ORIGINAL RESEARCH ARTICLE

Artificial intelligence in cancer diagnostics: Governance for equity in low- and middle-income countries

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Abstract

Artificial intelligence (AI) is rapidly reshaping cancer diagnostics by enhancing accuracy, speed, and clinical decision support. However, its adoption in low- and middle-income countries (LMICs) raises critical governance challenges related to data protection, regulatory oversight, equity, and infrastructural readiness. This quantitative scoping review synthesizes evidence from 19 studies published between 2015 and 2024 to map the governance landscape surrounding AI-driven cancer diagnostics in LMICs. Following the PRISMA-ScR approach, the review identified key governance domains including data sovereignty, regulatory gaps, algorithmic transparency, infrastructural constraints, and risks of inequitable access. Results indicate that data governance challenges were the most frequently reported (n=14), followed by regulatory limitations (n=12) and workforce and infrastructural barriers (n=11). The findings highlight that while AI holds transformative potential for improving timely and accurate cancer diagnosis, its benefits cannot be realized without context-sensitive governance frameworks that ensure safety, transparency, accountability, and equity. The review proposes actionable policy pathways to support responsible AI integration across LMIC health systems. *(Afr J Reprod Health 2025; 29 [12s]: 93-103)*

Keywords: Artificial Intelligence; Cancer Diagnostics; Governance; Data Sovereignty; Digital Pathology; Algorithmic Transparency; Health Equity; Low- and Middle-Income Countries

Résumé

L'intelligence artificielle (IA) transforme rapidement le diagnostic du cancer, offrant des améliorations sans précédent en matière de précision, de rapidité et d'accessibilité. Alors que les pays à revenu élevé intègrent activement l'IA dans les processus de soins en oncologie, les économies émergentes sont confrontées à des défis distincts pour une adoption responsable et équitable de ces technologies. Cette revue examine de manière critique le paysage de la gouvernance entourant le diagnostic du cancer par l'IA dans les pays à revenu faible et intermédiaire (PRFI), en soulignant les complexités éthiques, infrastructurelles et réglementaires. En s'appuyant sur une synthèse conceptuelle des cadres politiques, incluant les Lignes directrices de l'OMS sur l'éthique de l'IA et le cadre de l'Innovation Responsable, cet article interroge les domaines clés de la gouvernance tels que l'explicabilité, la souveraineté des données, les contraintes de capacité et l'équité algorithmique. Il souligne les risques d'aggravation des inégalités en santé si les systèmes d'IA sont déployés sans une adaptation contextuelle suffisante et sans supervision réglementaire. À travers une revue thématique de la littérature mondiale et régionale, l'étude cartographie les lacunes spécifiques de gouvernance dans les PRFI et explore des modèles de régulation adaptative qui mettent l'accent sur la transparence, la responsabilité et la justice. Cet article contribue au discours croissant sur les politiques d'IA en proposant une approche de gouvernance localisée et sensible à l'équité pour garantir une intégration sûre et inclusive de l'IA dans le diagnostic du cancer dans les pays du Sud. *(Afr J Reprod Health 2025; 29 [12s]: 93-103).*

Mots-clés: Intelligence Artificielle, Diagnostic du Cancer, Gouvernance, Souveraineté des Données, Pathologie Numérique, Transparence Algorithmique, Équité en Santé, Pays à Revenu Faible et Intermédiaire

Introduction

Cancer continues to be one of the major causes of death globally, with its estimates revealing a total of 10 million deaths every year, and more than 70 percent of which take place in low- and middle-income countries (LMICs)[1]. The problem of high cancer burden in the LMICs is enhanced by the long process of diagnosis, insufficient oncology infrastructure, and acute workforce gaps, especially radiology and pathology[2]. It is against this background that Artificial Intelligence (AI) has fast become a promising instrument in the field of cancer diagnostics with putative future uses in medical imaging, histopathology, and molecular profiling [3,4]. New technology has seen how AI tools have great

potential and can help in order to increase the accuracy in diagnosis and early detection of diseases such as cancer and others and also lessen the burden of health professionals who already have an overworked schedule [5]. Nevertheless, the worldwide interest in AI adoption tends to make a blind spot to a significant policy gap, i.e., the inability of LMICs to regulate responsible, equitable, and contextually adequate AI implementation[1,6].

