LEGAL AND ETHICAL DIMENSIONS OF ARTIFICIAL INTELLIGENCE IN MEDICAL DECISION-MAKING

Dissertation submitted to the National University of Advanced Legal Studies, Kochi in partial fulfilment of the requirements for the award of LL.M. Degree in Public Health Law

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Submitted by:

Gayathri P R

(Register Number: LM0324004)

Under the Guidance and Supervision of

Dr. Namitha K L

Assistant Professor

May 2025

NUALS, Kochi

CERTIFICATE

This is to certify that **Gayathri P R (Reg. No.: LM0324004)** has submitted her Dissertation titled **"Legal and Ethical Dimensions of Artificial Intelligence in Medical Decision-Making"** in partial fulfillment of the requirement for the award of Degree of "Master of Laws in Public Health Law" to the National University of Advanced Legal Studies, Kochi under my guidance and supervision.

It is also affirmed that, the dissertation submitted is original, bonafide and genuine.

Date: **28th May, 2025**

Place: **Ernakulam**

Dr. Namitha K L

Guide and Supervisor

NUALS, Kochi

DECLARATION

I, Gayathri P R, do hereby declare that this Dissertation titled "**Legal and Ethical Dimensions of Artificial Intelligence in Medical Decision-Making",** researched and submitted by me to the National University of Advanced Legal Studies, Kochi in partial fulfillment of the requirement for the award of Degree of "Master of Laws in Public Health Law", under the guidance and supervision of Dr. Namitha K L, Assistant Professor, NUALS, Kochi, is an original, bonafide and legitimate work and it has been pursued for an academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this University of any other University.

Date: **28th May, 2025**

Place: **Ernakulam**

Gayathri P R

Reg. No.: LM0324004

LL.M., Public Health Law

NUALS, Kochi

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Gayathri P R

LM0324004

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LIST OF ABBREVIATIONS

AI	Artificial Intelligence
US	United States
FDA	Food and Drug Administration
ML	Machine Learning
DL	Deep Learning
NLP	Natural Language Processing
CT	Computed Tomography
MRI	Magnetic Resonance Imaging
OCT	Optical Coherence Tomography
ICH	Intracranial Haemorrhage
PE	Pulmonary Embolism
ESM	Epic Sepsis Model
RPM	Remote Patient Monitoring
CDSS	Clinical Decision Support Systems
CNN	Convolutional Neural Network
RNN	Recurrent Neural Network
SARs	Socially Assistive Robots
AIST	Advanced Industrial Science and Technology
EHR	Electronic Health Records
CBT	Cognitive Behavioural Therapy

PHM	Population Health Management
NLOS	National Liver Offering Scheme
CVD	Cardiovascular disease
UDHR	Universal Declaration of Human Rights
ECHR	European Convention on Human Rights
HIPAA	Health Insurance Portability and Accountability Act
MoHFW	Ministry of Health and Family Welfare
MCI	Medical Council of India
NHP	National Health Policy
NMC	National Medical Commission
NITI	National Institution for Transforming India
NHA	National Health Authority
NSAI	National Strategy for Artificial Intelligence
CORE	Centres of Research Excellence
NDHM	National Digital Health Mission
UDI	Unique Device Identification
ABDM	Ayushman Bharat Digital Mission
DPDPA	Digital Personal Data Protection Act
ICMR	Indian Council of Medical Research
IT	Information Technology
SDPI	Sensitive Personal Data or Information
MDR	Medical Devices Rules
CDSCO	Central Drugs Standard Control Organisation

TGA	Therapeutic Goods Administration
WHO	World Health Organisation
LMMs	Large Multi-Modal Models
GPAI	Global Partnership on Artificial Intelligence
UNESCO	United Nations Educational, Scientific and Cultural Organization
EC	Ethics Committee
OECD	Organisation for Economic Cooperation and Development
HITL	Human in the Loop
SaMD	Software as a Medical Device
IMDRF	International Medical Device Regulators Forum
RMP	Registered Medical Practitioners
IoT	Internet of Things
GDPR	General Data Protection Right
SDF	Significant Data Fiduciary
DPBI	Data Protection Board of India
CAC	Cyberspace Administration of China
NMPA	National Medical Products Administration
R&D	Research and Development
PIPL	Personal Information Protection Law
DISER	Department of Industry, Science, Energy and Resources
EU	European Union

IVDR	In Vitro Diagnostic Medical Device Regulation
MHRA	Medicines and Healthcare Products Regulatory Agency
CMA	Competition and Markets Authority
Ofcom	Office of Communications
DSIT	Department for Science, Innovation and Technology
GMLP	Good Machine Learning Practices
ONC	Office of the National Coordinator for Health Information Technology
FTC	Federal Trade Commission
HTI	Health Data, Technology, and Interoperability
CMS	Centers for Medicare & Medicaid Services
TPLC	Total Product Life Cycle

