

# CHALLENGES AND OPPORTUNITIES THROUGH ARTIFICIAL INTELLIGENCE IN HEALTHCARE



## Introduction

Healthcare is starting to develop tools around artificial intelligence (AI) and associated technologies, which are becoming more and more common in industry and society. Numerous facets of patient care as well as administrative procedures in payer, provider, and pharmaceutical organizations could be revolutionized by these technologies.

Numerous studies have already indicated that AI is capable of doing as well as or better than humans in critical healthcare jobs including disease diagnosis. Algorithms currently surpass radiologists in identifying malignant tumors and in assisting researchers in cohort construction for expensive clinical studies.

In this report, we will explore (1) the main issues in Healthcare, including (2) new issues that are caused by the development or use of AI in Healthcare, we will discuss some of (3) the challenges posed by AI between the Global North and Global South in Health, and explore (4) opportunities that AI provides to improve Healthcare and we will conclude with a series of (5) solutions needed to allow AI to be impactful in Healthcare.

### A. Current Issues in Healthcare

#### 1. Shortages of Professionals

Health workers are essential to the operation of health systems; their availability, accessibility, acceptability, and quality all play a role in enhancing the coverage of health services and achieving the right to the best possible standard of health.

By 2030, the WHO projects that there will be a shortage of 10 million health workers, primarily in low- and lower-middle-income countries. Nonetheless, challenges with workforce performance, retention, deployment, education, and employment exist in countries with different levels of socioeconomic development, including High Income Countries.

Continuous shortages are a result of several factors, including persistent underfunding of health worker education and training in some countries and a misalignment of employment and education policies with respect to population demands and health systems. The challenges of sending health professionals to isolated, rural, and underprivileged communities exacerbate them. Furthermore, the exodus of health professionals abroad could make the scarcity of health workers worse, especially in low- and lower-middle-income countries. Health information systems frequently lack the human resources necessary to assess a subset of public sector healthcare workers.

In certain countries, the public sector's inability to accommodate the supply of health workers because of financial limitations may also contribute to issues with universal access to healthcare providers. Consequently, certain nations encounter the conundrum of significant unfulfilled health requirements and the unemployment of health workers.

AI can help healthcare providers develop personalized treatment plans based on a patient's medical history, genetic information, and other relevant data, potentially reducing the workload of medical professionals and increasing their efficiency.

## 2. Uneven Resource Distribution between urban and rural areas

Due to an unequal labor distribution, shortages of healthcare providers are a problem in many nations, including High-Income Countries, and these shortages are frequently worse in rural areas. The majority of countries' healthcare systems continue to be plagued by this maldistribution issue.

Health disparities in rural areas are made worse by this lack of medical professionals. Economic, social, racial, ethnic, regional, and health workforce characteristics are the fundamental causes of these disparities. This complicated mixture exacerbates issues for rural populations worldwide, restricts access to care, and makes problem-solving more challenging.

Ensuring that rural communities have access to high-quality healthcare requires maintaining the workforce in the healthcare industry. In order to serve the needs of the community, rural healthcare facilities must hire a sufficient number of medical personnel. In order to offer care that is culturally relevant, they should possess the necessary knowledge and training.

AI-powered chatbots and virtual assistants can triage patients, provide basic health information, and assist in remote consultations, potentially increasing access to health care in underserved areas.

## 3. Rising Costs

A recent PwC report<sup>1</sup> on the annual medical cost trend projects that the growth in commercial health care spending will reach its highest point in 13 years. According to the analysis, medical costs will trend upward by 8% for the group market and 7.5% for the individual market in 2025. Prescription drug spending, mental health utilization, and inflationary pressure are the main drivers of this near-record trend.

Furthermore, compared to earlier reports, the medical expense trends for 2023 and 2024 were greater. Demand from care postponed since the pandemic drove the use of inpatient and outpatient facilities, which were filled by newly built capacity as treatment locations moved to ambulatory, professional, and outpatient settings. Baseline costs have increased significantly in several critical sectors during and after the pandemic, including personnel, medicine and medication charges, and administrative costs, to mention a few.

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<sup>1</sup> <https://www.pwc.com/us/en/industries/health-industries/library/assets/pwc-behind-the-numbers-2025.pdf>

It is anticipated that the healthcare sector will continue to experience inflationary pressure until 2025 as providers seek to increase their margins and use health plan contracts to offset rising operating costs. This pressure has been present since 2022. Prescription medication innovation for long-term illnesses and the growing demand for mental health services are about to hit a tipping point that will probably lead to increased cost inflation.

The increasing cost of healthcare puts pressure on the workforce to become more efficient and productive.

#### 4. Administrative Burdens

Administrative burden in healthcare is the time and effort spent on tasks that support clinical care but take away from direct patient care. These tasks can include:

- Documenting patient visits and treatment plans
- Navigating health insurance claims
- Managing patient referrals
- Coordinating care across multiple providers
- Complying with organizational policies, governmental reporting requirements, and other non-patient-care activities

Administrative burden has increased in recent decades due to quality initiatives, value-based healthcare, and data collection and reporting. Research suggests that administrative burden can negatively impact clinician autonomy, morale, direct patient care, and outcomes. For example, up to 57% of doctors experience burnout (see next section), and many cite administrative tasks as the main reason. Physicians spend an average of 15.5 hours per week on paperwork and administration, and almost half of their workday may be spent on administrative work instead of patient care.

AI-powered tools can automate tasks, such as data entry, appointment scheduling, and medical coding, allowing healthcare professionals to focus more on patient care.

#### 5. High Level of burnout among Staff

Healthcare workers experience high levels of burnout due to a variety of factors, including workplace systems, societal, cultural, structural, and organizational factors. Some examples of these factors include:

- Excessive workloads
- Administrative burdens
- Limited say in scheduling
- Lack of organizational support
- Workforce shortages
- Long hours
- Risk for hazardous exposures

According to the CDC, health workers reported higher levels of burnout in 2022 compared to 2018.

Healthcare workers who experience burnout may find it difficult to make clinical decisions, communicate effectively with patients and colleagues, handle pressure from the workplace, and ultimately provide lower-quality care and worse patient outcomes.

A recent survey on the prevalence of burnout among medical professionals was published in the journal *Nature*<sup>2</sup>. Burnout scores ranged from 16% to 86%, with an overall mean burnout score of 57%. Physically demanding labor, resource limitations, and inequities in the distribution of responsibilities were identified as significant causes of burnout. The findings showed that moderate burnout affects the majority of healthcare workers, and that hospital administration has the authority and ability to address the majority of the issues that lead to burnout.

AI-powered tools can assist in alleviating many of the causes of burnout by automating administrative tasks, reducing the workload of healthcare workers and allowing them to focus more on patient care.

## B. Current Issues related to AI in Healthcare

### 1. Job Displacements

In 2017, during a panel at the Canadian Agency for Drugs and Technologies in Health Symposium<sup>3</sup>, five private-sector leaders assured that Artificial Intelligence would not be a threat to health workers. AI, according to the panelists, was about using technology to increase human productivity. They contended that AI would, among other things, lessen the number of disruptions a nurse experiences throughout a shift, assist with diagnosis, and manage routine duties like scheduling and keeping track of the number of available beds. Panelists emphasized that artificial intelligence cannot replace health professionals, and that those with intuition and the capacity to weigh other considerations when making decisions were still needed.

However, as AI is becoming increasingly more sophisticated, certain roles in healthcare, such as medical coding and basic diagnostic tasks, may become automated, potentially leading to job losses. Is it possible to quantify the job displacement rate caused by AI in the healthcare field?

Recently published research "Beyond AI Exposure: Which Tasks are Cost-Effective to Automate with Computer Vision?"<sup>4</sup> provides a means of measuring the impact of smart devices and task automation. The level of performance required to complete a task, the technical capabilities of the AI system required to obtain that performance, and the economics of building such a system are all taken into account by the proposed AI task automation model. Overall, the results point to a "substantial, but also gradual" loss of jobs due to AI. Even though the study's scope was limited to tasks that might use computer vision, its conclusions were unexpected and encouraging: Because of the high upfront costs of AI systems, only 23% of worker wages currently paid for vision-related tasks would be attractive to automate using computer vision AI.

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<sup>2</sup> <https://www.nature.com/articles/s44184-024-00061-2>

<sup>3</sup> [https://www.cadth.ca/sites/default/files/symp-2017/2017\\_CADTH\\_Symposium\\_Program-e.pdf](https://www.cadth.ca/sites/default/files/symp-2017/2017_CADTH_Symposium_Program-e.pdf)

<sup>4</sup> <https://futuretech.mit.edu/news/beyond-ai-exposure-which-tasks-are-cost-effective-to-automate-with-computer-vision>

Similarly, a PwC analysis<sup>5</sup> from 2021 forecast that "AI and related technologies" would not be as likely to eliminate jobs in the health and social care sectors as they are in many other industries. In fact, the analysis predicted that, given the increasing demand from patients, the health and social care sectors will experience the most net employment growth of any industry over the next 20 years, with technology functioning as a "complementary" factor in most cases.