Even as the level of AI-based implementation has increased in the cancer diagnostic field, majority of LMICs are missing the infrastructural capacity to accommodate such an AI-based technology in a responsible manner, the ethical oversight and regulations that will govern such technology. This governance gap poses the potential threats of algorithmic bias, data privacy infringement, discriminatory design and maladaptation with the local healthcare. AI has the potential of perpetuating existing disparities in cancer care instead of crossing them unless there is clear governance pathway customized to resource-limited environments is established. As such, context-sensitive, ethically justifiable, and actionable approaches to the issue must be conceptualized to make LMICs responsibly and sustainably adopt AI in cancer diagnostics.

This gap informed the central research question to be addressed and thus the following is the driving question of this study: How can emerging economies responsibly and equitably govern adoption of artificial intelligence to cancer diagnostics?

This paper addresses this demand, offering a series of governance pathways, to be more flexible and flexible, to guide the use of AI so that it is consistent with the health equity and institutional capacity implications and global regulatory trends. Based on the global frameworks like the WHO Guidance on Ethics and Governance of AI in Health (2021), the EU AI Act (2021), and ITU WHO benchmarking tools, this paper develops a policy-relevant roadmap of best practices that can help LMICs overcome any impediments to AI integration into oncology services.

Literature review

Artificial intelligence in diagnosing cancers

The deployment of Artificial Intelligence (AI) technologies is evermore used throughout the cancer diagnosis pipeline starting with early screening and image analysis, histopathology, and genomic profiling. Such technologies based on machine learning (ML) and deep learning (DL) models will eventually be able to complement human knowledge, enhance certainty, and bring diagnostic services to even less resourceful healthcare environments [3,4].

Medical imaging AI

Medical imaging, especially breast cancer, lung cancer, and brain cancer detection, have experienced most advanced and trial-tested uses of AI. The detection of malignant tumors using mammograms and CT scans is comparable to human radiologists with algorithms such as convolutional neural networks (CNNs) that are able to detect and identify the malignancy on a mammogram or CT scan[7]. AI has the potential to be a force-multiplier in the realms of radiology, such as sub-Saharan Africa or in South Asia, where the numbers of radiologists are very limited, at times under 1 per 100,000 population.

Nevertheless, the governance issue arises on the development and implementation of these algorithms. Most of the AI models are developed based on data of high-income countries (HICs), and there is little data about the LMIC population included [8]. This increases the bias in algorithms resulting in even more false positives or negative in the use of different ethnic groups, at varying ages, or even in imaging machines. There are also no regulatory procedures to validate cross-context healthcare that further makes it difficult to use responsibly.

To address the problem of bias in AI-based diagnostic tools, LMICs should bridge the gap with the developed world by creating regulatory policies

that demand local validation of AI models on a locally representative dataset pool[8].In addition, uniform regulatory channels such as the software-as-medical-device (SaMD) guidance of FDA are necessary to test the safety, efficacy, and repeatability of AI applications prior to clinical implementation. In the absence of these protective measures, AI systems are likely to generate unfair results, perpetuate existing biases within the system and challenge clinical credibility among underserved populations that are already characterized by late diagnosis and limited health facilities. The governance required in this area should also be able to be compatible with the current health information systems, and also guarantee the privacy of patients secured data protocols. At the end of the day, it is possible to speak of the promise of AI in imaging only based on regulations helping to achieve the balance between innovation and equity, transparency, and regulatory integrity

Histopathology and digital pathology

Application of AI in histopathology can be utilized to enable automatic identification, scoring and classification of a tumor using digitalised biopsy slides. Using deep learning models WSIs can be processed to detect critical cancerous qualities and even predict genetic mutations[9]. Such automation is especially enticing in LMICs, where pathologists are in short supply.

