



Artificial intelligence in laboratory medicine

*Leveraging laboratory expertise
to improve patient care*



| Executive summary

Artificial intelligence (AI) is evolving rapidly, and new applications are being integrated into healthcare delivery, influencing diagnostic testing, clinical decision support, workflow automation, population health management, and personalized medicine. As AI systems increasingly contribute to clinical decision-making, policymakers, regulators, healthcare organizations, and technology developers face challenges related to validation, transparency, accountability, interoperability, patient safety, and equitable performance. Although substantial attention has focused on the development of AI algorithms, comparatively less attention has been devoted to ensuring that these systems perform safely and effectively in real-world clinical practice.

Clinical laboratories occupy a unique position within the healthcare ecosystem and are well-suited to help address these challenges. Laboratory medicine already operates within mature quality-management and regulatory frameworks that emphasize validation, quality assurance, continuous monitoring, proficiency testing, documentation, and accountability. Laboratory professionals routinely oversee complex diagnostic systems, manage large volumes of clinical data, evaluate analytical performance, and provide consultation regarding the appropriate interpretation and use of diagnostic information. These responsibilities closely parallel the governance requirements of clinical AI systems.

Despite this alignment, many healthcare AI tools are currently implemented through fragmented operational models that exist outside established laboratory governance structures. AI applications are frequently deployed as laboratory- or locally developed solutions managed through research, information technology, or vendor-controlled environments rather than through coordinated clinical quality systems. Furthermore,

variation in the underlying data, often stemming from non-standardized or non-harmonized laboratory data, can affect the performance and generalizability of AI systems, underscoring the need for ongoing oversight by laboratory professionals with expertise in laboratory data-generation processes. Harmonization of laboratory data is therefore a prerequisite for trustworthy, scalable, and interoperable clinical AI, enabling models to perform more consistently across institutions, patient populations, and testing platforms.

Clinical laboratories should serve as foundational governance and operational partners in implementing healthcare AI. Rather than creating entirely new oversight paradigms, policymakers should build upon proven frameworks already used to ensure the quality and safety of diagnostic testing.

To support the responsible adoption of AI in healthcare, this brief recommends investment and support of translational research to establish a solid evidence base, developing risk-based regulatory standards for clinical AI, establishing independent validation and post-deployment monitoring requirements, expanding laboratory data interoperability standards, creating external quality-assessment programs, developing sustainable reimbursement models, and investing in workforce development.

The future success of healthcare AI will depend not only on advances in computational methods, but also on the development of trustworthy systems capable of delivering safe, effective, equitable, and clinically meaningful outcomes. Clinical laboratories possess many of the operational, regulatory, and scientific capabilities necessary to support these goals and should play a central role in shaping the future governance of healthcare AI.

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Why AI in healthcare requires policy attention

AI has moved rapidly from a topic of academic research towards deployment in healthcare delivery. AI systems are now being used to support a broad range of activities, including diagnostic interpretation, clinical decision support, utilization management, workflow automation, population health analytics, and operational planning. Regulatory agencies have authorized hundreds of AI-enabled medical devices and software systems for clinical use, and healthcare organizations are investing heavily in technologies designed to improve efficiency, enhance diagnostic accuracy, and support more personalized care.

Several factors have accelerated the adoption of AI within healthcare. First, with the adoption of electronic health records (EHRs), modern healthcare systems generate enormous volumes of digital data, including laboratory data, medical imaging reports, pathology reports, genomic data, physiologic monitoring data, and clinical documentation. At the same time, healthcare organizations face growing pressures related to workforce shortages, rising costs, increasing complexity of care, and expanding expectations for quality and safety. AI offers the potential to help address these challenges by identifying patterns within complex datasets, automating repetitive tasks, and generating insights that support clinical decision-making.

AI raises patient safety questions

Unlike many previous healthcare technologies, AI systems increasingly influence how clinical information is interpreted and how decisions are made and will shape the quality of patient care. Consequently, questions regarding reliability, transparency, fairness, and accountability of AI systems become matters of patient safety rather than simply technical performance.

The growing use of AI has also highlighted important limitations of existing regulatory and operational frameworks. Traditional medical devices and software systems are often evaluated at a single point in time and expected to perform

consistently thereafter. AI systems present unique challenges because their performance may depend heavily on the data used for development, validation, and deployment. Models developed in one institution may not perform similarly in another. Changes in patient populations, clinical practices, laboratory methods, or disease prevalence may affect performance over time. In addition, many AI systems operate using complex computational approaches that can make independent evaluation and interpretation difficult for end users.

Accountability for AI remains unclear

Healthcare organizations increasingly face questions regarding who should be responsible for validating AI systems, monitoring performance after deployment, investigating failures, detecting unintended bias, and determining when an AI system should be modified or removed from clinical use. These challenges extend beyond traditional information technology functions and require expertise in clinical operations, diagnostic testing and interpretation, quality management, regulatory compliance, and patient safety.