Because automation pertains to tasks rather than roles per se, and because few health care occupations are entirely composed of automatable tasks, there is a decreased chance of widespread job displacement in the healthcare industry. A research study on the possibilities for automation in primary care<sup>6</sup> concluded that no single occupation could be fully automated, even though a limited number of occupations (such a prescription clerk) were likely to be significantly impacted.

When only a portion of a task can be automated, employees can adjust by taking on more responsibilities or changing their roles. The occupational categories of "healthcare support" and "healthcare practitioners and technical staff" will largely be complemented rather than replaced by AI, according to research by Goldman Sachs<sup>7</sup> on the exposure of various industries to automation and generative AI. This is because of the mix of tasks involved. Similarly, a study by Accenture<sup>8</sup> revealed that, in contrast to many other industries, a smaller share of health work has high potential for automation, but a higher share of health-related activity has a high potential for technological "augmentation".

## 2. Disruption of Existing Workflows

The integration of AI and Generative AI in healthcare is poised to significantly disrupt existing work practices and workflows, necessitating adaptation from healthcare professionals. These technologies bring about new methods for diagnosing and treating diseases, managing patient information, and delivering care, which can shift traditional roles and responsibilities within healthcare settings.

The adoption of AI technologies may also lead to the redefinition of roles within healthcare teams. For example, data scientists and AI specialists might become integral parts of healthcare teams, working alongside clinicians to interpret AI findings and implement AI-driven solutions. This interdisciplinary collaboration will require a cultural shift within the healthcare workforce, emphasizing continuous learning and adaptation.

Healthcare professionals will need to embrace these changes, develop new competencies, and be open to evolving their practice to align with the rapidly advancing technological landscape.

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<sup>5</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1023590/impact-of-ai-on-jobs.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1023590/impact-of-ai-on-jobs.pdf)

<sup>6</sup> <https://www.oii.ox.ac.uk/research/projects/the-future-of-healthcare-computerisation-and-automation-and-general-practice-services/>

<sup>7</sup> <https://www.key4biz.it/wp-content/uploads/2023/03/Global-Economics-Analyst--The-Potentially-Large-Effects-of-Artificial-Intelligence-on-Economic-Growth-Briggs-Kodnani.pdf>

<sup>8</sup> <https://www.accenture.com/content/dam/accenture/final/accenture-com/document/Accenture-A-New-Era-of-Generative-AI-for-Everyone.pdf>

### 3. Necessity to Develop New Skill Sets

As the integration of AI and Generative AI into healthcare is set to disrupt existing work practices and workflows, it will compel healthcare professionals to develop new skill sets to remain competitive in the job market. As these technologies automate routine and administrative tasks, such as data entry, appointment scheduling, and initial patient assessments, the role of healthcare workers is shifting towards more specialized and patient-focused functions.

To effectively utilize AI tools, healthcare professionals will need to acquire skills in data interpretation and analysis, as these technologies generate vast amounts of information that can inform clinical decisions. Proficiency in using AI systems and understanding their outputs will be crucial for integrating AI-driven insights into everyday practice. This requires not only technical training but also a deeper understanding of how AI can enhance patient care and streamline workflows.

Generative AI, with its ability to generate personalized treatment plans and synthesize medical literature, adds another layer of complexity. Healthcare professionals will need to learn how to collaborate with AI systems to provide tailored care and to stay updated with rapidly evolving AI-generated medical knowledge. This involves continuous learning and adaptability, as the healthcare landscape becomes increasingly digital and data-driven.

As mentioned in the previous section, the emergence of AI in healthcare also emphasizes the need for interdisciplinary collaboration. Healthcare teams are likely to include data scientists and AI specialists, who will work alongside clinicians to interpret AI findings and implement AI-driven solutions. For healthcare professionals, developing skills in interdisciplinary communication and collaboration will be essential to integrate these new roles effectively.

Overall, to thrive in this evolving environment, healthcare professionals will need to embrace the need for lifelong learning and adaptability.

### 4. Overreliance on Technology

Patients seeking online sources to learn more about their possible medical conditions has led to an overreliance on digital information sources in the past. In the era of Generative AI, healthcare professionals may now also show signs of overreliance on technology through AI-assisted decision-making.

Although the use of Generative AI in healthcare has produced encouraging outcomes, it is important to understand that this technology is not a panacea. It cannot be used everywhere to address every issue in every healthcare environment. In order to minimize unforeseen repercussions, doctors and other healthcare professionals must employ Generative AI carefully.

For example, AI is devoid of the interpersonal abilities and human touch necessary for productive teamwork. Building trust and understanding requires the emotional intelligence and empathic communication that human team members, such as nurses or community health workers, bring to the table.

Certain patient cases require a profound awareness of context and unique circumstances, which AI systems may find difficult to interpret in their current format. The ability to navigate these complexities requires both clinical judgment and human intuition. The healthcare team may have trust concerns as a result of an overreliance on AI technology without thorough review. Healthcare workers must be able to assess and verify AI-generated data with some degree of skepticism.

## 5. Necessity of Integration with Existing IT Systems

The smooth integration of AI into healthcare systems is significantly hampered by interoperability problems since AI integration frequently necessitates data exchange across multiple platforms and systems.

It is therefore extremely difficult to ensure the safe transfer of this data while preserving its integrity and confidentiality. In order to address interoperability challenges, healthcare institutions need to make investments in systems that have good interoperability. Interoperability and data interchange between various systems and technologies can be facilitated by adopting standardized formats and protocols. To create interoperable solutions that smoothly incorporate AI into the current healthcare infrastructure, technology suppliers and healthcare institutions must work together.

Since many healthcare organizations have their own data storage systems and formats and since formal data sharing agreements might not be in place, it can be difficult to move and analyze data across numerous institutions, further hampering the integration of AI systems<sup>9</sup>.

Sub-Saharan Africa (SSA) and other developing regions face a greater problem because systematic electronic healthcare data collecting is not practiced there. Therefore, developing AI systems tailored to the demography of SSA may be difficult. A lack of proper or clear legal and policy frameworks, poor finance, and inadequate infrastructure are some of the obstacles in Africa, in addition to problems with data availability and quality.

By examining present digital health policies that may serve as hurdles to AI deployment, health bodies in SSA can eliminate these obstacles. Since AI depends on having access to high-quality clinical data, these healthcare organizations must consciously establish a regulatory framework to control the gathering and use of health data. The already-existing disparity in global health outcomes could get worse as AI technology advances in underdeveloped nations.

## 6. Need for representative and adaptive datasets for training and evaluation

The success of AI in healthcare depends on the availability of representative and adaptive datasets for training and evaluation. Human health is influenced by a combination of genetic, environmental, and lifestyle factors, which demand that AI models be trained on datasets that accurately reflect this diversity.

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<sup>9</sup> Rajkomar A, Oren E, Chen K, Dai AM, Hajaj N, Hardt M, Liu PJ, Liu X, Marcus J, Sun M, Sundberg P. Scalable and accurate deep learning with electronic health records. NPJ digital medicine. 2018 May 8;1(1):1-0.

However, current datasets often underrepresent certain populations, especially those from low- and middle-income countries (LMICs), leading to biased models that may yield inaccurate predictions or miss critical diagnostic and therapeutic opportunities for these underrepresented groups<sup>10</sup>.

To develop AI models that generalize well across different demographics, it is essential to ensure diverse representation in datasets, including various age groups, ethnicities, and individuals with complex medical conditions. The challenge lies not only in collecting diverse data but also in maintaining high quality through consistent labeling and comprehensive annotations. Adaptability is also crucial, as the healthcare landscape continuously evolves with new diseases, changing treatments, and shifting patient behaviors. Adaptive datasets, which integrate updates from real-world evidence (RWE), digital health technologies (DHTs), and longitudinal patient records, help ensure AI models remain relevant and accurate over time.

Collaboration among healthcare providers, researchers, and regulatory bodies is essential to create these adaptive datasets. Data sharing frameworks and interoperability standards are needed to integrate diverse data sources while maintaining patient privacy and security. Federated learning approaches can also be used to train models on decentralized data without direct data sharing, helping to overcome privacy challenges. Addressing the need for representative and adaptive datasets is not only a technical challenge but an ethical imperative. Ensuring that AI models are trained on diverse, high-quality data is key to advancing equitable healthcare outcomes and improving patient care across all populations.