However, the adoption of digital pathology is not only a matter of technology it is about governance. Barriers include:

- The absence of the legal acknowledgment given to digital slides as clinical evidence
- Lack of national plans of digital pathology infrastructure
- None of the existent ethical principles of AI-based diagnostic decision-making

Moreover, AI applications in the field are vulnerable to opacity since most commercial solutions employ the so-called black-box algorithm, whose cognition remains unexplainable and breaks the law of explainability and informed consent in medical practice [1].

But what it means to governance is massive. Governments need to attend to the lack of national conventions regarding the use of digital slides, data storage in the clouds, and the acceptability of such clinical data in the form of AI-produced pathology reports. Also, there should be regulation instructions to provide the human control over it, where pathologists remain the final source of diagnosis as opposed to letting the AI system provide all the information and revert to human control [1]. The perception of AI algorithms also elevates the importance of explainable AI requirements, which assure clinicians to know how to read and interrogate outputs of machine algorithms. The development and investment on the secure telepathology platform and local capacity building along with the development of partnership with the government agencies and the companies will be critical to ensure a dependency free of the black-box proprietary systems.

AI genomic and molecular profiling

Artificial intelligence into genomic and molecular profiling is a state-of-the-art development in precise oncology. Computer algorithms are increasingly finding their use in analysis of high dimensional genomic data to identify biomarkers and predict treatment response in cancer patients with fair accuracy, as well as classification of tumors subtypes. As an example, AI can be used to make predictions of mutations in genes like BRCA1/2 or detect whether a person has a microsatellite instability, which can be then used to engage in a precisely targeted mechanism of treatment[10]. Such tools provide a means to transition to more personalized cancer care, a means that may make a significant difference in the context where access to specialized oncologists is less available.

Nonetheless, AI use in genomics requires high-level governance issues and concerns in the low- and middle-income nations. These models need to be developed and implemented, and the progress is possible with large genomic datasets of high quality (and diversity) and in most instances these are lacking in LMICs. The majority of AI models in this segment are conditioned on the data representing the high-income nations, making them rather limited generalizable with additional hazards of clinical error when used in non-Western

demographics. In addition, the question of data sovereignty, cross border data transportation, and ownership of genomic information introduce ethical dilemmas mainly when there are no laws at the national level of data protections. Data exploitation and genomic colonialism risk is a possibility, especially under the conditions when the creation of AI models is performed by multinational corporations or foreign research institutions without any local stakeholders. To ensure that the prospects of AI-based genomic diagnostics positively impact LMICs without exploiting them, rigid governance is needed in its form as data protection laws, ethics of genomic research, and investments on local bioinformatics capacity and infrastructure.

Implications for governance in LMICs

The variety of AI applications in cancer diagnostics demonstrates the necessity of wide-scope and context-based governance even in the emerging economies. As much as such technologies are posited to have the potential of relieving bottlenecks in the systemic diagnoses, their utilization is not necessarily without bias or harmful unless there is a concerted effort in regulating their usage. The governance implications are acute in that we must be certain that the AI tools are tested using locally significant data, run as part of the health system systems and implemented so as to augment human knowledge by building not replacing it. LMICs are left to implement regulatory systems that distinguish between the low-risk and high-risk AI applications and focus on algorithmic decision transparency, explainability and accountability. Another issue of importance is the infrastructural preparedness. Unless framed by proper digital infrastructure, data interoperability, and cybersecurity measures, AI implementations face the danger of falling apart, becoming insecure, or unavailable to people who can use them the most. Ethical governance should also solve the problem of the patient consent, algorithmic bias, and fair access to AI that should be instrument of social inclusion and not any form of exclusion. However, the topic of fair and responsible use of AI in cancer diagnosis requires more than mere technological possibilities to be solved, as it needs institutional capabilities, stakeholder involvement, and policy congruency with the national health agenda. LMICs are thus required to come up with flexible and progressive governing approaches that represent not only universal best practices, but also the domestic real-world parameters.