Current implementation models often struggle to address these issues. Many AI applications are introduced as isolated solutions focused on specific use cases rather than as components of an integrated clinical governance framework. Responsibility for implementation may be distributed across clinical departments, information technology groups, research teams, vendors, or administrative offices, creating uncertainty regarding accountability and oversight. As a result, healthcare organizations may possess sophisticated AI tools without having equally sophisticated systems for ensuring their safe and effective use.

The policy challenge, therefore, is not simply how to develop more advanced AI systems. Rather, it is about establishing governance structures that ensure AI technologies remain safe, effective, equitable, and trustworthy throughout their lifecycle.

A male doctor with a beard and dark hair, wearing a white lab coat over a light blue shirt, is focused on a computer monitor. He is standing in a modern hospital or clinic environment with large windows in the background. Another person in a white coat is visible in the background, slightly out of focus. The doctor's lab coat has a name tag that reads "HOSPITAL BAHAMAS" and "DR. JAY BISHOP".

AI depends not only on better algorithms, but on the clinical expertise needed to ensure they improve patient care.

Why laboratory medicine is central to healthcare AI

The successful implementation of healthcare AI depends fundamentally on the quality, reliability, and interpretation of clinical data. While discussions surrounding AI often focus on algorithms and computational methods, the performance of AI systems is constrained by the quality of the data on which they are developed, validated, and deployed. Few areas of healthcare possess more experience managing complex clinical data than laboratory medicine.

Clinical laboratories generate a substantial proportion of the structured data used in healthcare decision-making. Laboratory testing informs diagnosis, disease monitoring, therapeutic management, population health initiatives, and clinical research across nearly every medical specialty. As healthcare increasingly adopts data-driven approaches to care, laboratory data serves as a foundational component of many existing and emerging AI systems. Consequently, laboratory medicine has a direct stake in ensuring that these systems are developed and implemented responsibly.

A built-in quality culture

Beyond their role as data generators, laboratories also function as stewards of diagnostic quality. Laboratory professionals

are responsible for ensuring that diagnostic information is accurate, reliable, reproducible, and clinically meaningful. This responsibility extends far beyond the technical performance of an assay. Laboratory oversight encompasses specimen collection and handling, analytical validation, quality control, quality assurance, result reporting, clinical interpretation, and continuous performance monitoring. These same principles are increasingly relevant to the governance of clinical AI systems.

A distinguishing feature of laboratory medicine is its long-standing culture of validation and quality management. Before a diagnostic test can be implemented in clinical practice, laboratories are required to establish its intended use, evaluate analytical and clinical performance characteristics, document limitations, and develop



procedures for ongoing quality monitoring. Performance is continually assessed through internal quality-control processes, proficiency testing, and external quality-assessment programs. Importantly, laboratories recognize that validation is not a one-time event but rather a continuous process of monitoring and improvement throughout the lifecycle of a diagnostic system.

These established practices offer valuable lessons for healthcare AI. Like diagnostic tests, AI systems should be evaluated within the clinical environments in which they will be used. Performance characteristics should be clearly defined and verified, limitations should be understood, and ongoing monitoring should be conducted to ensure that performance remains acceptable over time. The laboratory profession has decades of experience managing these responsibilities and can provide a practical framework for AI governance.

Managing data variability

Laboratory professionals also possess expertise that is particularly relevant to one of the most significant challenges facing healthcare AI: data variability. Laboratory data are influenced by numerous factors, including specimen quality, collection methods, analytical platforms, reference intervals, reporting conventions, and clinical context. Minor differences in testing methods or workflows can have meaningful effects on the interpretation of results. Laboratory professionals routinely manage these sources of variation and understand the challenges associated with harmonizing data across institutions, patient populations, and testing platforms. This expertise is increasingly important as AI systems are deployed across diverse healthcare environments.

The need for such expertise becomes especially apparent when considering model generalizability. Many AI systems are developed using data derived from a limited number of institutions or patient populations. Models

that perform well in one setting may perform differently elsewhere due to differences in disease prevalence, demographics, clinical workflows, or laboratory methods. Understanding and mitigating these challenges requires knowledge of both the data and the clinical processes that generate them. Laboratory medicine occupies a unique position at the intersection of these domains.

Regulatory systems can be adapted

Laboratories also possess extensive experience operating within regulated healthcare environments. Under frameworks such as the Clinical Laboratory Improvement Amendments (CLIA), laboratories maintain formal systems for documentation, quality assurance, personnel competency assessment, incident investigation, corrective action, and regulatory compliance. These systems provide organizational infrastructure that can be adapted to support the implementation and oversight of healthcare AI.

Rather than creating entirely new governance models, healthcare organizations may benefit from leveraging existing quality-management principles that have proven effective in laboratory medicine for decades.

Clinical interpretation, not just data production

Importantly, laboratory professionals routinely serve as consultants who help clinicians understand the strengths, limitations, and appropriate use of diagnostic information. The value of laboratory medicine lies not only in generating results but also in supporting their interpretation and application in patient care. A similar need exists for AI systems. Clinicians, patients, administrators, and policymakers increasingly require guidance regarding the capabilities and limitations of AI technologies, appropriate use cases, and potential sources of error. Laboratory professionals are well-positioned to contribute to these discussions because they are accustomed to translating technical performance characteristics into clinically meaningful information.

