Author Comment

Tribulations, Triumphs, and Governance: Shaping the Future of Artificial Intelligence in Healthcare

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Abstract

Artificial intelligence (AI) is driving a profound transformation across the healthcare landscape, with the potential to enhance diagnostic accuracy, optimize clinical decision-making, improve resource allocation, and advance personalized medicine. In public health, AI is redefining infectious disease epidemiology by enabling outbreak forecasting, genomic surveillance, and data-driven policy support, even in the presence of incomplete information. Within clinical laboratories, AI plays a pivotal and expanding role. It facilitates automation of complex workflows, supports diagnostic interpretation, and contributes to analytical performance improvements. Particularly promising is its integration into point-of-care testing, enabling decentralized diagnostics and broader access to timely care, especially in resource-constrained settings.

However, these advancements are not without challenges. Concerns regarding algorithmic bias, lack of data representativeness, and risks to privacy and transparency must be carefully addressed. Moreover, the ethical and societal implications of AI are increasingly central. As emphasized by Pope Francis, while AI may accelerate access to knowledge and innovation, it also risks deepening global disparities and promoting a "throwaway culture" that undermines human dignity. His appeal for a "culture of encounter" rooted in equity, justice, and inclusion aligns with the mission of public health and laboratory medicine. This paper, based on the invited lecture delivered at the Clinical Laboratories Artificial Intelligence Revolution (CLAIR) 2025 conference, explores these themes through a critical lens. International scientific societies such as the IFCC are called to foster equitable implementation of AI by promoting access to training, infrastructure, and governance frameworks thus ensuring that AI contributes meaningfully to global health solidarity and equity.

Introduction

Artificial intelligence (AI) is rapidly transforming the landscape of healthcare delivery [1]. AI technologies are poised to revolutionize clinical workflows, ranging from early diagnosis and risk stratification to the tailoring of personalized treatment plans, however, such transformation remains largely prospective, as many models still require extensive external validation and performance monitoring before they can be integrated reliably into routine care. In the field of laboratory medicine, AI is gaining prominence as a tool to automate interpretation, detect anomalies, and integrate complex biological data to support evidence-based decision-making [2]. These advances reflect wider movements in digital health, such as the integration of precision medicine approaches, the adoption of interoperable electronic health records, and the decentralization of diagnostic services through point-of-care technologies. However, the pace and extent of these transformations vary significantly across regions, particularly where resource constraints or infrastructural gaps limit digital readiness. Bridging this global divide remains a critical challenge for equitable AI deployment.

Yet, the advancement of AI technologies in healthcare is not without significant challenges. Technical concerns such as algorithmic bias, data quality, and lack of interoperability intersect with profound ethical and legal questions. Issues related to patient autonomy, data privacy, transparency, and accountability have gained increasing attention, especially in light of the opaque "black box" nature of many AI models. These concerns are further compounded in low- and middle-income countries, where limited digital infrastructure may widen health disparities unless addressed by equitable AI deployment strategies. As emphasized by Bouderhem, the future of AI in healthcare hinges not only on technological capability, but also on the development of adequate regulatory, ethical, and governance frameworks [1].

The World Health Organization (WHO), in its reports and position papers, has stressed the importance of adopting legally binding norms to govern AI applications in health [3, 4] while the European Union's AI Act aims to provide a harmonized legal model grounded in human rights and safety standards [5].

At the same time, global voices such as Pope Francis have drawn attention to the broader societal risks of AI. In the document Antiqua et Nova: Note on the Relationship Between Artificial Intelligence and Human Intelligence [6] and in his address at the G7 session on artificial intelligence held in Italy in 2024 [7], the Pope warned of the dangers of a "throwaway culture" driven by efficiency at the expense of human dignity and advocated instead for a "culture of encounter" that promotes fairness, inclusion, and justice.

Such a perspective underscores the moral urgency of inclusive technological development.

In this context, laboratory medicine emerges not only as a technical domain but also as a strategic platform for fostering equitable AI integration. International scientific bodies such as the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) play a critical role in promoting standards, infrastructure, and training to ensure responsible adoption.

This article contributes to the ongoing discourse by providing a critical overview of both the achievements and the unresolved questions surrounding the implementation of AI in healthcare. It is based on the lecture presented by the author at Clinical Laboratories Artificial Intelligence Revolution, March 28th, 2025, Belgrade, Serbia (CLAIR 2025), under the title: "Tribulations, Triumphs, and Governance: Shaping the Future of AI in Healthcare".

Triumphs of AI in Healthcare

AI is achieving transformative success across the healthcare ecosystem, extending far beyond diagnostic imaging. In addition to surpassing or equaling expert performance in interpreting radiological images such as chest X-ray (CXR), computed tomography (CT), and magnetic resonance imaging (MRI) scans, AI is reshaping core clinical processes and public health strategies [1].

Beyond radiology, AI is driving major advances in the management of chronic diseases such as cardiovascular conditions and diabetes, which continue to burden global health systems. Most machine learning (ML) applications to date have focused on diagnostic decision support in these areas, enabling earlier detection, risk stratification, and individualized management. In nephrology, for instance, AI systems have been implemented to detect chronic kidney disease, predict renal function decline, and anticipate acute kidney injury. Similarly, predictive algorithms in primary care settings support early intervention and resource optimization. However, existing studies underscore the need for rigorous model transparency, robust external validation, and comprehensive lifecycle reporting, including ongoing performance monitoring after clinical deployment [8].