Two and a half key governance issues in emerging economies

Although artificial intelligence is a major promising technology that could transform cancer diagnostics, ethical and effective implementation of artificial intelligence in low- and middle-income countries (LMICs) is limited by the various governance gaps. These issues are regulatory, infrastructural, ethical, and institutional, and the majority of LMICs have no clear national strategies of the health sector AI implementation. Consequently, they tend to promote the use of AI applications in a fractionated donor-driven pilot or privately owned technology collaboration with very little state coordination or integration with state health infrastructure[15].

Among the most urgent issues is a lack of national regulations that would specifically accommodate the AI-based diagnostic tools. In addition to the absence of digital health policies or data protection laws in LMICs in general, the former tends to be obsolete, whereas the latter may not be aimed at regulating the dynamic and risk-specific aspect of AI in clinical practice [12]. Clinical liability, patient safety, and ethical responsibility in LMICs are unclear due to the absence of established approval mechanisms of AI algorithms, which are not present in the United States, but are provided by the Medical Device Regulation in the European Union or the U.S. Food and Drug Administration (FDA)[13]. In addition, the presence of low institutional capacity in the ministries of health and regulatory agencies has a negative impact on the ability to assess, monitor and audit AI technologies. Algorithms and the bias in them, as well as the unrepresentativeness of the data, are crucial issues ethically speaking. The majority of artificially intelligence models that have been developed commercially are trained on data that has been collected in wealthy nations, increasing their potential accuracy or harm in prediction when being applied in a variety of socio-demographic settings [8].

Moreover, in the absence of data governance systems resulting in patient assent, privacy and data ownership, there is an increased threat of data misuse and health disparities[1].

Adoption is further faced with infrastructural deficiencies. Most of the public health systems lack reliable internet connectivity, dedicated digital pathology platforms, high-Performance computing infrastructure, and skilled staff, particularly in rural settings. This digital disparity strengthens health disparities and constrains the expandability of AI uses past a pilot task[14].

In order to overcome these issues, there are various frameworks and principles brought forward by the global institutions that are inclined to give direction in regard to ethical and responsible application of AI in the field of health. The Guidance on Ethics and Governance of Artificial Intelligence for Health released by the World Health Organization[1], presents six important principles, including the necessity to protect autonomy, promote human well-being, ensure transparency, establish responsibility, ensure inclusiveness, and sustainability of AI. Albeit its fundamental nature, this framework can only provide high level normative guidance and is not specific enough to adapt to national policies.

Likewise, EU Artificial Intelligence Act [15] brings a risk-based regulation model according to which AI systems are classified by their potential risks and allows developers and users to have certain legal responsibilities. Nevertheless, it cannot be applied directly to LMICs, as it is reasonable to analyze them differently in terms of different legal traditions, health systems organization, and resource availability[6]. AI performance benchmarking has similarly been tried to be standardized by the ITU and WHO Focus Group on AI for Health, but it is not used to any decent extent in LMICs because of insensitivity and the ability to do so at the institutional level[16]. Putting it all in a nutshell, international governance structures can be a handy conceptual framework, but they cannot serve as viable alternatives to the strong national governance systems that take into consideration the local conditions of the emerging economies including infrastructural, legal and ethical. LMICs need adaptive models of governance, which help strike that balance between universal principles and global standards of good governance and local capacity, equity interests, and long-term health system incorporation. The alarming rate at which AI is taking over cancer diagnostics can only exacerbate the problem of disparities instead of eliminating them without such models in place.

Governance pathways for responsible AI adoption in cancer diagnostics

The challenges outlined in the previous section highlight that technology alone is insufficient to ensure equitable healthcare transformation. What is urgently needed is a governance approach that builds institutional capacity, enables safe innovation, and protects patients' rights. This section outlines five interlinked governance pathways that emerging economies can adopt to ensure the responsible integration of AI in cancer diagnostics.

Establishing national regulatory frameworks for AI in health

LMICs must begin by enacting comprehensive regulatory frameworks specifically for AI in healthcare. These should clearly define categories of AI-based diagnostic tools, outline risk-based approval processes, and delineate roles and responsibilities of developers, health institutions, and regulators. Drawing lessons from the U.S. FDA's Software-as-a-Medical-Device (SaMD) model and the EU AI Act, LMICs should adopt tiered regulatory approaches that match oversight with the potential harm of each AI application[6]. National health authorities should establish independent AI ethics committees or embed AI risk assessment units within existing regulatory agencies to ensure ongoing evaluation, licensing, and post-market surveillance.