Taken together, these capabilities suggest that laboratory medicine should be viewed not simply as another stakeholder affected by AI adoption, but as a critical source of governance expertise for healthcare AI. As healthcare organizations seek scalable approaches to AI oversight, laboratory medicine offers both practical experience and operational infrastructure to bridge the gap between technological innovation and safe clinical implementation.

Many AI systems are developed using data derived from a limited number of institutions or patient populations. Models that perform well in one setting may perform differently elsewhere.

Current gaps and challenges in healthcare AI

Despite remarkable advances in AI, the healthcare system has not yet developed a consistent framework for ensuring that AI technologies are deployed, monitored, and maintained in a safe and effective manner. While many organizations have focused significant effort on developing new AI capabilities, comparatively less attention has been devoted to the governance structures necessary to support their long-term use in clinical practice. As a result, healthcare organizations increasingly find themselves implementing powerful technologies within operational environments that were not designed to manage them.

One of the most significant challenges is the fragmented manner in which AI is currently deployed. Many healthcare AI systems are implemented as isolated solutions designed to address a specific clinical or operational problem. Responsibility for these systems may reside within information technology departments, research groups, administrative offices, individual clinical departments, or external vendors. While such approaches may accelerate adoption, they can create uncertainty regarding ownership, oversight, and accountability. In many organizations, no single governance framework exists to ensure consistent standards for validation, monitoring, documentation, performance review, and incident management across AI applications. As the number and complexity of AI systems continue to grow, this fragmentation may become increasingly difficult to manage.

Healthcare organizations must also address concerns regarding fairness and equity. Because AI systems learn from historical data, they may inadvertently perpetuate or amplify existing disparities in healthcare delivery.

Model drift and generalizability

The challenge of generalizability is further complicated by the dynamic nature of healthcare. Patient populations evolve, clinical practices change, diagnostic technologies improve, and new diseases emerge. As these changes occur, the performance of AI systems may degrade over time, a phenomenon commonly referred to as model drift.

Unlike traditional medical devices that may remain stable throughout their lifecycle, AI systems often require continuous monitoring and periodic reassessment to ensure that performance remains acceptable. Many healthcare organizations currently lack the infrastructure necessary to conduct this level of ongoing evaluation.

Transparency and accountability gaps

Transparency and accountability represent additional areas of concern. Many contemporary AI systems utilize complex computational methods that may be difficult for clinicians, patients, and administrators to fully understand. Although these systems may demonstrate strong performance characteristics, limited transparency can make it challenging to independently evaluate their behavior, identify sources of error, or understand why specific recommendations are generated. This issue is particularly important in healthcare, where clinical decisions may have significant consequences for patient outcomes.

The increasing reliance on proprietary AI systems introduces additional challenges related to transparency and independent oversight.

Healthcare organizations may have limited access to information regarding training datasets, model development methods, performance limitations, or ongoing modifications to deployed systems. Without sufficient transparency, independent validation becomes more difficult and confidence in AI-generated recommendations may be diminished. Policymakers, regulators, and healthcare organizations continue to grapple with questions regarding the appropriate balance between intellectual property protections and the need for independent evaluation of technologies that influence patient care.

Closely related to transparency is the issue of accountability. As AI systems become more deeply integrated into healthcare delivery, questions arise regarding responsibility for validation, oversight, monitoring, and management of adverse events. Determining accountability may be particularly challenging when decisions involve interactions among clinicians, healthcare organizations, software vendors, and AI systems. Clear governance structures and defined oversight responsibilities will be essential to ensuring that AI technologies are implemented and maintained responsibly.

Fairness and bias

Healthcare organizations must also address concerns regarding fairness and equity. Because AI systems learn from historical data, they may inadvertently perpetuate or amplify existing disparities in healthcare delivery. Differences in