TABLE OF CASES

Sl.no.	**Case title**
1.	Dinerstein v. Google LLC, No. 20-3134 (7th Cir 2023)
2.	K.S. Puttaswamy v. Union of India (2017) 10 SCC 1

CHAPTER 1

INTRODUCTION

1.1 Introduction

Artificial intelligence (AI) stands as a highly promising technological advancement in the coming decade, with the healthcare industry poised to reap significant advantages through its integration. AI in medicine has enormous potential to address key healthcare obstacles such as lack of medical professionals, inadequate infrastructure and facilities, escalating healthcare costs, and difficulties implementing novel technology due to the complex healthcare system. This potential is particularly relevant in a diverse country like India, where the public healthcare system faces acute shortages of healthcare workers and medical facilities. Many primary health centres (PHCs) and sub-centres lack essential infrastructure, diagnostic equipment, and other critical resources, making it hard to provide even basic healthcare services to large and varied sections of the population. Artificial intelligence can transform healthcare by significantly improving its access, quality, and efficiency, particularly in underserved and remote areas.

Integrating Artificial Intelligence in healthcare offers a transformative potential to revolutionize patient care by enhancing clinical efficiency, resulting in improved health outcomes. AI-driven predictive analytics can significantly increase the accuracy and efficiency of disease diagnosis and clinical laboratory testing. AI can support population health management and the development of clinical guidelines by providing real-time, precise information that optimizes treatment choices. By rapidly and efficiently processing vast amounts of data, AI systems can support healthcare professionals in medical decision-making capacity by assessing patient data, identifying patterns, and offering evidence-based recommendations. Artificial Intelligence systems generate insights that can enhance the approach to complex healthcare challenges such as triage, stratifying patients for interventions, identifying those most at risk of imminent decompensation, limiting unnecessary and inappropriate assessments, and evaluating multiple small outcomes to optimize overall patient outcomes. Furthermore, AI algorithms can evaluate a patient's medical history and suggest tailored treatment options for a specific condition, helping clinicians choose the most effective interventions.

Medical decision-making capacity refers to an individual's ability to comprehend relevant medical information, recognize the implications and consequences of proposed treatments, and make informed choices based on their values and preferences. Respecting patients' rights to autonomy and self-determination is vital in allowing them to make their own healthcare decisions. However, as artificial intelligence increasingly plays a role in healthcare, it introduces a challenge to maintaining this autonomy. Aligning AI's embedded values with patient priorities is a significant ethical concern. AI systems may prioritise quantifiable outcomes, such as survival rates, clinical efficiency, or cost-effectiveness, which can conflict with patients' subjective experiences, personal values, or quality-of-life goals. This mismatch can potentially undermine patient autonomy, especially when AI recommendations conflict with a patient's beliefs, or preferences. In such cases, the ethical principle of informed consent may be compromised, as patients may feel pressured to accept recommendations that do not fully reflect their individual priorities or understanding of their condition.

The opacity of AI systems can make it challenging to comprehend how decisions are reached, hindering medical practitioners' ability to interpret and justify AI-driven diagnoses and treatments. Medical practitioners rely not only on the accuracy of AI recommendations but also on understanding the rationale behind them so they can confidently communicate treatment options to patients. Healthcare providers may be reluctant to trust or adopt AI-driven solutions without sufficient transparency. Despite growing concerns regarding transparency, the ongoing debate questions whether a lack of explainability impedes clinical outcomes. While some contend that explainability is fundamental in cultivating trust and enhancing the clinical decision-making process, others posit that AI systems could still provide value even without full transparency, especially when their results are consistently accurate. Nonetheless, for artificial intelligence to be seamlessly incorporated into the healthcare sector, it is imperative to achieve a harmonious balance. This entails guaranteeing that such systems are not only efficient but also interpretable, thereby enabling healthcare providers to make well-informed decisions and patients to have confidence in the care they receive.

Traditionally, trained clinicians have led patient care, bearing professional accountability through established codes of conduct and facing legal responsibilities under both civil and criminal law. If an AI system makes an error or provides incorrect recommendations, it is important to determine who is accountable. The accountability could lie with the developers of the AI system, the healthcare providers who employed it, or the healthcare institutions that adopt these systems. Therefore, it is imperative to delineate clear lines of accountability between technologists, healthcare providers, and institutions to ensure that AI is used effectively and safely in medical decision-making. The legal question of liability for AI-driven medical errors remains unresolved under existing tort law and professional negligence standards. In India, the absence of a specific legal framework for liability further complicates the attribution of fault, creating hurdles in determining legal responsibility when AI-assisted care leads to harm.