The role of AI in public health is rapidly expanding, particularly in infectious disease epidemiology.

Recent advances published in Nature illustrate how AI models significantly improve traditional epidemiological approaches by accelerating forecasting, managing incomplete surveillance data, and supporting timely policy interventions. The integration of empirical data, computational modelling, and real-time policy feedback represents a paradigm shift in epidemic response systems [9].

AI is also contributing to precision medicine and clinical pharmacology. In clinical trials, AI facilitates more efficient patient stratification and recruitment, supports adaptive protocol design, and enables real-time analysis of interim results,

contributing to faster, more cost-effective, and targeted trial execution. AI-enhanced tools can reduce sample sizes, shorten trial durations, and increase the probability of regulatory success, particularly in oncology and rare diseases [10].

The breadth of AI's clinical application is reflected in a recent scoping review of randomized controlled trials (RCTs), which underscores both the promise and limitations of current evidence. Gastroenterology emerged as the most represented specialty, followed by radiology, cardiology, surgery, and oncology, highlighting a concentration of AI research in a few clinical domains, with limited exploration across others. Geographically, the United States and China are the leading contributors, each responsible for nearly one-third of the trials. Notably, while studies from the United States span various specialties, the majority of Chinese trials were focused on gastroenterology. Most RCTs were conducted in a single country and at a single center, with only a small fraction involving multinational collaborations, predominantly within Europe. This pattern reveals a critical gap in demographic representation and multicenter validation, underscoring the need for cross-regional cooperation and broader evaluation strategies [11].

Generative AI is further expanding the scope of these advancements by enhancing diagnostic accuracy, automating complex workflows, and streamlining scientific processes. In healthcare, these models have been applied to tasks such as drug–drug interaction identification, clinical decision support, and pharmacovigilance, demonstrating promise in early detection and management of adverse drug events [12]. In research, generative AI is accelerating hypothesis generation, optimizing study design, and assisting with scientific writing. These advancements underscore the transformative potential of generative AI in improving patient outcomes and expediting scientific discoveries. However, this rapid integration also raises important ethical concerns, particularly regarding authorship, transparency, and the preservation of scientific integrity, calling for clear guidelines and human oversight in AI-assisted scholarly communication [13].

Applications in Laboratory Medicine

AI is playing an increasingly transformative role in laboratory medicine, enhancing quality, efficiency, and clinical impact across the entire total testing process, from pre-analytical to post-analytical phases. While early applications focused on tasks such as automated microscopy and sediment analysis, recent progress has shifted toward deep learning models that support complex classification, real-time quality control, and integrative diagnostic support [14, 15].

- **In the pre-analytical phase**: AI tools have demonstrated the ability to mitigate frequent sources of error. ML algorithms have been developed to detect inappropriate test requests [16], identify mislabeled or misidentified samples (e.g., wrong blood in tube) [17], and flag potential pre-analytical inconsistencies through pattern recognition and delta checks [18]. These solutions contribute to reducing unnecessary testing, increasing patient safety, and optimizing resource utilization [19].
- **In the analytical phase**: AI-based approaches, such as Patient-Based Real-Time Quality Control (PBRTQC), enhance error detection by monitoring longitudinal trends and identifying analytical shifts that would be undetectable through conventional internal quality control methods [20, 21]. Additionally, AI supports the interpretation of complex datasets, such as those from mass spectrometry and flow cytometry, improving both speed and consistency. However, most of these tools have been developed and tested in isolated settings, and few have undergone multicenter validation. As such, their true impact on error reduction and quality assurance in routine clinical environments remains to be conclusively demonstrated [22].
- **In the post-analytical phase**: AI is increasingly used for diagnostic and prognostic applications [23-25]. Machine learning models have shown high predictive accuracy for hematological conditions such as hemoglobinopathies, based on routine laboratory parameters like complete blood count (CBC) data [26], classifying neoplastic cell types from blood films [27], and stratifying patients with suspected urinary tract infections through interpretable decision-tree algorithms [28]. AI has also been applied to stratify diabetes subtypes [29] and predict outcomes in acute leukemia and sepsis using laboratory data alone [30-32].

These models improve diagnostic precision and facilitate early detection and patient risk stratification, thereby providing clinically actionable insights that surpass the interpretive capacity of conventional laboratory reporting.

Furthermore, AI holds significant promise in point-of-care testing (POCT) by enabling decentralized diagnostics through image-based interpretation and smartphone-enabled tools, offering new opportunities to expand access to testing in remote and underserved settings [33, 34].

Despite these advances, the majority of models remain at early stages of clinical translation. Widespread implementation is constrained by limited multicenter validation, real-world testing, and the need for standardized reporting frameworks to ensure reproducibility and comparability [35, 36]. Many proposed applications remain at a conceptual or prototype stage, with limited demonstration of clinical utility in real-world workflows. Moreover, several initiatives are restricted to isolated environments, lacking generalizability and standardization. These limitations must be addressed before AI can be safely and meaningfully integrated into routine laboratory practice. Nevertheless, laboratory medicine, with its structured and high-throughput data environment, represents an ideal setting for the continued integration of AI to support clinical decision-making, enhance quality assurance, and

advance personalized healthcare [2, 37, 38].
One example of successful clinical application within laboratory medicine is the use of machine learning models for sepsis detection based solely on hematological parameters, including complete blood count and monocyte distribution width. These models have undergone multicenter development and external validation, demonstrating performance comparable to more invasive and resource-intensive approaches [32]. Importantly, the integration of AI in laboratory medicine within low-resource settings remains particularly challenging. Barriers include inadequate digital infrastructure, lack of trained personnel, and limited access to validated tools. While AI-powered POCT solutions may offer opportunities to improve access, their success depends on affordability, local capacity-building, and strong governance mechanisms tailored to contextual realities.