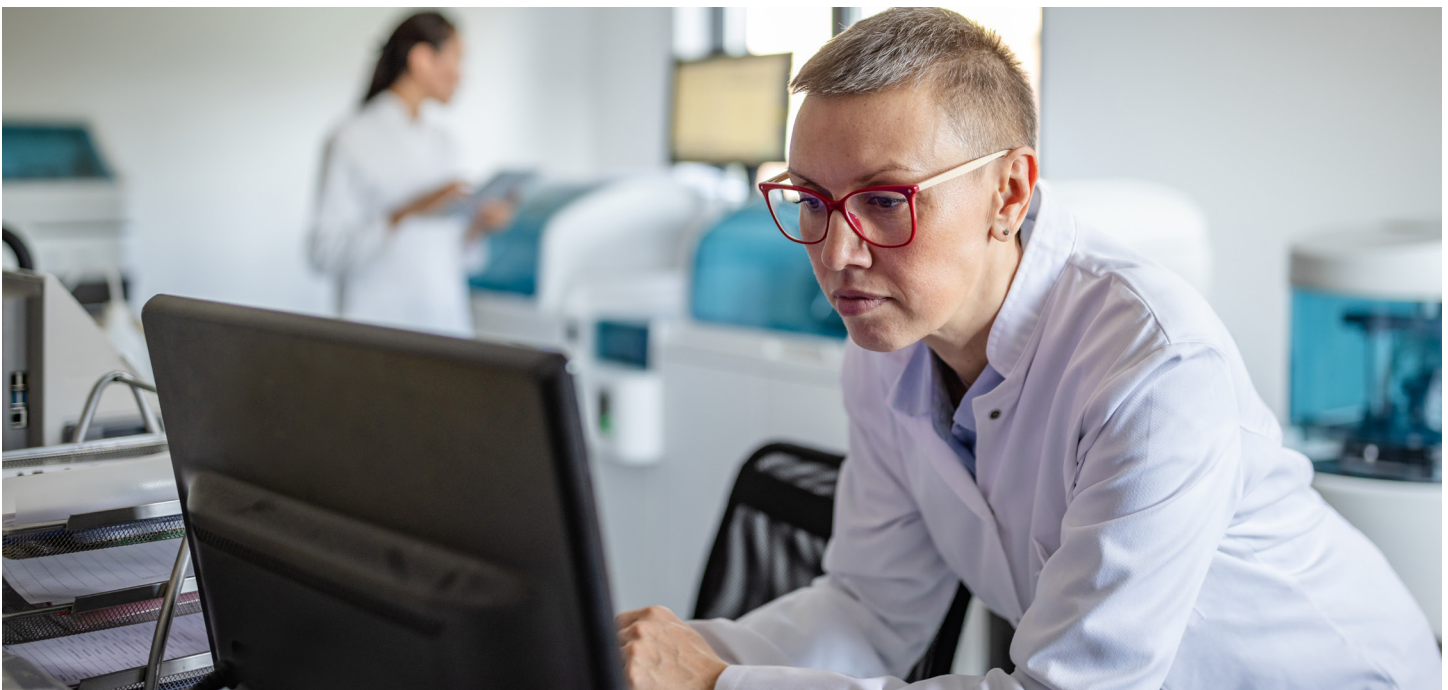
access to care, diagnostic testing, treatment, and health outcomes may become embedded within training datasets and subsequently influence model behavior.

Ensuring equitable performance requires ongoing evaluation across diverse patient populations and careful attention to potential sources of bias throughout the development and deployment process.

Operational and workforce barriers

Finally, operational and workforce challenges may limit the successful adoption of healthcare AI. Implementing AI systems often requires substantial investments in infrastructure, data management, workflow redesign, personnel training, and ongoing maintenance. Healthcare organizations must develop new competencies related to AI evaluation, governance, and monitoring while balancing competing operational priorities. At the same time, the introduction of AI may alter traditional professional roles and responsibilities, requiring clinicians, laboratorians, and healthcare administrators to acquire new skills and adapt to evolving workflows.

Addressing these challenges will require coordinated efforts among policymakers, regulators, healthcare organizations, technology developers, and clinical professionals, including laboratory medicine specialists whose expertise in quality management and diagnostic oversight offers important guidance for the future governance of healthcare AI.



A governance framework for clinical AI

The rapid adoption of AI within healthcare has created an urgent need for governance frameworks capable of ensuring that AI systems remain safe, effective, equitable, and clinically meaningful throughout their lifecycle. While healthcare organizations have accumulated considerable experience evaluating new diagnostic tests, therapies, and medical devices, many institutions are still developing processes for the implementation and oversight of AI technologies. Rather than creating entirely new governance paradigms, healthcare organizations should apply principles that have long been used to manage other high-impact clinical technologies.



Clinical laboratory medicine provides one such model. For decades, laboratories have operated within quality-management frameworks that emphasize validation, quality assurance, continuous monitoring, documentation, accountability, and ongoing performance improvement. Although AI systems differ from traditional diagnostic tests in important ways, many of the governance challenges are remarkably similar. Both involve the generation of information that may influence patient care, both require evaluation of performance and limitations, and both demand ongoing oversight to ensure that performance remains acceptable over time.

Define intended use first

A governance framework for healthcare AI should begin with a clearly defined intended use.

Before implementation, organizations should establish the clinical purpose of an AI system, the patient populations for which it is intended, the decisions it is expected to support, and the environments in which it will operate.

Defining intended use is essential because performance cannot be meaningfully evaluated without understanding the specific clinical context in which a system will be used. A model designed to support population health management may require a different level of scrutiny than a model that directly influences diagnosis or treatment decisions.

Once intended use has been established, AI systems should undergo rigorous verification and validation before clinical deployment. Verification assesses whether a system performs according to its stated specifications, while

validation evaluates whether the system performs adequately for its intended clinical purpose. Both commercial and locally developed AI systems should be evaluated using representative patient populations and clinically relevant datasets. Performance assessments should extend beyond measures of technical accuracy to include considerations such as workflow impact, usability, robustness, and performance across diverse patient populations.