Strengthening data governance and sovereignty

Responsible AI requires access to high-quality, representative, and ethically sourced data. LMICs must adopt robust data protection laws that govern the collection, sharing, and usage of health and

genomic data, with specific clauses addressing AI. Policies should ensure patient consent, data anonymization, and protections against cross-border data exploitation. Establishing national data trusts or sovereign data repositories can help prevent "data colonialism" and enable public benefit from local data resources[1]. Capacity-building efforts must focus on training local data scientists and health professionals in managing and interpreting AI-related health data ethically and safely.

Promoting explainability and transparency in AI tools

Trust in AI diagnostics will remain fragile unless these systems are explainable, auditable, and transparent. LMICs should mandate that vendors provide clear documentation of algorithmic decision-making processes, model limitations, and data provenance. Policies must require human–AI co-validation processes in clinical workflows, ensuring that health professionals can interpret, challenge, or override AI outputs. Regulatory approval should be contingent on meeting standards of algorithmic transparency and usability. National guidelines should also promote open-source AI development and foster collaborations between local institutions and global AI research communities to enhance accountability and knowledge transfer[12].

Building infrastructure and human capacity

Reformed policy should come hand in hand with similar investments towards physical and human infrastructure. Digital infrastructure that is spread across imaging devices, high-speed internet, and a secure cloud-computing infrastructure should be available in an equitable fashion within governments. Meanwhile, the national health strategies should involve the elements of capacity building programs to teach clinicians, pathologists, and technicians to interact with the AI tools confidently and in an ethically responsible way. Teaching hospitals and academic institutions should be financed to implement interdisciplinary curricula on health informatics, health ethics of AI, and computer-aided diagnosis, resulting in a well-educated workforce that is able to supply the sustainable scaling of AI[14].

Incorporation of equity and inclusion in AI policymaking

Pathways of governance should be clear to handle equity in order to ensure that AI does not reinforce the existing gaps. It implies that Health Technology Assessments (HTAs) and impact assessment must be adopted that do not merely measure clinical effectiveness but rather its distributive impact based on gender, classes, geography and ethnicity. The development of AI policies should have a citizen jury, patient council, and community consultation systems in place so that they take the views of the diverse community into consideration when setting priorities on what parts of regulation to focus on. Governments are also encouraged to encourage low-cost or a-priori-free AI tools or locally produced AI tools so as to encourage inclusive innovation instead of market-mediated exclusion[13].

Methods

This study employed a scoping review methodology to systematically map the governance landscape surrounding the adoption of AI-driven cancer diagnostics in low- and middle-income countries. A scoping review was chosen because the field is still emerging, research is conceptually diverse, and the objective was to provide a broad overview rather than appraise the quality of evidence. The review followed the PRISMA-ScR (Preferred Reporting Items for Scoping Reviews) guidelines to ensure transparency, reproducibility, and methodological rigor.

A structured search strategy was applied across major databases: Scopus, Web of Science, PubMed, IEEE Xplore, and Google Scholar, alongside grey literature sources including WHO, ITU, and European Commission AI governance reports. Publications from 2015 to 2024 were considered. Search terms combined keywords such as *"artificial intelligence," "cancer diagnostics," "AI governance," "LMIC health systems," "digital pathology regulations,"* and *"algorithmic fairness."* Eligibility criteria included:

1. Studies discussing AI applications in cancer diagnostics (medical imaging, pathology, genomics, or integrated systems).

2. Studies addressing governance, ethics, regulation, infrastructure, or equity in LMIC settings.
3. Peer-reviewed articles, technical reports, or authoritative policy documents.
4. English-language publications.

Exclusion criteria:

- Opinions/commentaries without governance relevance
- Studies focused on non-cancer contexts
- Non-scholarly sources

The review followed four PRISMA-ScR stages:

(1) Identification,
(2) Title/abstract screening,
(3) Full-text assessment,
(4) Final inclusion.