Concerns about privacy and data security provide a significant obstacle to the use of AI in healthcare. Healthcare institutions are a prime target for hackers because they handle enormous volumes of sensitive patient data. A data breach can have serious repercussions, including the possibility of financial fraud, identity theft, and compromised patient care.

## 7. Ethical Concerns

- Data Privacy

Healthcare companies need to use strategies like strong encryption, access limits, frequent audits, and staff training to address data security and privacy issues. To maintain compliance, it is also critical to stay current on the newest legal standards, such as the Health Insurance Portability and Accountability Act (HIPAA). Healthcare companies can lessen the dangers involved with integrating AI by emphasizing patient privacy and making investments in safe technologies.

- Algorithmic Bias

The integration of AI in healthcare presents substantial hurdles, including ethical and bias concerns, which need to be addressed. AI systems have the capacity to reinforce pre-existing biases in healthcare, if not create new ones.

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<sup>10</sup> K. E. Paik et al., "Digital Determinants of Health: Health data poverty amplifies existing health disparities—A scoping review," *PLoS Digit. Heal.*, vol. 2, no. 10, p. e0000313, 2023, doi: 10.1371/journal.pdig.0000313.

The application of AI in decision-making processes also raises ethical questions, particularly in crucial domains like diagnosis and treatment planning.

Healthcare companies need to make sure that AI systems are created and implemented in an ethical and responsible way in order to solve ethical and bias problems. It is crucial to regularly audit algorithms for bias, maintain openness in the decision-making process, and take responsibility for the results of judgments made using AI. Furthermore, prejudice problems can be lessened by informing medical personnel about the advantages and restrictions of AI and by promoting a diverse and inclusive workplace.

## 8. Issues with Regulatory Compliance

Another major obstacle to the use of AI in healthcare is regulatory compliance. Strict laws, such as HIPAA, must be followed by healthcare institutions in order to preserve patient privacy. It can be difficult to integrate AI while yet adhering to these rules.

It is imperative for organizations to remain current with the most recent regulatory standards and to put measures in place to guarantee compliance. This entails putting strong data security measures in place, making sure AI-driven decision-making processes are transparent, and holding AI-driven decision-makers accountable for their actions. Moreover, frequent training initiatives and audits can guarantee that medical personnel understand and abide by regulatory obligations.

## 9. Trust and Reliability in AI-Driven Decisions

The one factor influencing how clinicians use and accept AI in the changing human-AI connection is trust. Trust is a psychological defense against the ambiguity that exists between the known and unknown. It is important to pay close attention to evaluating the extent and influence of human trust on AI technology. Can a physician have faith in an AI-driven system? What aspects of AI do people find trustworthy? Is it possible to maximize AI trust in order to enhance decision-making processes?

As AI develops, its applications will go beyond automating routine, well-defined tasks to include assisting medical professionals with decision-making under uncertainty. A healthy trust relationship, also known as calibrated trust<sup>11</sup>, becomes necessary for making wise decisions as health care practitioners depend more and more on AI. One of the key elements influencing the growth of user trust in a rule-based software system is its deterministic and reasonably predictable nature. A deterministic system's initial state and inputs define all of its subsequent behavior. However, the concept of trust may take on new meanings due to the nondeterministic nature of AI, which allows an algorithm to display different behaviors for the same input in successive iterations.

Currently, a major barrier to the use of AI in healthcare is a lack of confidence in the systems.

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<sup>11</sup> Hoffman RR, Johnson M, Bradshaw JM, Underbrink A. Trust in automation. IEEE Intelligent Systems. 2013 Feb 21;28(1):84-8.

A number of human factors, including user education, prior experiences, prejudices, and perceptions regarding automation, as well as characteristics of the AI system, such as controllability, transparency, and model complexity, as well as associated hazards, can all have an impact on trust in AI. Reliability, or the capacity of AI technology to execute a task consistently and predictably, is one of these criteria that may be especially important in the healthcare industry because AI's dependability can vary when new data becomes available.

An AI system's dependability depends on the user and the data they provide. Because AI systems may be trained on incomplete and subjective data from various sources, AI may produce biased or overfitted results that a clinical user may not be aware of. These worries impair the technology's functionality, which discourages users from accepting and putting their trust in AI systems.

#### 10. Balance between Technological Advancement and Human Compassion and Empathy

The rapid advancement of AI technology in healthcare offers substantial benefits, including enhanced diagnostic accuracy, streamlined workflows, and personalized treatment plans<sup>12</sup>. However, it is crucial to balance these technological innovations with human compassion and empathy to ensure comprehensive patient care.

While AI can significantly improve clinical efficiency and outcomes, it lacks the ability to fully replicate the empathetic communication and personal connection that are vital to patient care. Research has shown that compassionate interactions between patients and healthcare providers lead to higher patient satisfaction, better adherence to treatment, patient trust and improved overall health outcomes<sup>13</sup>.

The key challenge is to use AI as a tool to support and enhance, rather than replace human interaction. For example, AI can manage routine tasks, analyze large datasets, and provide decision support, freeing up healthcare professionals to focus on meaningful patient interactions. By leveraging AI for operational efficiency and data analysis, healthcare providers can devote more time to understanding patient needs, offering emotional support, and building trust.

This balanced approach ensures that while AI drives technological progress, the human aspects of care remain central to the patient experience. It creates an environment where technological advancements and compassionate care work together, enhancing the overall quality of healthcare.

#### 11. Acceptance from Medical Professionals

One final major obstacle to the use of AI in healthcare is adoption resistance or acceptance from medical professionals. Because of their unfamiliarity with the technology or worries

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<sup>12</sup> A. Kerasidou, "Artificial intelligence and the ongoing need for empathy, compassion and trust in healthcare," *Bull. World Health Organ.*, vol. 98, no. 4, pp. 245–250, 2020, doi: 10.2471/BLT.19.237198.

<sup>13</sup> J. M. Kelley, G. Kraft-Todd, L. Schapira, J. Kossowsky, and H. Riess, "The influence of the patient-clinician relationship on healthcare outcomes: A systematic review and meta-analysis of randomized controlled trials," *PLoS One*, vol. 9, no. 4, 2014, doi: 10.1371/journal.pone.0094207.

about how AI-driven technologies may affect their job security, healthcare professionals may be reluctant to adopt AI-driven technologies.

Training, education, and effective change management techniques are necessary to overcome adoption resistance. To promote acceptance, healthcare companies should involve frontline personnel in the implementation process, address their concerns, and highlight the advantages of AI integration. Overcoming opposition to adoption can be facilitated by cultivating a culture that values innovation and ongoing development. Continuing education and assistance can also make healthcare workers feel more at ease and certain when utilizing AI-driven solutions.

## C. Challenges Posed by AI between the Global North and Global South in the Health Sector

### 1. Digital Divide

While AI technologies offer numerous opportunities for enhancing healthcare, research, and innovation, their widespread adoption and effective utilization require substantial resources, infrastructure, and expertise. This discrepancy in resources between HICs and EMDEs could rapidly widen the AI gap. There are fundamental differences between the Global South and the Global North in Computational Power, Availability of Data, Expertise and Talent Readiness, as well as fundamental differences in Financial Resources.

These aspects, and many more, were developed in our report entitled “Closing the AI gap between High Income Countries and Emerging Markets and Developing Economies” available [here](#).

### 2. Lack of AI workforce program and training in Global South

The potential of AI to revolutionize healthcare in the Global South is immense, offering solutions for improved diagnostics, treatment personalization, and healthcare delivery. However, the existing infrastructure and skills gaps severely inhibit the ability of many African countries to fully leverage this potential<sup>14</sup>. Developing a home-grown talent base capable of executing AI-driven healthcare innovations remains a significant challenge due to the limitations of the current educational systems and infrastructural deficits.

A recent review of AI capacity in Africa highlighted several critical challenges, including a significant shortage of AI experts and lecturers, limited capacity within educational institutions, and inadequate funding for AI research, infrastructure, and entrepreneurship<sup>15</sup>.

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<sup>14</sup> A. Sey and O. Mudongo, “Case Studies on AI Skills Capacity-building and AI in Workforce Development in Africa,” Res. ICT Africa, 2021.

<sup>15</sup> N. Butcher, M. Wilson-Strydom, and M. Bajnath, “Artificial intelligence capacity in Sub-Saharan Africa: Compendium report,” AI4D Africa, pp. 1–98, 2021, [Online]. Available: <https://idl-bnc-idrc.dspacedirect.org/items/27ea1089-760f-4136-b637-16367161edcc>

These issues are compounded by the underrepresentation of women in the AI community, further limiting the diversity and breadth of perspectives in AI development.