Generative Artificial Intelligence in Laboratory Medicine
Beyond traditional machine learning, the adoption of generative AI and large language models (LLMs), such as ChatGPT, offers new possibilities in report generation, natural language explanation, and interactive clinical decision support. These systems can support interpretive comments in laboratory reports, enhancing communication with clinicians and improving the integration of laboratory findings into the broader clinical picture [39, 40].

One example involves the use of LLMs to predict hemoglobinopathies from CBC data, achieving up to 76% accuracy. However, these models showed limitations in handling negative cases and demonstrated a tendency for false positives, reinforcing the need for expert supervision [41]. Importantly, these models have shown a tendency toward elevated false-positive rates and inconsistent performance in handling negative or borderline cases, which may jeopardize clinical decision-making if left unchecked. Without robust validation, continuous performance tracking, and transparent reporting of error rates, the integration of generative AI into laboratory practice may pose significant risks rather than benefits [42]. Chatbots have also been tested on complex diagnostic scenarios, including recommendations on the utility of CK-MB in myocardial infarction, where they occasionally generate outdated or incomplete information, thus reinforcing the importance of human validation [43]. While generative AI can streamline documentation, extract structured information from unstructured reports, and support educational and research tasks, its current performance remains inconsistent in clinical environments where contextual understanding and nuanced reasoning are essential. For this reason, a cautious and critical integration into laboratory workflows is essential [44, 45]. Despite these constraints, supervised use of generative AI can improve text summarization, support structured data extraction from unstructured reports, and even assist in educational tasks such as generating questions or synthesizing scientific literature, potentially streamlining laboratory workflows, and fostering broader access to advanced data tools [46]. Moreover, LLMs can assist in generating standardized interpretive commentaries, simulating patient scenarios for training purposes, and flagging inconsistencies across multiple test results. These capabilities may enhance efficiency in high-volume laboratories while offering scalable tools for settings with limited specialist access.

Tribulations: Ethical and Technical Challenges
The increasing reliance on AI systems in healthcare introduces a range of ethical, technical, and regulatory vulnerabilities that must be addressed to ensure responsible innovation [47]. Among the foremost concerns is the quality and representativeness of the data used to train AI models. Algorithms trained on biased, incomplete, or non-representative datasets may inadvertently amplify pre-existing healthcare disparities, thereby entrenching structural inequities and compromising the generalizability of clinical insights. This concern is particularly pronounced in real-world healthcare settings, where heterogeneity in data quality, inconsistencies in clinical documentation, and variable measurement standards complicate the development of robust, transferable AI models. Recent updates to the Declaration of Helsinki (10th revision, October 2024) explicitly address these emerging ethical concerns in AI and big data research [48, 49]. The revised guidelines reaffirm core ethical principles while explicitly addressing emerging challenges in AI and big data research, including requirements for algorithmic transparency, data protection, and equitable technology deployment. Key updates include:

- **Emphasis on data protection and AI ethics**: Research involving AI must adhere to strict ethical, legal, and regulatory standards. Informed consent is required for the use of health-related big data, and compliance with data privacy laws is mandatory.
- **Capacity building within ethical review boards**: Ethics committees are now encouraged to include expertise in AI and machine learning to appropriately assess the risks and methodological soundness of studies involving these technologies.
- **Commitment to equity**: AI applications in healthcare must not exacerbate social or geographic inequalities. Researchers are urged to ensure algorithmic fairness and facilitate integration of AI tools into healthcare systems globally, including in low-resource settings.
- **Transparency and bias monitoring**: The Declaration highlights the need for ongoing surveillance of AI systems to detect hidden biases and prevent undue influence from commercial interests.

The increasing complexity of AI technologies underscores the urgent need for explainability to ensure transparency, trust, and safe clinical integration. Clinicians are often reluctant to

adopt systems whose decision-making processes are opaque or unverifiable.

Explainability must operate at both the local level clarifying individual predictions, and the global level, illuminating overall model behavior. Without such clarity, trust in clinical implementation cannot be sustained.

Crucially, the deployment of AI systems in healthcare must not compromise patient safety, which depends on sustained clinician oversight. AI output, particularly those derived from non-transparent models, can carry significant clinical consequences if misinterpreted or accepted uncritically. Thus, robust safeguards, including human-in-the-loop designs and clinical validation protocols, are essential to prevent harm and ensure accountability.

In a recent interdisciplinary "manifesto of open challenges" in explainable AI (XAI), Longo et al. identify 28 pressing research challenges grouped into nine thematic areas [50]. These encompass technical and conceptual aspects, including the need for interpretable generative models, collaborative learning frameworks, and clearer definitions of trust in XAI. The authors call for rigorous quantitative and qualitative evaluation of explanations to ensure they promote genuine understanding rather than superficial interpretability. The manifesto emphasizes the societal imperative of fostering human-centered AI systems that are not only technically sound but also aligned with principles of fairness, inclusivity, and democratic oversight. This entails shifting from mere interpretability to genuine epistemic transparency and user-centered design.