Monitoring across the lifecycle

Unlike many traditional healthcare technologies, AI systems often require ongoing evaluation after deployment. Changes in patient populations, clinical workflows, laboratory methods, healthcare utilization patterns, and disease prevalence may affect performance over time. Consequently, AI governance should incorporate mechanisms for continuous monitoring and post-deployment surveillance. Healthcare organizations should establish processes to detect performance degradation, model drift, unintended bias, and unexpected operational consequences. Monitoring should be viewed as a continuous quality-improvement activity rather than a one-time compliance requirement.

Risk-based oversight should serve as a foundational principle of healthcare AI governance. Not all AI systems present the same potential for patient harm. Administrative systems that support scheduling or resource allocation may require limited oversight, whereas systems that influence diagnosis, treatment selection, or patient triage may warrant greater scrutiny. Governance requirements should be proportional to the level of clinical risk associated with a particular application. This approach allows organizations to focus oversight resources where they are most needed while continuing to support innovation and operational efficiency.

Independent evaluation should also play a significant role in AI governance. Clinical

laboratories have long relied upon external quality-assessment and proficiency-testing programs to provide objective evaluation of diagnostic performance. Similar mechanisms may prove valuable for healthcare AI. Independent benchmarking, external validation datasets, and standardized performance assessments could help establish confidence in AI systems while promoting consistency across healthcare organizations. Such programs may also facilitate the identification of common sources of failure and support broader quality-improvement efforts.

Preserve human accountability

Human oversight remains a critical requirement regardless of advances in AI capability. Healthcare organizations should establish clear lines of accountability for AI implementation, monitoring, and incident response. Responsibilities should be explicitly assigned to qualified individuals or governance committees with appropriate clinical, technical, operational, and regulatory expertise. Human oversight is particularly important when AI systems are used to support high-consequence clinical decisions, where contextual judgment and clinical expertise remain essential.

Finally, effective AI governance requires multidisciplinary collaboration. Successful implementation depends upon contributions from clinicians, laboratorians, data scientists, informaticians, quality specialists, ethicists, administrators, regulators, and patients. No single discipline possesses the expertise necessary to govern complex AI systems. However, laboratory medicine offers a particularly valuable perspective because it combines experience in diagnostic validation, quality management, regulatory oversight, and clinical consultation within a single operational framework.

The objective of healthcare AI governance should not be to slow innovation, but to ensure that innovation translates into meaningful improvements in patient care. By adapting proven quality-management principles and establishing clear expectations for validation, monitoring, transparency, accountability, and continuous improvement, healthcare organizations can create governance structures that support both innovation and patient safety. Such an approach provides a practical pathway toward trustworthy AI and establishes the foundation upon which future advances in healthcare AI can responsibly be built.

Laboratory medicine offers a particularly valuable perspective because it combines experience in diagnostic validation, quality management, regulatory oversight, and clinical consultation within a single operational framework.

Infrastructure and interoperability: Moving beyond isolated AI solutions

Much of the public discussion surrounding healthcare AI focuses on individual algorithms and their performance characteristics. However, the long-term success of healthcare AI will depend not only on the quality of individual models, but also on the infrastructure that supports their deployment, integration, monitoring, and governance. Even highly accurate AI systems provide limited value if they cannot be effectively incorporated into clinical workflows or if they create additional operational complexity for healthcare organizations.

The problem with point solutions

At present, many AI systems are implemented as isolated point solutions designed to address a specific clinical or operational problem. These systems may be deployed through vendor-managed platforms, research environments, or departmental initiatives that operate independently from broader healthcare infrastructure. While this approach may accelerate initial adoption, it often creates challenges related to interoperability, governance, scalability, and sustainability.

The limitations of this fragmented approach become increasingly apparent as healthcare organizations deploy larger numbers of AI systems. Independent applications may require separate data pipelines, monitoring processes, governance structures, and user interfaces. This increases operational complexity, creates inefficiencies, and may contribute to inconsistent oversight across different AI-enabled workflows. Over time, the cumulative burden of managing disconnected systems can diminish many of the efficiency gains that AI is intended to provide.

Prioritize workflow integrations

For these reasons, healthcare organizations should prioritize workflow integration over isolated AI deployment. The greatest value of AI is likely to

emerge when these technologies are embedded within existing clinical and operational processes rather than functioning as stand-alone tools. AI should be viewed as part of a broader healthcare information ecosystem that includes EHRs, laboratory information systems (LIS), radiology information systems, digital pathology platforms, enterprise analytics environments, and population health management tools.

Within laboratory medicine, workflow integration is particularly important because laboratory testing is inherently connected to a larger diagnostic process. The value of laboratory data depends not only on analytical performance but also on appropriate test selection, specimen collection, result interpretation, clinical follow-up, and communication among healthcare professionals. AI systems that operate within these workflows can support decision-making across the entire testing lifecycle, whereas isolated tools may only address a narrow segment of the process.