In the healthcare sector specifically, these challenges manifest in a lack of trained professionals who can develop and implement AI solutions tailored to local needs<sup>14</sup>. Without sufficient expertise, the healthcare systems in these regions may struggle to adopt advanced AI technologies that could improve patient outcomes and operational efficiency. For example, AI-driven tools for disease diagnosis and management require both sophisticated technical knowledge and a deep understanding of the local healthcare context, something that is currently lacking in many parts of the Global South.

Moreover, the absence of robust AI programs in educational institutions means that future generations of healthcare professionals may be inadequately prepared to work with AI technologies. This gap not only slows down the pace of AI adoption but also perpetuates reliance on external expertise, which may not always align with local healthcare needs and challenges.

Addressing these issues requires a multifaceted approach, including increased investment in AI education, infrastructure, and research. Governments and international organizations need to collaborate to build and sustain AI capacity within healthcare, ensuring that local talent is equipped with the necessary skills to drive innovation. Furthermore, efforts must be made to create more inclusive AI communities that encourage the participation of underrepresented groups, particularly women, to enrich the field with diverse perspectives.

By tackling these capacity challenges, the Global South can better position itself to harness the transformative power of AI in healthcare, ultimately leading to more resilient and equitable health systems.

### 3. Research and Development Funding

The advancement of AI in healthcare is critically hampered by inadequate funding for research and development (R&D). Limited financial resources restrict the capacity of institutions to conduct cutting-edge research, develop innovative healthcare solutions, and train the next generation of AI professionals<sup>16</sup>. This funding gap not only slows technological progress but also creates disparities in the adoption and implementation of AI technologies across different regions.

Moreover, the scarcity of funding affects the infrastructure necessary for AI research, including access to high-performance computing, data storage, and collaborative platforms. These essential resources are often underfunded, hindering the ability of researchers to manage and analyze large-scale datasets, which are crucial for developing robust AI models. Without these foundational elements, researchers face significant barriers to contributing meaningfully to AI advancements in healthcare, where data-intensive research is essential for breakthroughs in areas such as personalized medicine and predictive diagnostics.

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<sup>16</sup>D. Sharma and M. Cotton, "Overcoming the barriers between resource constraints and healthcare quality," *Trop. Doct.*, vol. 53, no. 3, pp. 341– 343, 2023, doi: 10.1177/00494755231183784.

Addressing these funding challenges requires targeted investments from both public and private sectors, as well as international collaborations. Strategic funding initiatives, such as public-private partnerships and global research consortia, can play a pivotal role in closing the gap. Such efforts can bolster the AI ecosystem, fostering a more inclusive and equitable global landscape for healthcare innovation.

## D. Opportunities for AI in Healthcare

### 1. Data Analysis

AI has fundamentally transformed healthcare data analysis by enabling the processing and interpretation of vast amounts of data from various sources, including electronic health records (EHRs), medical imaging, and genetic data. AI's advanced capabilities in handling large datasets and recognizing complex patterns lead to more accurate predictions, personalized treatment plans, and improved patient outcomes. By integrating data from diverse sources, AI allows for a comprehensive understanding of patient health, facilitating proactive rather than reactive care<sup>17,18</sup>.

AI's influence extends beyond data integration and pattern recognition. It is also redefining the speed and efficiency of data-driven decision-making in healthcare. Machine learning algorithms can continuously learn from new data, ensuring that predictive models are always up to date. For example, AI can be used to monitor patient data in real-time, alerting clinicians to potential health risks before they become critical. This ability to provide timely insights enhances the overall quality of care and helps in reducing healthcare costs by preventing complications through early intervention<sup>19</sup>.

Key Points:

- AI processes vast healthcare data efficiently, offering comprehensive insights.
- AI's pattern recognition capabilities enhance disease trend analysis and treatment customization.

### 2. Real-Time Monitoring & Disease Tracking Monitoring of antimicrobial resistance

AI plays a crucial role in the real-time monitoring and management of antimicrobial resistance (AMR). By analyzing large datasets from hospitals, laboratories, and public health records, AI can identify emerging resistance patterns, enabling early intervention. AI-driven predictive models.

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<sup>17</sup> Forouzanfar, M. (2024). The role of AI in hospitals and clinics: Transforming healthcare in the 21st century. *Bioengineering*, 11(4), 337. <https://doi.org/10.3390/bioengineering11040337>.

<sup>18</sup> Hayder, I. M., & Younis, H. A. (2024). A systematic review and meta-analysis of artificial intelligence tools in medicine and healthcare. *Diagnostics*, 14(1), 109. <https://doi.org/10.3390/diagnostics14010109>

<sup>19</sup> Topol, E. J. (2019). High-performance medicine: The convergence of human and artificial intelligence. *Nature Medicine*, 25(1), 44-56. <https://doi.org/10.1038/s41591-018-0300-7>

help anticipate the spread of resistant strains, supporting timely and targeted public health responses. Moreover, AI assists in optimizing antimicrobial use, reducing the development of resistance through personalized treatment recommendations based on local resistance patterns<sup>18</sup>.

AI is also facilitating global collaboration in the fight against AMR. AI-powered platforms enable the sharing of AMR data across borders, allowing for coordinated efforts to track and combat resistance on a global scale. These platforms can integrate data from various sources, such as genomic data, clinical records, and environmental samples, providing a comprehensive view of AMR dynamics. By enhancing the ability to monitor and respond to AMR, AI is helping to protect public health and preserve the effectiveness of existing antimicrobials<sup>20</sup>.

Key Points:

- AI identifies AMR patterns by processing vast data sources.
- AI-driven predictions aid in early detection and intervention against AMR.

### 3. Increased Diagnostic Accuracy

When it comes to the diagnosis of a wide range of illnesses and ailments, from malignancies to cardiac irregularities, medical imaging is indispensable. Medical imaging is changing as a result of AI-powered solutions that enhance image quality, automate image analysis, and promote early diagnosis<sup>21</sup>. Studies have shown that AI-powered medical imaging is improving the detection of problems. Better patient outcomes and faster interventions are the results of this advancement.

AI systems examine patient histories, test results, and genetic data to help physicians diagnose patients more accurately. Artificial intelligence improves diagnostic precision and facilitates individualized treatment planning by finding patterns and connections in the data. This is an excellent illustration of how AI forecasts patient outcomes and directs medical professionals to provide higher-quality patient care.

AI's capacity to expedite diagnostic procedures is among its most important benefits in medical diagnostics. Conventional diagnosis techniques generally entail the laborious and error-prone manual interpretation of medical data. This could be a time-consuming approach with inaccurate results.

Large volumes of data may be swiftly analyzed by AI systems, enabling earlier diagnosis and prompt response. We are seeing how AI can speed up the delivery of care, reduce delays in diagnosis, and increase patient satisfaction.

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<sup>20</sup> Chandra, M., & Tsai, T. (2021). Artificial intelligence applications in antimicrobial resistance surveillance and mitigation: A review. *Journal of Global Antimicrobial Resistance*, 24, 86-93. <https://doi.org/10.1016/j.jgar.2020.11.020>

<sup>21</sup> Mohamed Khalifa, Mona Albadawy, AI in diagnostic imaging: Revolutionizing accuracy and efficiency, *Computer Methods and Programs in Biomedicine Update*, Volume 5, 2024, 100146, ISSN 2666-9900, <https://doi.org/10.1016/j.cmpbup.2024.100146>.

4. Personalized Treatment Planning and Reduced Medication Errors
  - Improved Surgical Options

AI is revolutionizing personalized treatment planning, enhancing surgical options, and reducing surgical errors. In personalized medicine, AI tailors treatment plans based on a patient's genetic profile, medical history, and lifestyle. AI-powered tools improve surgical planning through detailed 3D modeling and simulations, allowing for more precise and less invasive procedures. During surgery, AI-driven robotic systems enhance precision and consistency, reducing the risk of errors and improving patient outcomes<sup>22</sup>.

The integration of AI into surgical practices also facilitates the standardization of complex procedures<sup>23</sup>. By utilizing AI-driven surgical guides and robotic assistance, surgeons can perform highly intricate operations with increased accuracy and reduced variability. This standardization not only improves patient outcomes but also reduces the likelihood of complications and the need for follow-up surgeries. Additionally, AI's real-time decision support during surgery provides critical insights, such as identifying unexpected anatomical structures or suggesting alternative approaches, further enhancing the safety and success of surgical interventions.

Key Points:

- AI enables highly personalized treatment plans by analyzing patient-specific data.
- AI-driven surgical planning and robotic systems reduce surgical errors and improve outcomes.