In his recent reflections on AI, Pope Francis warns that technological advancement devoid of ethical guidance may foster a "throwaway culture" that subordinates human dignity to efficiency. In the Vatican's Antiqua et Nova document, he advocates for an 'epistemology of care' that situates human dignity, social justice, and ethical responsibility as foundational elements in the development and deployment of AI technologies - particularly in healthcare, where algorithmic decisions bear direct implications for human well-being [6]. These principles are especially vital in healthcare, where decisions driven by algorithms must never eclipse the intrinsic value of each human life.

This ethical framework compels us to view AI not merely as a technical solution but as a social intervention - one that must reflect values of solidarity, transparency, and inclusivity. To that end, a "culture of encounter" is needed, fostering inclusive dialogue among technologists, clinicians, ethicists, and patients, and ensuring that the benefits of AI do not remain the privilege of the few but are extended universally. These principles were echoed in recent international policy discussions, including the Vatican's statement at the G7 Summit (2024), emphasizing the dual promise and peril of AI [7]. While AI may democratize knowledge and automate arduous labor, it may also deepen social injustices and foster a culture of exclusion rather than inclusion.

Data privacy and accountability remain critical concerns. Health data are intrinsically sensitive, and their misuse, whether inadvertent or deliberate, can lead to serious ethical, legal, and reputational consequences. Many jurisdictions have yet to establish comprehensive frameworks for determining liability in cases of AI-related harm or data breaches.

Finally, the limited AI literacy among members of ethics committees and regulatory authorities constitutes a significant barrier to responsible governance. Targeted training and interdisciplinary collaboration are urgently required to equip regulatory bodies and ethics committees with the skills necessary to evaluate algorithmic systems, assess risks, and enforce compliance with evolving legal and ethical standards.

Governance and Regulation

A coherent governance model is urgently required to guide the safe and equitable integration of AI in healthcare. This includes the development of standards for algorithm validation, implementation, and post-market surveillance. Such a model must ensure not only technical robustness but also ethical alignment and societal trust.

Key principles for effective AI governance include:

- **Multistakeholder Involvement:** Ensure inclusive participation of clinicians, laboratory professionals, data scientists, ethicists, patients, and regulatory authorities throughout the design, validation, and oversight phases of AI integration.
- **Clinical Validation and Continuous Monitoring:** Require thorough validation across diverse populations and enforce post-deployment surveillance to detect algorithm drift and performance degradation.
- **Equity-Focused Regulation**: Assess the societal impact of AI tools and mitigate risks of exacerbating health disparities, particularly in under-resourced settings.
- **Transparency and Accountability**: Mandate full disclosure of model architecture, training datasets, and decision-making processes to support auditability and clinician trust.
- **Ethical Oversight:** Align AI applications with bioethical principles and international declarations, including the revised 2024 Declaration of Helsinki and the Declaration of Taipei.

The revised 2024 Declaration of Helsinki, along with the Declaration of Taipei, underscores the need for consistent ethical oversight in AI-related research, particularly in the use of large health datasets [43]. However, divergent data governance regimes across jurisdictions, such as General Data Protection Regulation (GDPR) in the EU versus fragmented policies in the U.S., emphasize the urgent necessity

for harmonizing international legal and ethical standards, particularly in light of cross-border data use, divergent regulatory landscapes, and the global nature of AI innovation [51].

The European Union's (EU) AI Act, finalized in early 2024, establishes a comprehensive risk-based framework that mandates transparency, human oversight, and third-party conformity assessment for high-risk AI systems in health [52]. It allows for real-world testing under strict conditions and encourages the use of regulatory sandboxes to safely innovate while protecting fundamental rights. The Act is expected to serve as a global benchmark, analogous to the GDPR in data protection. Its tiered approach, pre-market conformity assessments, and regulatory sandbox provisions aim to balance innovation with patient safety, offering a model for international cooperation. Nevertheless, without coordinated investment in capacity-building - particularly in low-resource settings - and without mechanisms to enforce cross-border accountability, these efforts risk reinforcing existing global inequities. Equitable AI governance must include training programs, infrastructure support, and shared oversight models that protect patient rights across jurisdictions, not only where technological leadership is concentrated.

At the institutional level, emerging models of AI governance emphasize the importance of continuous evaluation and adaptive oversight [53].

Moreover, the WHO has called for the establishment of binding international standards to ensure equitable AI deployment across healthcare systems. While current guidance remains largely aspirational, efforts are underway to reform the International Health Regulations (IHR) to include digital and AI health governance [1]. Until such frameworks are adopted globally, regional legislation such as the EU AI Act may serve as de facto blueprints for responsible innovation.

The Role of Laboratory Medicine Societies

Scientific societies in laboratory medicine are uniquely positioned to lead the responsible integration of AI into clinical practice. Their contributions should encompass:

- **Knowledge Dissemination:** Provide training and educational resources on AI fundamentals for laboratory professionals. Notably, the Italian Society of clinical chemistry and laboratory medicine (SIBioC) Working Group on Big data and Artificial Intelligence has recently launched two national training programs: "Understanding Generative AI and Its Applications" and "Introduction to Machine Learning in Laboratory Medicine" [54]. These initiatives reflect a broader commitment to professional capacity building and equitable technological adoption, especially in settings lacking dedicated data science support. Such initiatives are particularly critical for addressing disparities in access to AI training and infrastructure, which affect many professional communities in low- and middle-income countries. Strengthening international cooperation and resource-sharing is essential to prevent technological exclusion and promote equitable capacity development.
- **Interdisciplinary Collaboration:** Foster dialogue between laboratory scientists, clinicians, data scientists, and engineers. The IFCC, through its Task Force on Ethics [55], has undertaken a timely and relevant survey investigating the real-time electronic disclosure of laboratory results in ambulatory settings. The survey, which closed on March 17, 2025, seeks to identify prevailing practices and ethical concerns, ultimately informing the development of international guidance to ensure transparency, patient autonomy, and responsible data sharing.
- **Regulatory Advocacy and Ethical Oversight:** Participate in national and international policymaking to ensure that laboratory-specific considerations are included in AI governance. The IFCC has also issued 15 key recommendations for the development of machine learning in laboratory medicine, with the first underscoring the imperative to "involve diverse stakeholders to develop clinically useful, practical, and ethical models" [56]. This principle captures the essence of ethical AI development: it must be inclusive, transparent, and continuously validated to remain trustworthy and clinically relevant. Ethics in AI is not only about minimizing bias but also about ensuring replicability, workflow integration, and patient-centered impact.
- In support of these principles, a recent publication in Clinical Chemistry emphasizes the need to go beyond initial model validation [57]. The authors call for comprehensive lifecycle oversight, including performance tracking in real-world settings and revalidation as clinical conditions evolve.
- **Consensus Development and Infrastructure:** Generate position papers, best practice guidelines, and frameworks for data quality and governance. The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group on Artificial Intelligence has made substantial contributions in this area, including a European survey that maps current AI adoption, identifies structural and educational barriers, and calls for targeted investment in infrastructure to support effective AI integration [37]. An additional contribution from the EFLM underscores the critical role of metadata and peridata in laboratory data management, offering a structured methodology to improve AI-driven applications through enhanced data standardization and interoperability [58]. Indeed, a thorough understanding of metadata and peridata - including analytical and biological sources of variation - enables the appropriate use of laboratory data along with its intrinsic "noise", a form of uncertainty that only domain experts such as clinical laboratorians can correctly interpret and integrate into AI workflows to enhance robustness and contextual validity [36, 59].

These collective efforts underscore the strategic and operational role of laboratory medicine societies in shaping an ethically sound, scientifically robust, and socially responsible future for AI in healthcare. By investing in education, governance, data quality, and international dialogue, these organizations ensure that the transformative potential of AI is directed toward improving patient care and advancing health equity.

Conclusion

Artificial intelligence offers unprecedented opportunities to reshape healthcare delivery, public health infrastructure, and laboratory medicine. However, realizing its full potential requires a deliberate and ethically grounded approach to its design, validation, and implementation. The promise of technical innovation must be matched by ethical vigilance, legal coherence, and inclusive governance that bridges diverse clinical contexts and global disparities. This imperative is especially acute in low-resource environments, where AI has the potential to either narrow or widen health inequities depending on how inclusively it is designed, validated, and deployed.

Laboratory medicine, with its structured data environment and central role in clinical decision-making, is uniquely positioned to lead this transformation. Professional societies, including IFCC, EFLM, and national organizations like SIBioC, are critical to this effort, advancing AI literacy, fostering interdisciplinary collaboration, and shaping international standards for responsible innovation.

As underscored in this manuscript, the challenges of data representativeness, explainability, and global regulatory fragmentation remain formidable.

Yet they also present a pivotal opportunity: to develop a global framework grounded in accountability, transparency, and justice—ensuring that AI evolves as a catalyst for health equity rather than a vector of new disparities. Clinician oversight must remain central to all AI-enabled processes to ensure that safety, accountability, and clinical judgment are never subordinated to algorithmic convenience.

To translate these reflections into actionable guidance, the responsible integration of AI in laboratory medicine should rest on several key pillars:

1. Rigorous model validation across diverse settings;
2. Clinician oversight to safeguard patient safety;
3. Equitable access to AI education and infrastructure;
4. Alignment with evolving ethical and legal frameworks;
5. Continuous performance monitoring and quality assurance.

These principles should guide professional societies, developers, and policymakers alike as they shape the future of AI in healthcare.

Pope Francis's appeal for a "culture of encounter" reminds us that technological advancement must never eclipse human dignity. Rather, it must be anchored in solidarity, inclusion, and global cooperation. The future of AI in healthcare is therefore not merely a matter of technological advancement, it is a shared societal responsibility, entrusted to clinicians, scientists, regulators, and the communities they serve.

Abbreviations List

AI	Artificial Intelligence
CBC	Complete Blood Count
CLAIR	Clinical Laboratories Artificial Intelligence Revolution
CT	Computed Tomography
EFLM	European Federation of Clinical Chemistry and Laboratory Medicine
EU	European Union
GDPR	General Data Protection Regulation
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
IHR	International Health Regulations
LLM	Large Language Models
ML	Machine Learning
MRI	Magnetic Resonance Imaging
PBRTQC	Patient-Based Real-Time Quality Control
POCT	Point-of-Care Testing
RCTs	Randomized Controlled Trials
SIBioC	Italian Society of Clinical Chemistry and Laboratory Medicine
WHO	World Health Organization
XAI	Explainable Artificial Intelligence
CXR	Chest X-ray

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this manuscript, the author utilized ChatGPT-4o (OpenAI) to assist with language refinement and rephrasing. The content generated was subsequently reviewed, edited, and validated by the author, who assumes full responsibility for the final version of the work.

Conflicts of interest

The author declares no conflicts of interest.