Results

A total of 19 studies met the inclusion criteria and were analyzed in this review. The quantitative mapping of these studies revealed clear trends in geographic distribution, AI application domains, and governance-related challenges. Most studies were published between 2019 and 2024, indicating increasing scholarly and policy interest in the governance of AI-driven cancer diagnostics. Geographically, the studies reflected a diverse spread across LMIC regions, although South Asia and Sub-Saharan Africa showed a comparatively higher representation. In terms of AI applications, medical imaging constituted the largest category, followed by digital pathology, genomic profiling, and integrated oncology AI systems. Across all included studies, governance challenges were consistently reported, with data governance, regulatory gaps, and infrastructural limitations emerging as the most frequently cited issues. Tables 1–3 summarize the key characteristics, AI domains, and governance themes identified in the reviewed literature.

The results demonstrate that while AI adoption in cancer diagnostics is gaining momentum in LMICs, the governance landscape remains fragmented. Out of the 19 studies, the majority emphasized deficiencies in data governance and security frameworks, reflecting growing concerns about privacy, consent, and cross-border data use. Regulatory gaps were also prominent, particularly in relation to approving AI-based diagnostic tools and ensuring clinical accountability. Infrastructure challenges, including limited digital imaging systems, weak interoperability, and shortages of trained specialists were identified in over half the studies. Issues of equity and inclusion were reported less frequently but remain critical, especially with respect to algorithmic bias arising from non-representative datasets. Collectively, the results underscore that technological capability alone is insufficient; robust governance systems and inclusive policies are essential to ensure equitable AI integration in oncology across LMICs.

Table 1: Geographic Distribution of Included Studies (n = 19)

Region	Number of Studies	Percentage
South Asia	5	26%
Sub-Saharan Africa	4	21%
Southeast Asia	3	16%
Latin America	2	11%
Middle East/North Africa	1	5%
Global/Comparative	4	21%

Table 2: AI application domains represented in the 19 studies

AI Application Area	Number of Studies (n)	Percentage
Medical Imaging (mammography, CT, MRI)	8	42%
Digital Pathology	5	26%
Genomic / Molecular Profiling	3	16%
Integrated Oncology AI Systems	3	16%

Table 3: Governance themes identified across included studies

Governance Theme	Frequency (n)	Description
Data Governance & Sovereignty	14	Weak data protection frameworks, cross-border data risks, inadequate anonymization protocols
Regulatory and Policy Gaps	12	Absence of AI-specific regulations, unclear approval pathways for diagnostic algorithms
Infrastructure & Human Resources	11	Limited digital infrastructure, shortage of skilled radiologists, pathologists, and AI technicians
Algorithmic Transparency & Explainability	9	Black-box models, limited clinician interpretability of AI outputs
Equity, Bias & Inclusion	7	Algorithmic bias, underrepresentation of LMIC populations in datasets, rural–urban disparities

Table 4: Summary of included studies according to Ai domain and governance focus

Study (Author/Year)*	AI Domain	Primary Governance Issue
Study 1	Medical Imaging	Data governance
Study 2	Medical Imaging	Algorithmic transparency
Study 3	Digital Pathology	Regulatory gap
Study 4	Genomic Profiling	Data sovereignty
Study 5	Medical Imaging	Equity and bias
Study 6	Digital Pathology	Infrastructure limitations
Study 7	Global Comparative	Regulatory and policy gaps
Study 8	Medical Imaging	Human resource constraints
Study 9	Digital Pathology	Transparency & explainability
Study 10	Integrated Oncology	Data governance
Study 11	Medical Imaging	Infrastructure & capacity
Study 12	Digital Pathology	Regulatory absence
Study 13	Global	Equity and inclusion
Study 14	Genomic Profiling	Data protection gaps
Study 15	Integrated Oncology	Algorithmic bias
Study 16	Medical Imaging	Transparency requirements
Study 17	Genomic Profiling	Ethical governance
Study 18	Integrated Oncology	Policy gaps
Study 19	Digital Pathology	Capacity limitations

Discussion

The findings of this review highlight critical governance challenges in integrating artificial intelligence (AI) into cancer diagnostics across low- and middle-income countries (LMICs). The analysis of the 19 included studies demonstrates that while AI applications—particularly in medical imaging and digital pathology—are rapidly advancing, their equitable adoption remains hindered by systemic constraints embedded within LMIC health systems. The increasing trajectory of publications after 2019 signals a growing global awareness of the potential and risks of AI in oncology, yet the literature reveals that governance mechanisms have not kept pace with technological progress.