#### 5. Acceleration of Drug Discovery and Increased Drug Safety

AI accelerates drug discovery by analyzing vast biological datasets to identify potential drug candidates, significantly reducing the time and cost of bringing new drugs to market<sup>18</sup>. AI also enhances drug safety by predicting adverse drug reactions and optimizing drug dosages based on a patient's genetic profile. In addition, AI supports pharmacovigilance by continuously monitoring real-world data for signs of adverse drug reactions, ensuring that new drugs remain safe after they enter the market.

Beyond drug discovery and safety, AI is transforming the entire drug development pipeline<sup>24</sup>. By integrating AI into early-stage research, pharmaceutical companies can identify promising compounds more quickly and accurately. AI models can predict the efficacy of these compounds in preclinical trials, reducing the reliance on animal testing and accelerating the transition to human trials. Additionally, AI helps in the design and execution of clinical trials by identifying optimal patient populations, predicting outcomes, and monitoring patient responses in real-time.

<sup>22</sup> Forouzanfar, M. (2024). The role of AI in hospitals and clinics: Transforming healthcare in the 21st century. *Bioengineering*, 11(4), 337. <https://doi.org/10.3390/bioengineering11040337>

<sup>23</sup> Hashimoto, D. A., Rosman, G., Rus, D., & Meireles, O. R. (2018). Artificial intelligence in surgery: Promises and perils. *Annals of Surgery*, 268(1), 70-76. <https://doi.org/10.1097/SLA.0000000000002693>

<sup>24</sup> Mak, K. K., & Pichika, M. R. (2019). Artificial intelligence in drug development: Present status and future prospects. *Drug Discovery Today*, 24(3), 773-780. <https://doi.org/10.1016/j.drudis.2018.11.014>

This holistic application of AI not only speeds up the drug development process but also enhances the precision and safety of new therapies.

Key Points:

- AI speeds up drug discovery by efficiently analyzing biological data.
- AI improves drug safety through predictive analytics and continuous monitoring.

## 6. Improved Efficiency and Effectiveness in Healthcare

- Reduced healthcare workers burnout (emotional AI)

AI, particularly emotional AI, has the potential to significantly reduce healthcare worker burnout by automating routine tasks, optimizing workloads, and providing emotional support<sup>18</sup>. AI-driven systems can monitor healthcare workers' stress levels and offer real-time interventions, such as recommending breaks or providing mental health resources. By easing the burden of administrative tasks and enhancing communication, AI allows healthcare workers to focus more on patient care, reducing the risk of burnout.

In addition to task automation, emotional AI can foster a more supportive work environment by identifying early signs of stress and burnout<sup>25</sup>. For example, AI can analyze voice tone, facial expressions, and behavioral patterns to detect when a healthcare worker may be experiencing emotional distress. Based on these insights, AI can suggest targeted interventions, such as peer support sessions or wellness programs, before burnout escalates. Moreover, AI can help optimize shift scheduling by considering factors like workload, personal preferences, and fatigue levels, further enhancing work-life balance and job satisfaction among healthcare workers

Key Points:

- Emotional AI monitors healthcare workers' well-being and provides timely interventions.
- AI reduces burnout by automating routine tasks and optimizing workload management.
- Reduced nosocomial transmission

AI is instrumental in reducing nosocomial infections by enhancing infection control practices, improving hygiene compliance, and optimizing patient management<sup>18</sup>. AI systems can monitor hand hygiene, track the use of personal protective equipment, and detect surface contamination in real-time.

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<sup>25</sup>Shanafelt, T. D., Boone, S., Tan, L., Dyrbye, L. N., Sotile, W., Satele, D., & West, C. P. (2012). Burnout and satisfaction with work-life balance among US physicians relative to the general US population. *Archives of Internal Medicine*, 172(18), 1377-1385. <https://doi.org/10.1001/archinternmed.2012.3199>

Predictive analytics help identify patients at higher risk of infection, allowing for proactive isolation and management. These AI-driven interventions lead to a significant reduction in hospital-acquired infections.

AI's role in infection control extends to environmental monitoring and disinfection practices. AI-powered robots equipped with UV light or other sterilization technologies can autonomously disinfect patient rooms, operating theaters, and other high-risk areas. By ensuring consistent and thorough disinfection, these robots help minimize the risk of pathogen transmission. Additionally, AI-driven analytics can track patterns of infection within a facility, allowing for targeted interventions that address specific areas of concern. Through these innovations, AI is not only enhancing infection control but also contributing to a safer healthcare environment for both patients and staff<sup>26</sup>.

Key Points:

- AI improves infection control through real-time monitoring and predictive analytics.
- AI-driven interventions reduce the incidence of hospital-acquired infections.

## 7. Enhanced Patient Education

AI enhances health literacy by providing personalized, accessible, and engaging educational content tailored to individual patients<sup>22</sup>. AI-powered chatbots and virtual assistants offer instant access to health information, answering questions and guiding patients through their care journey. Additionally, AI can adapt educational materials to match the patient's learning style, language, and cultural background, making health information more relatable and easier to understand.

Beyond delivering information, AI actively engages patients in their healthcare journey. AI-driven platforms can track a patient's progress in understanding their condition and provide reminders or additional resources to reinforce learning. This continuous engagement ensures that patients remain informed and empowered to manage their health effectively. Furthermore, AI's ability to personalize education based on real-time data allows healthcare providers to address specific concerns and misconceptions, thereby improving overall patient satisfaction and outcomes<sup>19</sup>.

Key Points:

- AI offers personalized health education tailored to patient needs.
- AI-driven tools improve health literacy by providing accessible and engaging content.

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<sup>26</sup> Tacconelli, E., Carrara, E., Savoldi, A., Harbarth, S., Mendelson, M., Monnet, D. L., ... & Magrini, N. (2018). Discovery, research, and development of new antibiotics: The WHO priority list of antibiotic-resistant bacteria and tuberculosis. *The Lancet Infectious Diseases*, 18(3), 318-327. [https://doi.org/10.1016/S1473-3099\(17\)30753-3](https://doi.org/10.1016/S1473-3099(17)30753-3)

## D. Solutions Needed

### 1. Need for AI Governance in Healthcare

The opportunity landscape for the use of AI in healthcare is large. As such, consideration of the necessary governance is specific to the nature or phase of the process: upstream research and drug development, regulatory processes, clinical practice, or health technologies<sup>27,28</sup>.

- Data sources

There are numerous ethical concerns about the use of AI in healthcare, specifically in privacy, bias, and fairness. It is widely acknowledged that the main source of these concerns stems from training data which frequently embodies an over-representation of a specific geography or demographic in clinical data samples. When results are extrapolated outside of the training/testing environment, ethical and generalizability issues can arise from preexisting biases in the training data. As the underrepresentation of LMICs in clinical trials is acknowledged<sup>29</sup>, it is equally likely that similar biases will exist in much AI training data. Hence, a sufficient level of training data validation is critical for the optimal performance of AI applications in LMIC contexts.

However, these biases are easily exacerbated when AI models are trained on increasingly heterogeneous data sources such as Real World Data<sup>30</sup>. Training data derived from non-experimental sources such as electronic health records, insurance data, public health registries, or data from digital health technologies (DHTs) offers new potential for AI health applications, along with commensurate risks for safety, reliability and bias reduction<sup>31</sup>. Of particular interest to regulators are advances in DHTs, both as consumer-oriented wearables, as well as electronic sensors that are implanted, ingested, or placed in a living environment. As these technologies become increasingly affordable, they offer great potential for LMICs by accommodating for limited healthcare infrastructures or large geographic dispersion through remote, continuous data collection in situations where face-to-face care or interaction is limited. However, the use of DHT presents unique statistical considerations related to variable data quality; technical data specifications; provenance; measures used (e.g., activity counts, steps, calories); techniques and algorithms used for processing (federated learning with non-IID data) or missing data<sup>32</sup>. Novel statistical methods for validating DHT-derived data are the subject of ongoing research<sup>33</sup>.

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<sup>27</sup> US Food and Drug Administration (2024) "Artificial Intelligence and Machine Learning (AI/ML) for Drug Development" <https://www.fda.gov/science-research/science-and-research-special-topics/artificial-intelligence-and-machine-learning-ai-ml-drug-development>

<sup>28</sup> Vamathevan, J., Clark, D., Czodrowski, P., Dunham, I., Ferran, E., Lee, G., Zhao, S. (2019). "Applications of machine learning in drug discovery and development" *Nature Reviews Drug Discovery*, 18(6), 463-477. doi:10.1038/s41573-019-0024-5

<sup>29</sup> Mumtaz H, Haider SMA, Neha F, Saqib M, Nadeem A, Seikha Z. Clinical trials landscape in a lower-middle-income country (Pakistan). *Journal of Clinical Translational Science* (2023) Dec 10;8(1):e7. doi: 10.1017/cts.2023.701.