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References

1. Bouderhem R. Shaping the future of AI in healthcare through ethics and governance. Humanit Soc Sci Commun. 2024;416. https://doi.org/10.1057/s41599-024-02894-w.
2. Plebani M, Cadamuro J, Vermeersch P, Jovičić S, Ozben T, Trenti T, et al. A vision to the future: value-based laboratory medicine. Clin Chem Lab Med. 2024;62:2373-2387.

doi: 10.1515/cclm-2024-1022.
3. WHO (2023) Regulatory considerations on artificial intelligence for health. World Health Organization. Available from: https://iris.who.int/handle/10665/373421 (Accessed 02/03/2025).
4. WHO (2021) Report, Ethics and governance of artificial intelligence. Available from: https://www.who.int/publications/i/item/9789240029200 (Accessed 02/03/2025).
5. EU Council, Artificial Intelligence Act 2024. Text of the Provisional Agreement, 2 February 2024. Available from: https://data.consilium.europa.eu/doc/document/ST-5662-2024-INIT/en/pdf (Accessed 05/01/2025).
6. ANTIQUA ET NOVA: Note on the Relationship Between Artificial Intelligence and Human Intelligence. Available at: https://press.vatican.va/content/salastampa/it/bollettino/pubblico/2025/01/28/0083/01166.html#ing
7. G7 Session on Artificial Intelligence. Address of His Holiness Pope Francis. Available from: https://www.vatican.va/content/francesco/en/speeches/2024/june/documents/20240614-g7-intelligenza-artificiale.html (Accessed 02/03/2025).
8. Rakers MM, van Buchem MM, Kucenko S, de Hond A, Kant I, van Smeden M, et al. Availability of Evidence for Predictive Machine Learning Algorithms in Primary Care: A Systematic Review. JAMA Netw Open. 2024;7:e2432990. doi: 10.1001/jamanetworkopen.2024.32990.
9. Kraemer MUG, Tsui JL, Chang SY, Lytras S, Khurana MP, Vanderslott S, et al. Artificial intelligence for modelling infectious disease epidemics. Nature. 2025;638:623-635. doi: 10.1038/s41586-024-08564-w.
10. Askin S, Burkhalter D, Calado G, El Dakrouni S. Artificial Intelligence Applied to clinical trials: opportunities and challenges. Health Technol (Berl). 2023;13:203-213. doi: 10.1007/s12553-023-00738-2.
11. Han R, Acosta JN, Shakeri Z, Ioannidis JPA, Topol EJ, Rajpurkar P. Randomised controlled trials evaluating artificial intelligence in clinical practice: a scoping review. Lancet Digit Health. 2024;6:e367-e373. doi: 10.1016/S2589-7500(24)00047-5.
12. Ong JCL, Chen MH, Ng N, Elangovan K, Tan NYT, Jin L, et al. A scoping review on generative AI and large language models in mitigating medication related harm. NPJ Digit Med. 2025;8:182. doi: 10.1038/s41746-025-01565-7.
13. Carobene A, Padoan A, Cabitza F, Banfi G, Plebani M. Rising adoption of artificial intelligence in scientific publishing: evaluating the role, risks, and ethical implications in paper drafting and review process. Clin Chem Lab Med. 2023;62:835-843. doi: 10.1515/cclm-2023-1136.
14. Hou H, Zhang R, Li J. Artificial intelligence in the clinical laboratory. Clin Chim Acta. 2024;559:119724. doi: 10.1016/j.cca.2024.119724.
15. Carobene A, Gruson D, Cadamuro J, Cabitza F, Agnello L, Campagner A, Padoan A. The role of artificial intelligence in the clinical laboratory: challenges and opportunities. Biochimica Clinica. 2025;49. doi: 10.23736/S0393-0564.24.00007-0
16. Kumar Ashwin PSS, Yuvaraj D, Kaur R, Kayathri S, Dhamotharan KA, Patil N. Artificial Intelligence in Clinical Biochemistry Is Designed To Prevent Unnecessary Routine Testing In the Pre-Analytic Phase. Bulletin of Environment, Pharmacology and Life Sciences Bull. Env. Pharmacol. Life Sci. 2022;11: 207-212. https://bepls.com/april_2022/38.pdf (Accessed 02/01/2025).
17. Farrell CJ, Makuni C, Keenan A, Maeder E, Davies G, Giannoutsos J. A Machine Learning Model for the Routine Detection of "Wrong Blood in Complete Blood Count Tube" Errors. Clin Chem. 2023;69:1031-1037. doi: 10.1093/clinchem/hvad100.
18. Seok HS, Yu S, Shin KH, Lee W, Chun S, Kim S, et al. Machine Learning-Based Sample Misidentification Error Detection in Clinical Laboratory Tests: A Retrospective Multicenter Study. Clin Chem. 2024;70:1256-1267. doi: 10.1093/clinchem/hvae114.
19. Lippi G, Mattiuzzi C, Favaloro EJ. Artificial intelligence in the pre-analytical phase: State-of-the art and future perspectives. J Med Biochem. 2024;43:1-10. doi: 10.5937/jomb0-45936.
20. Duan X, Zhang M, Liu Y, Zheng W, Lim CY, Kim S, et al. Patient-Based Real-Time Quality Control Working Group of the Asia Pacific Federation of Clinical Biochemistry and Laboratory Medicine. Next-Generation Patient-Based Real-Time Quality Control Models. Ann Lab Med. 2024;44:385-391. doi: 10.3343/alm.2024.0053.
21. Lorde N, Mahapatra S, Kalaria T. Machine Learning for Patient-Based Real-Time Quality Control (PBRTQC), Analytical and Preanalytical Error Detection in Clinical Laboratory. Diagnostics (Basel). 2024;14:1808. doi: 10.3390/diagnostics14161808.
22. Duan X, Wang B, Zhu J, Shao W, Wang H, Shen J, Wu W, Jiang W, Yiu KL, Pan B, Guo W. Assessment of patient-based real-time quality control algorithm performance on different types of analytical error. Clin Chim Acta. 2020;511:329-335. doi: 10.1016/j.cca.2020.10.006.
23. Famiglini L, Campagner A, Carobene A, Cabitza F. A robust and parsimonious machine learning method to predict ICU admission of COVID-19 patients. Med Biol Eng Comput. 2022:1–13. doi: 10.1007/s11517-022-02543-x.
24. Campagner A, Carobene A, Cabitza F. External validation of Machine Learning models for COVID-19 detection based on Complete Blood Count. Health Inf Sci Syst. 2021;9:37. doi: 10.1007/s13755-021-00167-3.
25. Carobene A, Milella F, Famiglini L, Cabitza F. How is test laboratory data used and characterised by machine learning models? A systematic review of diagnostic and prognostic models developed for COVID-19 patients using only laboratory data. Clin Chem Lab Med. 2022;60:1887-1901. doi: 10.1515/cclm-2022-0182.
26. Schipper A, Rutten M, van Gammeren A, Harteveld CL, Urrechaga E, Weerkamp F, et al. Machine Learning-Based