Data exchange standards alone are insufficient; trustworthy AI also requires harmonized laboratory results that are clinically and analytically comparable.

An integrated approach also supports more effective governance. Centralized platforms can provide standardized mechanisms for validation, auditing, monitoring, version control, performance assessment, and incident management. Organizations can establish common governance frameworks that apply across multiple systems. This approach promotes consistency, improves accountability, and facilitates continuous quality improvement.



Interoperability is foundational

Interoperability is a critical prerequisite for this vision. Effective AI systems depend upon access to diverse sources of clinical information. The ability to securely exchange, integrate, and interpret information across these domains is essential for maximizing the clinical value of AI. The importance of interoperability is likely to increase as healthcare adopts multimodal AI systems capable of integrating multiple forms of data into a unified analytical framework. Future systems may combine structured laboratory results, semi-structured operational data, unstructured clinical documentation, digital pathology images, radiologic studies, and genomic information to generate more comprehensive assessments than would be possible using any individual data source alone. Such systems have the potential to improve diagnostic accuracy, risk prediction, and clinical decision support, but their success will depend heavily on the quality and accessibility of underlying data infrastructure.

Laboratory medicine is particularly well positioned to contribute to these efforts because laboratories already operate at the intersection of numerous healthcare information systems. Laboratory professionals routinely manage data flows between instruments, middleware platforms, EHRs, LIS, public health reporting systems, and enterprise data warehouses. This experience provides valuable insight into the practical challenges of data integration, standardization, quality assurance, and

interoperability that increasingly influence AI performance.

Data exchange standards alone are insufficient; effective AI also requires harmonized laboratory results that are clinically and analytically comparable. Policies that support laboratory test harmonization, reference systems, common units, method metadata, and consistent reference-interval practices will make laboratory data more usable for model development, validation, monitoring, and cross-site deployment.

Healthcare policy should therefore support the development of interoperable infrastructure that enables secure and effective integration of AI into clinical workflows. Investment in data standards, interoperability frameworks, enterprise governance platforms, and scalable quality-management processes may prove as important as investment in AI development itself.

AI as healthcare infrastructure

Viewed through this lens, AI should not be understood as a collection of isolated technologies but as a new layer of healthcare infrastructure. Building that infrastructure will require coordinated efforts among healthcare organizations, technology developers, regulators, policymakers, and clinical professionals. By emphasizing workflow integration, interoperability, and centralized governance, healthcare systems can create an environment in which AI technologies are more scalable, more reliable, and more beneficial to patients.

Payment and economic considerations

Sustainable economic models supportive of responsible implementation will speed the successful adoption of healthcare AI. Healthcare organizations are unlikely to invest if payment systems fail to recognize the value of healthcare AI. Reimbursement should be viewed not merely as a payment mechanism for technology, but as a tool for shaping and promoting responsible AI adoption.

AI and reimbursement are particularly complex because AI's value differs from traditional healthcare technologies. Historically, payment systems were designed to reimburse tangible clinical services. AI systems, by contrast, frequently derive value through information synthesis, workflow optimization, risk prediction, decision support, and operational efficiency. These benefits may improve patient outcomes and reduce healthcare costs but are not easily captured within traditional fee-for-service models.

Diagnostic interpretation is undervalued

Laboratory medicine illustrates this challenge well. Payment is typically associated with individual assays, while the broader interpretive value derived from integrating laboratory information into clinical decision-making is less visible within reimbursement frameworks. Many emerging AI systems do not simply automate existing testing processes; rather, they enhance the clinical utility of diagnostic information. In these cases, the primary value may arise from interpretation and decision support rather than the performance of a specific test.

AI's economic value may therefore extend beyond traditional concepts of productivity. A well-designed AI system may improve diagnostic accuracy, reduce unnecessary testing, identify patients at risk for adverse outcomes, support earlier intervention, improve resource utilization, and/or reduce preventable harm. This can create substantial value for patients, healthcare organizations, and payers even when they do not directly correspond to a billable procedure or

service. Future reimbursement frameworks will need to account for these broader contributions to fully realize the benefits of AI.

Payment policy should recognize both the outputs of AI systems and the governance activities necessary to support their safe and effective use.

Evidence gaps limit reimbursement

The absence of robust evidence demonstrating clinical utility presents additional challenges for reimbursement. Payers and healthcare organizations are asked to evaluate AI technologies based on technical performance metrics, despite limited evidence regarding patient outcomes, healthcare utilization, or costs. Greater investment will be necessary to establish the evidence required for sustainable reimbursement and widespread adoption.

At the same time, responsible AI deployment requires significant investment to develop infrastructure for validation, quality assurance, monitoring, cybersecurity, governance, workforce training, and ongoing maintenance. Unlike traditional software systems that may require only periodic updates, many AI applications require continuous evaluation to detect performance drift, assess bias, and ensure clinical performance remains acceptable. These activities generate

real costs necessary to support patient safety and public trust. If reimbursement mechanisms recognize only the outputs of AI systems while ignoring the resources required to govern them, organizations may face incentives that favor rapid deployment over responsible implementation.