<sup>30</sup> US Food and Drug Administration (2023) "Real World Evidence" <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence>

<sup>31</sup> US Food and Drug Administration (2024) "Digital Health Technologies" <https://www.fda.gov/science-research/science-and-research-special-topics/digital-health-technologies-dhts-drug-development>

<sup>32</sup> Ratitch B, Trigg A, Majumder M, Vlajnic V, Rethemeier N, Nkulikiyinka R. "Clinical Validation of Novel Digital Measures: Statistical Methods for Reliability Evaluation." *Digital Biomarkers*. (2023) Aug 9;7(1):74-91. doi: 10.1159/000531054. PMID: 37588480; PMCID: PMC10425717.

<sup>33</sup> US Food and Drug Administration Center for Drug Evaluation and Research (2024) "Novel DHT-centric statistical methods for subject-level fingerprinting and handling missingness" <https://www.fda.gov/science-research/advancing-regulatory-science/novel-dht-centric-statistical-methods-subject-level-fingerprinting-and-handling-missingness>

- Transparency & Explainability

Another focal concern of governance is that the results of AI algorithms should be transparent and explainable (XAI)<sup>34</sup>. This is challenging in that many AI applications may not be transparent, either due to the proprietary nature, or the inaccessible logic of the deep learning algorithms<sup>35,36</sup>. Policymakers have struggled with fears of a theoretical void in AI that can render it less transparent, if not completely impenetrable to any scrutiny—and thus, largely ungovernable<sup>37</sup>. The challenge is that “explainable” is highly variable, depending on audience and context: Explainability, as a model property, does not equate to causal understandability as a human property. Furthermore, explainability and transparency do not necessarily equate to validity<sup>38</sup>. Additionally, AI systems can have different impacts in decision-making depending on their context of use and their interaction with other instruments and human judgment (i.e. human-in-the-loop). As a result, the appropriate regulation of AI in healthcare is not a “once-and-done” task. AI models evolve through time based on new data inputs, refinement, self-learning, and user modifications. This means that explainability and transparency in AI are not static properties: validation and verification should occur at appropriate points throughout development and deployment. Consequently, in the context of LMICs, regulation needs to be both adaptive to “unlocked” or adaptive algorithms, yet commensurately vigilant to the potential loss of control that can occur in more geographically distributed usage contexts. A “total life cycle approach”, with a balanced combination of ex ante, in itinere, and ex post verification will be needed to ensure monitoring in real world applications.

## 2. AI Powered Automation

There are a variety of areas where the automation capabilities of AI show great potential. In pharmaceuticals, AI-enabled process improvements in manufacturing are beneficial to improving quality, purity and safety compliance<sup>39</sup>. For both small molecule and biologics in particular, increased production batch yields can convey substantial economic benefits. Here, the use of digital twins as digital process representations empowered by real-time sensor data and AI/ML can help production planners adjust multiple input parameters to keep process output parameters at requisite levels. Across all phases of manufacturing that require measurement, modeling and control, AI/ML applications offer significant potential<sup>40</sup>.

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<sup>34</sup> Dwivedi, R., Dave, D., Naik, H., Singhal, S., Omer, R., Patel, P., Qian, B., Wen, Z., Shah, T., Morgan, G., & Ranjan, R. (2023) “Explainable AI (XAI): Core Ideas, Techniques, and Solutions.” *ACM Computing Surveys*, 55(9), 1–33. <https://doi.org/10.1145/3561048>

<sup>35</sup> Kawamleh, S. (2022) “Against explainability requirements for ethical artificial intelligence in health care.” *AI and Ethics*, 3(3), 901–916. <https://doi.org/10.1007/s43681-022-00212-1>

<sup>36</sup> Matulionyte, R., Nolan, P., Magrabi, F., & Beheshti, A (2022). “Should AI-enabled medical devices be explainable?” *International Journal of Law and Information Technology*, 30(2), 151–180. <https://doi.org/10.1093/ijlit/eaac015>

<sup>37</sup> London, A. J. (2019) “Artificial Intelligence and Black-Box Medical Decisions: Accuracy versus Explainability.” *Hastings Center Report*, 49(1), 15–21. <https://doi.org/10.1002/hast.973>

<sup>38</sup> Mitchell, M., & Krakauer, D. C. (2023) “The debate over understanding in AI’s large language models.” *Proceedings of the National Academy of Sciences*, 120(13)

<sup>39</sup> US Food and Drug Administration Center for Drug Evaluation and Research (2023) “Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products” <https://www.fda.gov/media/167973/download?attachment>

<sup>40</sup> US Food and Drug Administration Center for Drug Evaluation and Research (2023) “Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products” <https://www.fda.gov/media/167973/download?attachment>

The developments in advanced manufacturing are now facilitating innovations in integrated, flexible, and distributed manufacturing. These innovations include highly modular approaches to streamline drug development and production, and the deployment and use of highly portable manufacturing units. In response, the FDA has developed the FRAME initiative through its Emerging Technology Program that prioritizes four technologies: end-to-end continuous manufacturing (E2E CM); distributed manufacturing (DM) units at non-traditional host sites; AI powered cybernetic systems that can perceive the environment, interpret data, and adjust control parameters accordingly<sup>41</sup>. Clearly, a larger geographical dispersion of manufacturing sites complicates validation and compliance substantially. Here, standardized AI methods can be developed to generate data stability, method transfer, analytical comparability, and appropriate validation<sup>42</sup>. While they are still on the horizon, these methods are of interest to LMICs that can use distributed manufacturing locally and to realize the economic benefits.

Finally, developments in personalized medicine are largely driven by AI methods that can analyze patient-specific data to design tailored drug therapies. Many diseases, particularly cancer, are highly heterogeneous in nature, rendering a one-drug-fits-all approach ineffectual<sup>43</sup>. Personalized medicine represents a paradigm shift based on individualized interventions based on patient features and characteristics. Based on individual physiology, AI algorithms can be used to explore various aspects of a patients' physiology: identify genomic vulnerabilities, predictive biomarkers, and simulate therapeutic efficacy and toxicity<sup>44</sup>.

However, the acquisition and analysis of individual data differs from traditional evidence- and model-building from larger patient samples. This is further complicated by augmentation with vastly heterogeneous source of non-clinical and RWD and DHTs<sup>45</sup>. Here, AI can be used to accommodate data heterogeneity and internally and externally validate novel techniques for scientific evidence-building that is representative of LMIC populations.

### 3. Validation and Regulatory Approval of AI Technologies

Regulatory authorities have been relatively quick to acknowledge the relevance and potential of AI in many phases of drug discovery and evaluation and integrate them into evaluation processes when deemed reliable and trustworthy. These span across the regulatory processes, from target and lead identification, specification of mechanisms of actions, to the design of clinical trials and post approval safety monitoring<sup>46</sup>.

<sup>41</sup> US Food and Drug Administration Center for Drug Evaluation and Research (2022) "Distributed Manufacturing and Point-of-Care Manufacturing of Drugs" <https://www.fda.gov/media/162157/download?attachment>

<sup>42</sup> US Food and Drug Administration Center for Drug Evaluation and Research (2024) "Novel DHT-centric statistical methods for subject-level fingerprinting and handling missingness" <https://www.fda.gov/science-research/advancing-regulatory-science/novel-dht-centric-statistical-methods-subject-level-fingerprinting-and-handling-missingness>

<sup>43</sup> Schork NJ. "Artificial Intelligence and Personalized Medicine." *Cancer Treatment Research*. 2019;178:265-283. doi: 10.1007/978-3-030-16391-4\_11. PMID: 31209850; PMCID: PMC7580505.

<sup>44</sup> Ratitch B, Trigg A, Majumder M, Vljajic V, Rethemeier N, Nkulikiyinka R. "Clinical Validation of Novel Digital Measures: Statistical Methods for Reliability Evaluation." *Digital Biomarkers*. 2023 Aug 9;7(1):74-91. doi: 10.1159/000531054. PMID: 37588480; PMCID: PMC10425717.

<sup>45</sup> US Food and Drug Administration (2024) "Digital Health Technologies" <https://www.fda.gov/science-research/science-and-research-special-topics/digital-health-technologies-dhts-drug-development>

<sup>46</sup> Niazi SK. (2023) The Coming of Age of AI/ML in Drug Discovery, Development, Clinical Testing, and Manufacturing: The FDA Perspectives. *Drug Design, Development and Therapy*. Sep 6;17:2691-2725. doi:10.2147/DDDT.S424991.