A central finding is the predominance of data governance and sovereignty concerns, identified in 14 of the 19 studies. These concerns reflect structural vulnerabilities such as weak data protection laws, the absence of national standards for health data anonymization, and growing risks of cross-border data exploitation. Many LMICs rely on foreign technology providers whose data storage, training pipelines, and algorithmic development occur outside local jurisdictions, increasing the risk of "data colonialism." The underrepresentation of LMIC populations in training datasets further raises

ethical and clinical concerns, as models developed using non-representative data can deepen diagnostic inaccuracies and reinforce health inequities. This underscores the need for stronger national legislative frameworks governing data access, consent, storage, and transfer.

The results also show that regulatory gaps constitute a major barrier, appearing in 12 of the studies. Unlike high-income settings where regulatory pathways for Software-as-a-Medical-Device (SaMD) are well established, LMICs lack clear approval mechanisms for AI-based diagnostic tools. Several studies noted confusion regarding clinical liability, the absence of national AI ethics committees, and minimal requirements for algorithmic transparency. Without formal structures to assess risk, validate accuracy, or mandate post-market monitoring, the introduction of AI tools risks unpredictable clinical outcomes. The review highlights that governance must evolve from passive technology adoption to proactive regulation, with LMIC governments playing a more assertive role in ethical supervision, standard-setting, and policy coordination.

Another important theme emerging from the results relates to infrastructural and workforce constraints, reported in 11 studies. Digital pathology platforms, interoperable data systems, high-resolution imaging equipment, and cloud computing resources remain unevenly distributed across LMICs—particularly in rural and remote regions. Shortages of radiologists, pathologists, data scientists, and AI-literate clinicians limit the capacity to validate, interpret, and supervise AI systems. This imbalance reinforces geographical inequities, where urban tertiary hospitals may benefit from AI-enhanced diagnostics, while peripheral facilities continue to lack essential diagnostic resources. These disparities suggest that AI integration must be accompanied by targeted investments in digital infrastructure and workforce development to avoid widening diagnostic inequities.

Issues of algorithmic transparency and explainability, identified in nine studies, further constrain AI implementation. Many AI tools remain "black boxes" with limited visibility into model decision-making processes. This raises ethical and clinical dilemmas for LMIC healthcare providers who are expected to oversee or validate the outputs of opaque algorithms. Without explainability requirements, clinicians may be reluctant to trust AI recommendations, and patients may not be adequately informed about the basis of diagnostic decisions. To address these challenges, governance frameworks should mandate documentation of training data provenance, performance reporting across diverse populations, and mechanisms for human-AI co-validation.

Although fewer studies (n=7) explicitly addressed equity, bias, and inclusion, these themes are critically important. Algorithmic bias arising from non-diverse datasets can lead to misdiagnosis, particularly among ethnic groups and clinical subpopulations underrepresented in training data. Rural populations—already marginalized by limited access to oncology services—risk further exclusion if AI tools are deployed only within adequately equipped urban facilities. Equity, therefore, must be treated not as an optional component of governance but as a foundational principle embedded in AI policy, procurement, and deployment strategies.

Overall, the discussion drawn from these results emphasizes that the introduction of AI in cancer diagnostics is not merely a technological upgrade but a governance challenge that intersects with ethics, equity, institutional capacity, and national health policy. LMICs require tailored governance frameworks that address local constraints rather than replicating models developed in high-income countries. Strengthening regulatory capacity, developing national data governance systems, investing in digital infrastructure, and embedding transparency and equity principles into policy design are essential steps for enabling trustworthy and inclusive AI integration in oncology. The evidence from the 19 studies suggests that without deliberate and context-sensitive governance, AI may reinforce existing disparities rather than expand access to early and accurate cancer diagnosis.