Payment should reward responsible use

Therefore, payment policies should encourage both innovation and accountability. Healthcare AI reimbursement models should support the governance activities necessary to ensure safe and effective use. Approaches that align reimbursement with quality, outcomes, and value-based care are well suited for AI-enabled healthcare due to emphasis on patient care rather than on technology adoption. Such models may discourage the proliferation of low-value AI applications.

The role of laboratory medicine within these discussions is especially important. Laboratories have extensive experience operating under reimbursement systems that balance innovation,

quality requirements, regulatory compliance, and cost constraints. As AI becomes increasingly integrated into diagnostic workflows, laboratory professionals can provide valuable insight into how reimbursement policies influence implementation decisions, operational priorities, and quality-management activities. Their experience may inform the development of payment models supportive of technological advancement and responsible oversight.

Economic incentives shape adoption

Reimbursement policy should not be viewed as a secondary consideration in the adoption of healthcare AI. Economic incentives strongly influence how technologies are developed, deployed, and maintained. Payment frameworks that recognize the value of clinically validated AI systems, support ongoing governance activities, and align incentives with patient outcomes will be essential to creating a sustainable foundation for healthcare AI.





Responsible AI implementation requires transparency. Clinicians should understand the intended use, performance characteristics, and limitations of AI systems that influence patient care.

Ethical, legal, and equity considerations

Successful adoption of healthcare AI depends on public trust, not just technical performance. Patients, clinicians, healthcare organizations, and regulators must have confidence that AI is used responsibly, perform fairly, and that appropriate safeguards exist. As AI systems are integrated into healthcare delivery, considerations of ethics, legality, and equity become essential.

Bias must be actively monitored

Bias and inequitable performance are widely discussed challenges. AI systems learn from historical data. Those data often reflect existing biases in healthcare access, utilization, diagnostic practices, and patient outcomes. Consequently, AI systems can perpetuate or amplify disparities existing within healthcare systems. A model may perform well for one patient population but differently for others. To address these concerns, healthcare organizations should evaluate AI performance variation across patient populations both before and after initial deployment. Proactive bias evaluation should become a standard for AI quality management, like other forms of performance surveillance.

Privacy and data stewardship are another critical concern. Healthcare AI often requires large volumes of clinical data for development, validation, and monitoring. These activities must occur within established legal and ethical frameworks governing patient information. Compliance remains essential, but healthcare organizations should also recognize that AI may introduce new data challenges concerning secondary use, aggregation, and potential individual reidentification.

Laboratory medicine provides insight because they have managed highly sensitive clinical information, while operating within rigorous regulatory and quality-management frameworks. The same principles of data integrity, security, traceability, and appropriate access controls that

guide responsible laboratory data stewardship, can help inform healthcare AI governance. As AI systems increasingly integrate information from multiple sources, robust data governance practices will be essential to maintaining public trust.

Informed use requires transparency

Responsible AI implementation requires transparency. Clinicians should understand the intended use, performance characteristics, and limitations of AI systems that influence patient care. Healthcare organizations need sufficient information to evaluate an AI system for appropriateness in a particular clinical environment and for post-deployment performance monitoring. Transparency does not require disclosure of every technical detail but requires adequate documentation and communication to support informed decision-making.

Legal considerations around AI are evolving. Questions remain regarding healthcare AI liability, particularly when outcomes differ from expectations. Assigning responsibility is complex because healthcare AI involves interactions between clinicians, healthcare organizations, software vendors, and technology developers. Existing legal frameworks were developed for traditional healthcare technologies and do not address the unique needs of adaptive data-driven systems.

Importantly, ethical, legal, and equity considerations should not be viewed as innovation barriers. Rather, they represent essential safeguards enabling responsible innovation. Public confidence in healthcare AI depends both on evidence of technical performance and on secure, transparent systems fairly deployed with appropriate human oversight.

| Policy recommendations

Successful integration of AI into healthcare requires coordinated action by policymakers, regulators, healthcare organizations, technology developers, professional societies, and clinical leaders.

1. Establish risk-based governance frameworks for clinical AI

AI systems should be governed according to patient care risk assessment. Regulatory and organizational oversight should be proportional to the clinical risk level associated with an application. Systems that directly influence diagnosis, treatment decisions, or patient triage require more rigorous evaluation and monitoring than administrative or operational tools. Risk-based oversight balances innovation with patient safety while ensuring that governance resources are appropriately focused.

2. Leverage laboratory medicine expertise in AI governance

Laboratory medicine is a source of AI governance expertise that healthcare organizations and policymakers should recognize. Laboratory professionals possess extensive experience in validation, quality management, continuous monitoring, regulatory compliance, data stewardship, and clinical consultation. These capabilities provide a foundation for scalable governance frameworks that support trustworthy healthcare AI. Building upon proven laboratory quality systems can accelerate implementation, improve consistency, reduce administrative burden, and strengthen patient safety.