Of particular interest is in drug target and lead Identification. For example, the FDA's Center for Drug Evaluation and Research reports that over 100 drug and biologic submissions in 2021 alone<sup>47</sup>. Where computational models have long been used in computation chemistry and proteomics, new deep learning algorithms are now accelerating the identification of biomarkers, the discovery of protein structures, and the design of small molecule compounds and biologics that can effectively bind to them<sup>48</sup>. Of particular interest to regulators are how to embrace the benefits of theoretically agnostic deep learning algorithms without forfeiting insight into the physiological mechanisms of action. Regulators are now studying how traditional theoretical models (physics-based) can complement and validate theory-agnostic machine learning models to accelerate the development of novel therapeutics and medical devices. For example, the American Society of Mechanical Engineers<sup>49</sup> developed the V&V 40 standard as a method for assessing the reliability of computational models in medical devices. These guidelines have been further modified for physics-informed drug discovery, where deep learning models are validated with physics-based models.

Accordingly, the FDA's efforts are now focused on how the vast quantities of non-clinical data can be reliably analyzed with AI, yet verified with more traditional methods, to increase the speed of drug development without sacrificing safety and efficacy requisites<sup>50</sup>. This includes the analysis of high throughput compound screening, exploration of drug repurposing, as well as pharmacodynamics and pharmacokinetics simulations with other animal-based or organoid models across collaborative research infrastructures<sup>51</sup>.

A final area that has benefited from developments in AI is the design of clinical trials, from study structure and endpoints to data collection, management, analysis and post-marketing safety surveillance. For LMICs, this is particularly useful given the high financial costs of conducting clinical trials, as well as difficulties in recruitment adherence and retention. The effective use of AI can help study design and analysis in circumstances where obtaining the representative study samples is pragmatically challenging.

#### 4. Increased Computing Infrastructure

AI technology requires resources and infrastructure to train complex deep neural networks and large language models. These generally involve billions of parameters to converge to predictive and accurate models<sup>52</sup>.

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<sup>47</sup> US Food and Drug Administration (2024) "Artificial Intelligence and Machine Learning (AI/ML) for Drug Development" <https://www.fda.gov/science-research/science-and-research-special-topics/artificial-intelligence-and-machine-learning-aiml-drug-development>

<sup>48</sup> Jumper, J., Evans, R., Pritzel, A., ... Hassabis, D. (2021) "Highly accurate protein structure prediction with AlphaFold." Nature, 596(7873), Article 7873. <https://doi.org/10.1038/s41586-021-03819-2>

<sup>49</sup> The American Society of Mechanical Engineers "Verification, Validation and Uncertainty Quantification (VVUQ)" <https://www.asme.org/codes-standards/publications-information/verification-validation-uncertainty>

<sup>50</sup> US Food and Drug Administration (2023) "Real World Evidence" <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence>

<sup>51</sup> Pujol Priego, L. and Wareham, J. (2024) "Data Commoning in the Life Sciences." MIS Quarterly, (48: 2) pp.491-520.

Developing sophisticated models and deploying them effectively also require high-performance computing and cloud services. Additionally, models feed on enormous amounts of data. Access to a sheer volume of diverse datasets, requires important resources. Finally, AI deployment and success requires attracting and retaining top talents (Harvard Business Review, 2019).

## 5. Foster Collaboration between AI and Human Expertise

AI aims to build intelligent agents, where an intelligent agent is a system that perceives its environment and takes actions that maximize its chances of success<sup>53</sup>. Specifically, the core of AI is to build agents with large computational resources that allow them to make non-trivial decisions in complex environments. As human intelligence can't scale or have such large resources, Intelligent agents with these capabilities can become our intellectual extension.

To put it in the words of Andrew Ng, a notable AI researcher, and professor, "Just as the Industrial Revolution freed up a lot of humanity from physical drudgery, I think AI has the potential to free up humanity from a lot of the mental drudgery." Therefore, AI is akin to a revolution that can be transformative for a broad range of applications with potentially huge benefits to humanity.

In particular, AI is poised to impact our health and well-being dramatically. The potential for artificial intelligence in healthcare is tremendous<sup>54</sup>. By augmenting healthcare professionals with AI capabilities, there is hope they can fix and enhance a drained healthcare system and make leaps in medical research to address complex illnesses.

Data power AI. With the advent of deep neural networks, AI has become even more proficient at processing large amounts of data, including images, speech, text, and other structured and unstructured medical data. Doctors can see hundreds of patients, but AI can read and digest millions of medical records with different data modalities, including medical images, time series, and electronic health records (EHR).

In the collaboration AI+Human in healthcare, there are "low hanging fruits" and complex ones that require more resources and research to realize AI potential fully. One key AI application in healthcare is streamlining the many administrative tasks, including scheduling and workflow management. While they may not constitute the "meat" of AI applications in healthcare, they are imminent. They can contribute to an efficient and effective healthcare ecosystem<sup>54</sup>.

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<sup>52</sup> Harvard Business Review, 2019. <https://hbr.org/2019/05/ranking-countries-and-industries-by-tech-data-and-business-skills>

<sup>53</sup> Russell, S. J., & Norvig, P. (2021). Artificial Intelligence: A Modern Approach (4th ed.). Pearson. <https://doi.org/10.1109/MSP.2017.2765202>

<sup>54</sup> Davenport, T., & Kalakota, R. (2019). "The potential for artificial intelligence in healthcare." *Future Healthcare Journal*, 6(2), 94-98.

One immediately impactful application is capturing clinical notes to address the fatigue experienced by doctors and nurses doing "clerical" work instead of focusing on the patient<sup>55</sup>. By facing their computer to take notes during consultations, precious time is wasted typing patient information and encounters into the EHR system. Often, this misses critical patient perspectives. Emerging AI applications, such as [Tortus](#), capture the audio of the doctor's conversation with the patient using medical speech-to-text AI and turn it into curated notes, thus supporting clinicians at the bedside and restoring face-to-face relationships during consultations. Applications like these are easy to deploy and can tremendously reduce the paperwork burden and free doctors' time for what matters the most: the patient.

A timely and accurate diagnosis of a wide range of conditions, is another area where AI can support doctors<sup>56</sup>. In the field of computational diagnostic and screening tools, deep learning has proven useful in interpreting medical images (such as x-rays, computed tomography (CT), and magnetic resonance imaging (MRI) scans) in domains like ophthalmology, radiology, pathology, and gastroenterology. A recent study presented an AI system that outperformed radiologists in breast cancer identification<sup>57</sup>. Deep learning has also proven useful in diagnosing various eye diseases from retinal images. For example, a study used Deep Learning for Diabetic retinopathy screening to prevent blindness<sup>58</sup>. Finally, a recent study used AI to detect brain activity in patients with brain injuries<sup>59</sup>. AI systems like IBM Watson for Oncology analyze vast amounts of medical literature and patient data to suggest treatment options<sup>60</sup>.

Large Language Models could augment medical education. AI can also help doctors catch up with a growing medical literature, and keep up with medical advances. It can speed up medical literature search, comparison, and summarization. Deep Learning models were used to study the medical literature. For instance, a recent study used BioBERT to learn how drugs interact<sup>61</sup>.

Precision medicine could constitute the holy grail of AI applications in healthcare in the near future. In his book, Topol explores how AI can enhance personalized medicine and help healthcare professionals offer personalized treatment plans<sup>62</sup>. AI algorithms analyze patient data to recommend personalized care based on genetic information, lifestyle, and previous treatment responses. AI tools in precision medicine, like those used in cancer treatment, suggest therapies based on the tumor's genetic profile. AI becomes a prominent collaborator with oncologists in the refinement of treatment plans.

<sup>55</sup> Topol, Eric J. *Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again*. First edition. New York, Basic Books, 2019.

<sup>56</sup> Amisha, Malik, P., Pathania, M., & Rathaur, V. K. (2019). "Overview of artificial intelligence in medicine." *Journal of Family Medicine and Primary Care*, 8(7), 2328-2331.

<sup>57</sup> McKinney, S.M., Sieniek, M., Godbole, V. et al. International evaluation of an AI system for breast cancer screening. *Nature* 577, 89–94 (2020). <https://doi.org/10.1038/s41586-019-1799-6>

<sup>58</sup> Bora, Ashish, et al. "Predicting the risk of developing diabetic retinopathy using deep learning." *The Lancet Digital Health* 3.1 (2021): e10-e19.

<sup>59</sup> Claassen, J. et al. Detection of brain activation in unresponsive patients with acute brain injury. *N. Engl. J. Med.* 380, 2497–2505 (2019).