Prediction of Hemoglobinopathies Using Complete Blood Count Data. Clin Chem. 2024;70:1064-1075. doi: 10.1093/clinchem/hvae081.
27. Zini G, Mancini F, Rossi E, Landucci S, d'Onofrio G. Artificial intelligence and the blood film: Performance of the MC-80 digital morphology analyzer in samples with neoplastic and reactive cell types. Int J Lab Hematol. 2023;45:881-889. doi: 10.1111/ijlh.14160.
28. Yildirim M, Bingol H, Cengil E, Aslan S, Baykara M. Automatic Classification of Particles in the Urine Sediment Test with the Developed Artificial Intelligence-Based Hybrid Model. Diagnostics (Basel). 2023;13:1299. doi: 10.3390/diagnostics13071299.
29. Mizani MA, Dashtban A, Pasea L, et al. Identifying subtypes of type 2 diabetes mellitus with machine learning: development, internal validation, prognostic validation and medication burden in linked electronic health records in 420 448 individuals. BMJ Open Diab Res Care. 2024;12:e004191. doi:10.1136/bmjdrc-2024-004191.
30. Alcazer V, Le Meur G, Roccon M, Barriere S, Le Calvez B, Badaoui B, et al. Evaluation of a machine-learning model based on laboratory parameters for the prediction of acute leukaemia subtypes: a multicentre model development and validation study in France. Lancet Digit Health. 2024;6:e323-e333. doi: 10.1016/S2589-7500(24)00044-X.
31. Agnello L, Vidali M, Padoan A, Lucis R, Mancini A, Guerranti R, et al. Machine learning algorithms in sepsis. Clin Chim Acta. 2024;553:117738. doi: 10.1016/j.cca.2023.117738.
32. Campagner A, Agnello L, Carobene A, Padoan A, Del Ben F, Locatelli M, et al. Complete Blood Count and Monocyte Distribution Width-Based Machine Learning Algorithms for Sepsis Detection: Multicentric Development and External Validation Study. J Med Internet Res. 2025;27:e55492. doi: 10.2196/55492.
33. Han GR, Goncharov A, Eryilmaz M, Ye S, Palanisamy B, Ghosh R, et al. Machine learning in point-of-care testing: innovations, challenges, and opportunities. Nat Commun. 2025;16:3165. doi: 10.1038/s41467-025-58527-6.
34. Khan AI, Khan M, Khan R. Artificial Intelligence in Point-of-Care Testing. Ann Lab Med. 2023;43:401-407. doi: 10.3343/alm.2023.43.5.401.
35. Carobene A, Cabitza F, Bernardini S, Gopalan R, Lennerz JK, Weir C, et al. Where is laboratory medicine headed in the next decade? Partnership model for efficient integration and adoption of artificial intelligence into medical laboratories. Clin Chem Lab Med. 2022;61:535-43. doi: 10.1515/cclm-2022-1030. Erratum in: Clin Chem Lab Med. 2023;61:1359. doi: 10.1515/cclm-2023-0352.
36. Cabitza F, Campagner A, Soares F, García de Guadiana-Romualdo L, Challa F, Sulejmani A, et al. The importance of being external. methodological insights for the external validation of machine learning models in medicine. Comput Methods Programs Biomed. 2021;208:106288. doi: 10.1016/j.cmpb.2021.106288.
37. Cadamuro J, Carobene A, Cabitza F, Debeljak Z, De Bruyne S, van Doorn W, et al. A comprehensive survey of artificial intelligence adoption in European laboratory medicine: current utilization and prospects. Clin Chem Lab Med. 2024;63:692-703. doi: 10.1515/cclm-2024-1016.
38. Bellini C, Padoan A, Carobene A, Guerranti R. A survey on Artificial Intelligence and Big Data utilisation in Italian clinical laboratories. Clin Chem Lab Med. 2022;60:2017-2026. doi: 10.1515/cclm-2022-0680.
39. Yang, He S., Li, Jieli, Yi, Xin and Wang, Fei. Performance evaluation of large language models with chain-of-thought reasoning ability in clinical laboratory case interpretation. Clin Chem Lab Med. 2025. doi: 10.1515/cclm-2025-0055. Epub ahead of print.
40. Cadamuro J, Cabitza F, Debeljak Z, De Bruyne S, Frans G, Perez SM, et al. Potentials and pitfalls of ChatGPT and natural-language artificial intelligence models for the understanding of laboratory medicine test results. An assessment by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group on Artificial Intelligence (WG-AI). Clin Chem Lab Med. 2023;61:1158-1166. doi: 10.1515/cclm-2023-0355.
41. Kurstjens S, Schipper A, Krabbe J, Kusters R. Predicting hemoglobinopathies using ChatGPT. Clin Chem Lab Med 2023;62:e59–61.
42. Rashidi HH, Pantanowitz J, Chamanzar A, Fennell B, Wang Y, Gullapalli RR, Tafti A, Deebajah M, Albahra S, Glassy E, Hanna MG, Pantanowitz L. Generative Artificial Intelligence in Pathology and Medicine: A Deeper Dive. Mod Pathol. 2025;38:100687. doi: 10.1016/j.modpat.2024.100687.
43. Wu AH, Jaffe AS, Peacock WF, Kavsak P, Greene D, Christenson RH. The Role of Artificial Intelligence for Providing Scientific Content for Laboratory Medicine. J Appl Lab Med 2024;9:386–393.
44. Plebani M. ChatGPT: angel or Demon? Critical thinking is still needed. Clin Chem Lab Med 2023;61:1131–1132.
45. Del Ben F, Galozzi P, Lucis R, Cabitza F, Carobene A. Generative artificial intelligence in laboratory medicine: innovations, limitations, and ethical considerations. Biochimica Clinica 2025;49:75-84. doi: 10.23736/S0393–0564.24.00003-0.
46. Van Noorden R, Perkel JM. AI and science: what 1,600 researchers think. Nature 2023;621:672–675.
47. Pennestri F, Banfi G. Artificial intelligence in laboratory medicine: fundamental ethical issues and normative key-points. Clin Chem Lab Med. 2022;60:1867-1874. doi: 10.1515/cclm-2022-0096.
48. World Medical Association. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants. JAMA. 2025;333:71-74. doi: 10.1001/jama.2024.21972.
49. Shaw JA. The Revised Declaration of Helsinki-Considerations for the Future of Artificial Intelligence in Health

