortage of medical laboratory scientists nationwide. AI can optimize the allocation of limited resources, including personnel, equipment, and supplies. This may be accomplished by the provision of decision assistance, quality assurance, and predictive maintenance [39].

A further interesting domain for AI use is the exact interpretation of laboratory tests. This entails the amalgamation of genomic, proteomic, and metabolomic data to provide more comprehensive and individualized diagnostic insights. Furthermore, the impact of AI encompasses the improvement of laboratory medical information systems. This is accomplished by enhancing data management, security, and interoperability, thereby enabling seamless integration and exploitation of information. In the field of pathology, AI-driven algorithms have shown considerable potential in classifying central nervous system malignancies by DNA methylation profiling. This might enhance diagnostic precision and refine treatment strategies. The domain of digital pathology has significant benefits via the use of AI for picture analysis. This integration may provide critical support in diagnosis, prognosis, and therapy selection [40].

The use of big data analytics and natural language processing allows AI to monitor illness trends and occurrences, hence enhancing the accuracy and speed of disease detection. Artificial Intelligence possesses the ability to analyze extensive and varied data sets, encompassing electronic health records, genomic information, imaging data, and social media content, to discern patterns and biomarkers indicative of disease presence or risk [41]. By scrutinizing physiological signals or neuroimaging, AI can facilitate the prompt detection of numerous ailments, including sepsis, cancer, and Alzheimer's disease [34]. Furthermore, AI can aggregate and evaluate data from an array of sources, such as news articles, online discussions, official documents, and scientific literature. This allows AI to proficiently track disease trends and outbreaks. The use of mathematical models and machine learning algorithms enables AI to aid in forecasting the incidence and effects of infectious illnesses like COVID-19 [36].

Expert systems, chatbots, and mobile apps may communicate with patients and healthcare practitioners, offering assistance and decision support for diagnosis and treatment. This advice is based on evidence-based recommendations or patient-specific information. Artificial intelligence may aid in diagnosing skin lesions, ocular illnesses, and TB by using image recognition and deep learning algorithms. Robotics and AI can profoundly transform the medical field. These modifications may enhance patient care, resource distribution, and public health results within healthcare systems, particularly in laboratory medicine in these areas, which face several obstacles [34].

6. Obstacles To the Implementation of AI In Laboratory Medicine In Low-And-Middle-Income Countries

AI models may facilitate the identification of optimal pharmaceuticals and preventative measures, enhancing accuracy and efficiency in customized medicine. However, several challenges impede the integration of AI in laboratory medicine within low- and middle-income countries (LMICs). The challenges may be thoroughly analyzed by considering infrastructure, resources, staff, data management, and cultural issues [2].

Low- and middle-income countries often have infrastructural limitations with the adoption of artificial intelligence in laboratory medicine [5]. Examples of this include inadequate laboratory facilities, an inconsistent power supply, restricted internet access, and insufficient hardware and software resources. There is a deficiency of proficient individuals capable of effectively using AI tools and technology for diagnosis and analysis. The absence of requisite infrastructure and resources hinders the deployment and sustainability of AI technology in laboratory medicine [7].

A further obstacle is restricted access to high-quality data for AI training. AI models need substantial quantities of high-quality data for training. Nevertheless, owing to constrained resources, disjointed health information systems, the absence of interoperable electronic health records, and insufficient data management practices, LMICs often encounter challenges in obtaining comprehensive and varied data sets. Inadequate data for training AI systems can lead to inferior performance and limited generalizability. Concerns over data privacy and security, coupled with insufficient data governance regulations, may aggravate data management in LMICs [42].

The integration of AI in laboratory medicine is significantly influenced by ethical considerations and regulatory frameworks. The use of AI in laboratory medicine raises ethical and legal issues, including patient privacy, data protection, informed consent, and responsibility. Due to the potential absence of robust rules and frameworks in low- and middle-income countries (LMICs), uncertainties and risks may emerge. Robust ethical norms and regulatory frameworks specific to AI in healthcare are essential to mitigate challenges related to bias, transparency, accountability, and liability [2,5].

Contextual bias arises as AI is predominantly developed and implemented in high-income countries, with the data used for AI system creation closely linked to specific contexts. Consequently, the adoption of these systems in low- and middle-income countries (LMICs) may lead to contextual bias. Furthermore, integrating AI technologies with current laboratory information systems in LMICs may pose significant challenges. Obsolete technology, interoperability challenges, and insufficient technical expertise hinder the smooth exchange and integration of data between AI systems and laboratory processes [43].

Restricted access to quality-assured laboratory diagnostics is an obstacle. Access to superior laboratory diagnostics is essential for illness detection, surveillance, and treatment. Numerous LMICs face challenges stemming from insufficient critical infrastructure, laboratory supplies, fundamental equipment, skilled personnel, and quality management systems. These limitations adversely affect the reliability and precision of laboratory data, which can subsequently influence patient care [7].