<sup>60</sup> Jie, Z., Zhiying, Z. & Li, L. A meta-analysis of Watson for Oncology in clinical application. *Sci Rep* 11, 5792 (2021). <https://doi.org/10.1038/s41598-021-84973-5>

<sup>61</sup> Zhu, Y., Li, L., Lu, H., Zhou, A. Qin, X. Extracting drug-drug interactions from texts with BioBERT and multiple entity-aware attentions. *J. Biomed. Inform.* 106, 103451 (2020).

<sup>62</sup> Topol, E. J. (2019). "Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again." Basic Books.

Multimodal data promises to multiply the potential applications of AI in healthcare<sup>63</sup>. Deep learning can analyze layers of data, including the EHR (lab results, family history, doctor notes), medical images, biomarkers of physiology through sensors, and all the omics<sup>64</sup>, focusing on different types of biological data and their comprehensive analyses. Leveraging these layers simultaneously is unprecedented and yet to be achieved<sup>58</sup>. In the years to come, with more research, AI paired with human expertise can seize the vibrant and untapped potential of multimodal data in healthcare.

In predictive analytics for patient care, AI models can assist doctors in proactive patient care<sup>65</sup> and identify patients at risk of developing certain conditions or experiencing adverse events. Health professionals can intervene early, providing preventive care or adjusting treatment plans. In a recent study, an AI was able to predict which patients in the ICU are at high risk for sepsis, allowing healthcare teams to act swiftly and potentially save lives<sup>66</sup>.

Other areas with a high potential for fruitful collaboration include telemedicine and remote monitoring, especially in chronic disease management<sup>67</sup>, generative AI for surgery<sup>68</sup>, understanding disease phenotypes<sup>69</sup>, medical research, and clinical trials<sup>70</sup>.

AI collaboration with healthcare professionals is emerging and has yet to reach its full potential. There is still a need for large sample sizes for evaluating AI in healthcare, along with major ethical, fairness, and privacy concerns, especially in high-stakes applications, such as healthcare, to unlock the enormous potential of AI+human in healthcare<sup>71</sup>.

## 6. Invest in Training and Upskilling

AI has the potential to play a key role in medical training and education<sup>72</sup>. Through simulations and personalized learning platforms, AI applications provide medical students and professionals with state-of-the-art training opportunities. AI can also analyze performance and suggest areas for improvement.

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<sup>63</sup> Eric J. Topol, As artificial intelligence goes multimodal, medical applications multiply. *Science* 381, eadk6139(2023). DOI:10.1126/science.adk6139

<sup>64</sup> Omics refers to the fields of study of a particular set of biological molecules such as genome, microbiome, metabolome, immunome, cellular-level transcriptome, proteome, and epigenome.

<sup>65</sup> Rajkomar, A., Dean, J., & Kohane, I. (2018). "Machine learning in medicine." *New England Journal of Medicine*, 380(14), 1347-1358.

<sup>66</sup> Adams, R., Henry, K.E., Sridharan, A. et al. Prospective, multi-site study of patient outcomes after implementation of the TREWS machine learning-based early warning system for sepsis. *Nat Med* 28, 1455–1460 (2022). <https://doi.org/10.1038/s41591-022-01894-0>

<sup>67</sup> Bini, S. A. (2018). "Artificial intelligence, machine learning, deep learning, and cognitive computing: What do these terms mean and how will they impact health care?" *The Journal of Arthroplasty*, 33(8), 2358-2361.

<sup>68</sup> Rodler S, Ganjavi C, De Backer P, Magoulianitis V, Ramacciotti LS, De Castro Abreu AL, Gill IS, Cacciamani GE. Generative artificial intelligence in surgery. *Surgery*. 2024 Jun;175(6):1496-1502. doi: 10.1016/j.surg.2024.02.019. Epub 2024 Apr 6. PMID: 38582732.

<sup>69</sup> Wright JT, Herzberg MC. Science for the Next Century: Deep Phenotyping. *Journal of Dental Research*. 2021;100(8):785-789. doi:10.1177/00220345211001850

<sup>70</sup> Esteva, A., et al. (2019). "A guide to deep learning in healthcare." *Nature Medicine*, 25(1), 24-29.

<sup>71</sup> Jenna Wiens, Suchi Saria, Mark Sendak, Marzyeh Ghassemi, Vincent X. Liu, Finale Doshi-Velez, Kenneth Jung, Katherine Heller, David Kale, Mohammed Saeed, Pilar N. Ossorio, Sonoo Thadaney-Israni, and Anna Goldenberg. Do no harm: a roadmap for responsible machine learning for health care. *Nature Medicine*, 25(9):1337–1340, 2019.

<sup>72</sup> Chan, T. M., et al. (2020). "AI in medical education: The potential and the pitfalls." *JAMA Network Open*, 3(1), e2025404.

It is important to leverage different mediums and adopt interdisciplinary approaches in healthcare technology, and integrating technology into medical education.

## 7. Address Ethical and Legal Implications

Although regulating AI in healthcare is a complicated problem, there are possible answers. To guarantee that AI is applied to improve healthcare systems around the world based on the concepts of fairness and health equity, precise rules and standards are required. Guidelines and recommendations at the national, regional, and worldwide levels ought to be as specific as possible, taking into account a number of crucial issues such as data privacy, informed permission, security, accuracy, and ethics when using gathered health data.

Third-party unauthorized access is unethical as well as a breach of informed consent and data privacy. It is important to address potential risks like cybersecurity; self-adaptive AI technologies may be able to help. Government agencies will have to establish new oversight organizations or grant current watchdogs additional authority and responsibilities. Regulatory agencies like the Medicines and Healthcare Products Regulatory Agency (UK) and the Food and Drug Administration (US) monitor all stakeholders and make sure they comply with their obligations regarding privacy, efficiency, safety, and quality during audits and inspections.

Promoting accountability and openness is essential because IT businesses are aware that their sharing practices could have serious repercussions, including financial penalties. If there are any security or privacy breaches involving data, they should also be held responsible. Since codes of behavior can support international standards like data protection, self-regulation needs to be supported. Governments and international organizations must work together to unify national laws and to advance the ethical and safe application of AI systems.

## 8. Address Acceptance from Healthcare Workforce

Successfully adopting AI in healthcare requires a structured change management plan that addresses potential resistance and promotes acceptance among healthcare workers<sup>73</sup>. This plan includes comprehensive training programs, transparent communication about AI's benefits, and phased implementation strategies. Involving healthcare workers in the development and refinement of AI tools ensures that the technology is user-friendly and aligns with clinical needs. Addressing ethical concerns, such as data privacy and bias, is also crucial for gaining trust and ensuring the successful integration of AI.

To further ease the transition, it is essential to create a culture that embraces innovation and continuous learning. This involves not only formal training but also fostering an environment where healthcare workers feel supported in adopting new technologies<sup>74</sup>.

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<sup>73</sup> Forouzanfar, M. (2024). The role of AI in hospitals and clinics: Transforming healthcare in the 21st century. *Bioengineering*, 11(4), 337. <https://doi.org/10.3390/bioengineering11040337>

<sup>74</sup> Wears, R. L., & Berg, M. (2005). Computer technology and clinical work: Still waiting for Godot. *JAMA*, 293(10), 1261-1263. <https://doi.org/10.1001/jama.293.10.1261>

Encouraging feedback and open dialogue can help identify challenges early and allow for timely adjustments to the implementation strategy. Additionally, showcasing early successes and sharing positive outcomes can build momentum and confidence in AI initiatives, ultimately leading to smoother adoption across the organization.

Key Points:

- A structured change management plan is essential for AI adoption in healthcare.
- Training, communication, and involvement of healthcare workers are critical for successful AI integration.

## Conclusion

AI will play a significant part in future healthcare services. Securing the technologies' integration into routine clinical practice is a bigger problem for AI in various healthcare sectors than the technologies' potential usefulness. The approval of regulators, integration with EHR systems, standardization to the extent that comparable products function similarly, clinician education, payment from public or private payer organizations, and ongoing field updates are all necessary for the widespread adoption of AI systems. In the end, these obstacles will be overcome, but it will take a lot longer than it takes for the technology to advance. Thus, we anticipate that within five years, there will be a limited application of AI in clinical practice, and within ten, a more widespread use.

The term "AI chasm" refers to the fact that few models have advanced past retrospective creation or validation despite the explosive expansion of AI applications in healthcare. Even fewer of the models that have advanced to randomized controlled trials have shown clinically significant advantages. This fact serves as a grim reminder that it is still very difficult to translate AI algorithms from in silico settings to actual clinical settings. A substantial risk of bias during model building or dataset alterations during prospective validation could be the cause of this translational gap.