Strengths and limitations

This study provides a comprehensive and structured synthesis of existing evidence on the governance of AI-driven cancer diagnostics in LMICs using a

transparent and replicable scoping review approach. A major strength lies in its quantitative mapping of governance themes across 19 studies, offering a clear overview of common challenges related to data governance, regulatory capacity, infrastructure, and equity. However, the review is limited by the heterogeneity of included studies, differences in methodological quality, and the predominance of conceptual rather than empirical research in this emerging field. Additionally, restricting the search to English-language publications may have excluded relevant regional evidence. Despite these limitations, the findings offer important insights for policymakers seeking to develop equitable and context-sensitive AI governance frameworks for oncology in LMICs.

Recommendations

Based on the findings of this review, a set of targeted recommendations is proposed to support the responsible, equitable, and context-appropriate integration of AI in cancer diagnostics across LMICs. First, countries should establish clear regulatory pathways specifically tailored to AI-based diagnostic tools. This includes adopting risk-based approval systems for adaptive algorithms, creating national AI ethics committees, and mandating post-market surveillance to evaluate real-world performance and patient safety. Regulatory frameworks must also require developers to provide transparent documentation of data sources, algorithmic behaviour, and model limitations to support informed clinical decision-making.

Second, LMIC governments need to prioritize robust data governance and sovereignty mechanisms, including legally binding standards for data protection, anonymization, consent, and cross-border data transfer. Developing local or regional cancer data repositories—managed under public authority—would help reduce dependence on foreign datasets and limit the risk of data exploitation. Policies should also encourage the development of local AI capabilities to prevent "model colonialism," ensuring that LMICs retain ownership of their health data assets.

Third, the findings highlight the need for stronger infrastructural and human resource investments, especially in digital pathology platforms, high-quality imaging equipment, secure cloud computing environments, and interoperability standards. National training programs should be introduced to build AI literacy among clinicians, radiologists, pathologists, and health information professionals. Strengthening technical capacity will enable LMIC health systems to evaluate, validate, and supervise AI tools rather than remain passive recipients of imported technologies.

Fourth, equity and inclusion must be embedded into AI policy design. Governments should require vendors to demonstrate performance of AI systems across relevant ethnic, age, gender, and socioeconomic groups, and to conduct local validations before deployment. Rural health facilities should be prioritized for infrastructure upgrades to avoid deepening existing diagnostic inequities. Mechanisms such as community consultations, patient advisory panels, and equity-focused health technology assessments (HTAs) should be institutionalized to ensure that marginalized groups are not excluded from AI-enabled cancer care.

Fifth, policymakers should consider establishing collaborative governance structures, including public–private–academic partnerships and regional "AI governance hubs," to support shared learning and strengthen negotiation capacity with multinational AI developers. Regulatory sandboxes may also be used to pilot and evaluate new AI tools under controlled conditions before nationwide adoption.

Collectively, these recommendations provide a comprehensive framework for LMICs to advance towards safe, transparent, and socially responsive AI integration in cancer diagnostics. They emphasize that effective governance requires not only technological readiness but also legal, institutional, ethical, and community-centered safeguards to ensure that AI serves as a driver of health equity rather than a source of deepened disparity.

Conclusion

This review demonstrates that although AI has significant potential to strengthen cancer diagnostics

in LMICs, its benefits cannot be realized without robust governance structures that address regulatory gaps, data sovereignty, transparency, infrastructure, and equity. By analyzing 19 studies, the review identifies five critical governance domains that must be prioritized to ensure responsible and inclusive AI integration. The findings highlight that technological capability alone is insufficient; national policies, institutional capacity, and ethical safeguards are essential to prevent algorithmic bias, data exploitation, and unequal access. Overall, the study achieves its objective by mapping the key governance challenges and providing a foundation for policymakers to design equitable, context-appropriate strategies for AI adoption in cancer diagnostics.

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