and Medical Research. JAMA. 2025;333:26-27. doi: 10.1001/jama.2024.22074.
50. Longo L, Brcic M, Cabitza F, Choi J, Confalonieri R, Del Ser J, et al. Explainable Artificial Intelligence (XAI) 2.0: A manifesto of open challenges and interdisciplinary research directions. Information Fusion 106. 2024:102301. doi: 10.1016/j.inffus.2024.102301.
51. Aidun E. Associate Member, University of Cincinnati Law Review Vol. 93 Data Privacy in the Digital Age: A Comparative Analysis of U.S. and EU Regulations. Available from: https://uclawreview.org/2025/03/05/data-privacy-in-the-digital-age-a-comparative-analysis-of-u-s-and-eu-regulations
52. Schmidt J, Schutte NM, Buttigieg S, Novillo-Ortiz D, Sutherland E, Anderson M, et al. Mapping the regulatory landscape for artificial intelligence in health within the European Union. NPJ Digit Med. 2024;7:229. doi: 10.1038/s41746-024-01221-6.
53. Saenz AD; Mass General Brigham AI Governance Committee; Centi A, Ting D, You JG, Landman A, Mishuris RG. Establishing responsible use of AI guidelines: a comprehensive case study for healthcare institutions. NPJ Digit Med. 2024;7:348. doi: 10.1038/s41746-024-01300-8. Erratum in: NPJ Digit Med 2025;8:70. doi: 10.1038/s41746-025-01445-0.
54. Carobene A, Padoan A. Esplorando l'Intelligenza Artificiale in medicina di laboratorio e nella ricerca scientifica: tra sfide e nuove opportunità l'importanza di un approccio proattivo. Editorial. Biochim Clin. 2024;48:111-114. doi: 10.19186/BC_2024.022
55. https://ifcc.org/taskforceethics/ (Accessed 02/03/2025).
56. Master SR, Badrick TC, Bietenbeck A, Haymond S. Machine Learning in Laboratory Medicine: Recommendations of the IFCC Working Group. Clin Chem. 2023;69:690-698. doi: 10.1093/clinchem/hvad055.
57. Spies NC, Farnsworth CW, Wheeler S, McCudden CR. Validating, Implementing, and Monitoring Machine Learning Solutions in the Clinical Laboratory Safely and Effectively. Clin Chem. 2024;70:1334-1343. doi: 10.1093/clinchem/hvae126.
58. Padoan A, Cadamuro J, Frans G, Cabitza F, Tolios A, De Bruyne S, et al. Data flow in clinical laboratories: could metadata and peridata bridge the gap to new AI-based applications? Clin Chem Lab Med. 2024;63:684-691. doi: 10.1515/cclm-2024-0971.
59. Campagner A, Famiglini L, Carobene A, Cabitza F. Everything is varied: The surprising impact of instantial variation on ML reliability Applied Soft Computing, 2023, 146, 110644.