In low- and middle-income countries (LMICs), constrained resources, inadequate personnel, and capacity limitations result in subpar laboratory services. A deficiency of qualified laboratory specialists, including pathologists and technicians, may impede the implementation of AI systems. The cost of implementing and maintaining AI systems may provide a significant challenge for low- and middle-income countries with constrained financial resources. AI technologies can need substantial expenditures in infrastructure, software, and continuous upgrades. To ensure the long-term viability of AI implementation in laboratory medicine, sustainable funding models and cost-effective solutions are essential. Pathology and laboratory medicine are often undervalued in low- and middle-income countries (LMICs), leading to inadequate investment, limited resources, and a lack of awareness regarding their importance. This deficiency in funding and understanding hinders the advancement and utilization of AI technologies in laboratory medicine [23,40].

The deficiency of resources and expertise for executing AI is an additional obstacle. In low- and middle-income countries (LMICs), there is often a scarcity of data scientists and AI specialists capable of developing, implementing, and managing AI systems. Furthermore, the cost of adopting AI technology and integrating it into existing laboratory operations can be prohibitively high in resource-constrained settings. The challenges of AI implementation are further intensified by funding limitations and competing healthcare priorities [15].

Resolving these difficulties would need a comprehensive plan. It involves enhancing laboratory infrastructure, refining data collection and management systems, instituting ethical and legal frameworks, fostering capacity-building and training initiatives, and increasing awareness of the significance of pathology and laboratory medicine among policymakers and stakeholders [2,7].

7. Conclusion

This review article examines the advancements of AI in low- and middle-income countries (LMICs). Artificial intelligence technologies are exerting a transformational influence on low- and middle-income countries across several industries, including healthcare and medicine. Low- and middle-income countries have adeptly used artificial intelligence to overcome resource and infrastructural constraints, therefore promoting sustainable development. Nonetheless, several hurdles persist in the progression of AI; yet, AI can mitigate inequities and promote transformational social development in LMICs by fostering multidisciplinary partnerships, information sharing, and strategic investments. This essay elucidates the need to create AI ecosystems specifically designed for LMIC settings to promote a more equal and inclusive global technology landscape.

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دور الذكاء الاصطناعي في تعزيز أنظمة إدارة الجودة داخل المختبرات السريرية: الآثار المترتبة على دقة التشخيص وسلامة المرضى

الملخص

الخلفية :أصبح دمج الذكاء الاصطناعي (AI) في المختبرات السريرية تقدمًا محوريًا يهدف إلى تحسين دقة التشخيص وسلامة المرضى. ومع مواجهة أنظمة الرعاية الصحية لزيادة الطلب على الطب الدقيق والتخصيص الفعال للموارد، توفر تقنيات الذكاء الاصطناعي حلولًا مبتكرة لتعزيز أنظمة إدارة الجودة .(QMS) تراجع هذه الدراسة بشكل منهجي الأدبيات الحالية حول تطبيقات الذكاء الاصطناعي في المختبرات السريرية، مع التركيز على تأثيرها على عمليات التشخيص، وتقليل الأخطاء، وتحسين نتائج المرضى.

الطرق :تم إجراء بحث شامل عبر قواعد بيانات متعددة، بما في ذلك PubMed و ScopusوWeb of Science، لتحديد الدراسات المنشورة حتى عام 2023.

النتائج :كشفت التحليلات أن الخوارزميات المعتمدة على الذكاء الاصطناعي تعزز بشكل كبير تفسير نتائج المختبرات، وتحسن كفاءة سير العمل، وتقلل من أخطاء التشخيص. وأظهرت النتائج الرئيسية أن تطبيقات الذكاء الاصطناعي، مثل التعلم الآلي والتحليلات التنبؤية، تُحسن بشكل ملحوظ دقة تفسير الاختبارات وتُسهم في اتخاذ قرارات سريعة في البيئات السريرية.

الاستنتاجات :في الختام، يعد اعتماد تقنيات الذكاء الاصطناعي داخل أنظمة إدارة الجودة في المختبرات السريرية أمرًا ضروريًا لتعزيز دقة التشخيص وضمان سلامة المرضى. تؤكد هذه الدراسة الحاجة إلى أن يستثمر صانعو السياسات الصحية ومسؤولو المختبرات في حلول قائمة على الذكاء الاصطناعي يمكنها تحسين العمليات وتعزيز جودة الخدمات المخبرية. يجب أن تركز الأبحاث المستقبلية على تطوير بروتوكولات معيارية لتطبيق الذكاء الاصطناعي وتقييم تأثيراته طويلة المدى على رعاية المرضى وسلامتهم.

الكلمات المفتاحية :الذكاء الاصطناعي، المختبرات السريرية، أنظمة إدارة الجودة، دقة التشخيص، سلامة المرضى.