3. Require independent verification and validation prior to clinical deployment

Healthcare organizations must establish standard processes to evaluate AI systems before implementation. Validation must assess performance within an institution's

clinical environment using representative patient populations and clinically relevant datasets. Both vendor- and locally developed systems should undergo independent evaluation to confirm the intended use performance.

4. Require continuous monitoring and post-deployment surveillance

AI governance should extend beyond initial implementation. Healthcare organizations need processes for ongoing performance monitoring, drift detection, bias assessment, incident reporting, and periodic reassessment. Continuous monitoring, AI lifecycle management, and quality assurance should become a standard.

5. Develop external quality-assessment and benchmarking programs

Independent evaluation programs, analogous to laboratory proficiency testing, should be established for healthcare AI to support objective performance assessment, facilitate benchmarking across organizations, identify emerging risks, and promote continuous quality improvement. Professional societies, regulatory agencies, and accrediting organizations should collaborate to develop healthcare AI external quality assessments.

6. Promote interoperability and trustworthy AI through the harmonization of test results

Healthcare policy should support interoperable infrastructure that enables AI systems to function within existing clinical workflows. AI technologies should be

integrated with EHRs, LIS, imaging platforms, and other healthcare information systems rather than deployed as isolated point solutions. Interoperability standards must prioritize secure data exchange, transparency, scalability, and long-term sustainability. To achieve this goal, clinical laboratory test results must be harmonized so that the results are analytically and clinically comparable.

7. Establish clear accountability and human oversight requirements

Healthcare organizations should designate governance bodies of qualified individuals for AI implementation, monitoring, incident management, and lifecycle oversight. Human accountability remains a central component regardless of the degree of automation. Clear oversight structures support transparency, patient safety, and organizational accountability.

8. Advance transparency standards for healthcare AI

Organizations implementing AI need access to sufficient information regarding intended use, performance characteristics, limitations, validation methods, and monitoring requirements for proper governance. Transparency standards are required to support informed adoption, independent evaluation, and responsible clinical use, while balancing intellectual property considerations.

9. Support workforce development and AI literacy

Healthcare professionals will require new knowledge and skills to effectively evaluate, implement, monitor, and govern AI systems. Policymakers, educational institutions, healthcare organizations, and professional societies must invest in workforce development initiatives that promote AI literacy among clinicians, laboratorians, informaticians, administrators, and quality professionals.

10. Align reimbursement policies with clinical value and responsible governance

Payment models should recognize both the outputs of AI systems and the governance activities necessary to support their safe and effective use. Reimbursement policies should encourage clinically validated applications that improve laboratory operations and patient outcomes without promoting low-value or inadequately validated technologies.

11. Invest in research that demonstrates clinical utility and value

Healthcare policymakers, funding agencies, healthcare systems, and industry partners should support research that evaluates the real-world impact of healthcare AI. While substantial resources have been devoted to algorithm development and technical validation, less investment has been directed toward clinical utility, patient outcomes, operational impact, equity, and economic value. Future research should prioritize real-world applications with prospective implementation studies, pragmatic clinical trials, health services research, and post-deployment evaluations to assess AI. Generating this evidence will be essential for reimbursement decisions, regulatory oversight, implementation strategies, and public trust.

Collectively, these recommendations seek to create synergy between innovation and accountability. The end-goal is to accelerate the adoption of AI technologies, while ensuring they improve patient care, strengthen healthcare systems, and maintain public trust. By establishing robust governance structures, supporting interoperability, investing in workforce development, and leveraging existing quality-management expertise, policymakers and healthcare organizations can create a sustainable foundation for the future of healthcare AI.

| Future directions

AI remains an evolving technology. As healthcare continues to generate larger volumes of data, AI has the potential to serve as an important tool, transforming data into information and information into actionable knowledge. Advances in multimodal AI may enable further integration of laboratory data with pathology, imaging, genomic, and clinical information, creating more comprehensive models of patient health than previously possible.

Healthcare professionals' roles will continue to evolve. Rather than replacing clinicians, AI is likely to augment human expertise by supporting information synthesis, prioritization, and decision-making. Human judgment remains essential for interpreting complex clinical situations, understanding patient preferences, evaluating unexpected findings, and balancing competing considerations. Successful AI implementations will therefore strengthen collaboration between technology and healthcare professionals rather than attempting to substitute one for the other.

Ultimately, the future of healthcare AI is not defined by the algorithm's capabilities, but by the ability of healthcare systems to deploy it responsibly, equitably, and effectively in service to patient care.

AI is rapidly becoming part of the healthcare landscape. However, AI also introduces new challenges related to validation, transparency, accountability, interoperability, and long-term oversight. This policy brief outlines the central role laboratory medicine can play in the responsible use of healthcare AI. Clinical laboratories have decades of experience managing complex diagnostic systems. These capabilities align with the governance requirements of healthcare AI and provide a practical foundation for building broader oversight frameworks. **Just as interoperability enabled the exchange of healthcare information, harmonization will be essential to ensuring that AI systems can reliably interpret and act upon laboratory data across institutions, platforms, and patient populations.**

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