Privacy and data security concerns are important, as developing robust algorithms relies on large volumes of sensitive patient data. Data privacy breaches can have serious implications for an individual's autonomy and dignity. There have to be proper data governance frameworks to safeguard personal information, maintain strict privacy protocols, and uphold rigorous ethical standards. The Digital Personal Data Protection Act (DPDPA) 2023, yet to be enforced, introduces consent-based data processing. However, it falls short by not providing clear guidelines on how secondary health data can be used for training AI models, creating a significant legal and ethical void. Algorithmic bias poses another significant risk. Algorithmic bias denotes systematic and unfair discrimination against certain groups based on the data used to train AI models. Algorithmic biases in AI-integrated medical applications may perpetuate or exacerbate societal biases, leading to unfair and discriminatory healthcare practices. In diverse populations, such as those in India, where genetic, cultural, and socioeconomic factors vary widely, the use of biased algorithms could result in healthcare solutions that are not tailored to the specific needs of each individual. Furthermore, as AI models train on specific datasets, their performance may deteriorate in the long run or when applied to different populations, resulting in further inconsistencies in care.

Ultimately, the successful integration of AI into clinical decision-making hinges on the healthcare sector's ability to balance technological innovation with ethical responsibility. Addressing the legal and ethical implications is vital in order to uphold patient autonomy and privacy, mitigate potential biases, ensure accountability in clinical decision-making, and preserve the overall integrity of the healthcare system. A balanced approach is crucial to navigating these complexities while ensuring that AI technologies are implemented responsibly without reinforcing existing disparities or introducing new ethical dilemmas.

1.2 Statement of Problem

AI in healthcare offers significant benefits, such as enhancing decision-making processes and improving patient care. However, there exists a significant gap in understanding the ethical and legal implications of its application. The existing framework of regulations does not adequately address the complexities of patient rights, algorithmic transparency and explainability, the accountability and oversight of AI systems, clarity on liability, and the potential for algorithmic bias and discrimination, leading to uncertainties in both practice and policy.

1.3 Research Objectives

- To analyse the ethical implications of Artificial Intelligence in medical decision-making, emphasizing issues such as patient autonomy, informed consent, and bias.

- To examine the existing legal frameworks governing Artificial Intelligence technologies in healthcare, assessing their adequacy and effectiveness.

- To identify the gaps in current regulations and propose recommendations for policy improvements to address identified ethical and legal challenges.

1.4 Research Questions

1) What are the major ethical concerns associated with using AI in medical decision-making?

2) How does AI impact patient autonomy and informed consent in healthcare, and how can consent processes be adapted to accommodate AI-driven decision-making?

3) How does algorithmic bias in AI-driven healthcare systems impact patient outcomes?

4) How do existing legal frameworks address the integration of AI in healthcare, and are the existing legal frameworks adequate to address the challenges posed by AI in medical decision-making?

5) To what extent should AI be allowed to take over decision-making in critical healthcare situations?

6) How can healthcare providers balance the significant advancements of AI with ethical obligations and legal responsibilities?

7) How can AI technologies be regulated to ensure equitable access to healthcare and avoid exacerbating healthcare disparities, especially in diverse populations?

1.5 Hypothesis

1. AI in healthcare offers significant benefits in improving medical decision-making and patient outcomes, but it also raises ethical challenges that compromise patient autonomy, privacy and informed consent.
2. Existing legal frameworks are insufficient to address the unique challenges presented by AI in medical decision-making.

1.6 Methodology

The methodology applied in this study is a doctrinal research method. This legal research technique employs a systematic approach that emphasizes the examination of existing legal principles, legislation, cases, authoritative books, research journals, scholarly articles, and other relevant publications to critically analyse the current gamut of the problems.

1.7 Scope and Delimitation

- The study primarily focuses on the ethical and legal implications of AI in healthcare.
- It will examine issues such as patient autonomy, informed consent, accountability and liability, algorithmic bias, data privacy and the potential for AI to conflict with patient values in medical decision-making.
- The scope will cover the effects of AI integration on both healthcare professionals and patients, particularly regarding decision-making, transparency, and the overall quality of care.
- This study will not explore the technical details of AI systems or their specific applications in healthcare in depth.
- As doctrinal research, it will primarily draw upon existing legal principles, legislation, and scholarly articles**.**

1.8 Literature Review

AI-based technologies can democratize healthcare access by enhancing clinical efficiency and improving health outcomes. AI-powered diagnostic tools can outperform human experts in accuracy, speed, and precision, addressing the critical shortage of physicians in developing nations. Furthermore, AI can uncover complex relationships within large datasets, generating novel insights that could lead to breakthroughs in medical knowledge.[1]

[1] Debesh Jha et al., *Ensuring Trustworthy Medical Artificial Intelligence through Ethical and Philosophical Principles*. arXiv, 2304.11530 (2023) https://doi.org/10.48550/arXiv.2304.11530

Various applications use AI to improve healthcare. For instance, Google's AI-based application called Automated Retinal Disease Assessment can analyse retinal images and give physician-level specificity and sensitivity to detect early signs of diabetic retinopathy. This enables timely intervention and has the potential to reduce preventable blindness significantly.[2]

Apollo Hospitals has integrated IBM's Watson for Oncology and Watson for Genomics platforms to enhance physician decision-making in cancer treatment. Watson for Oncology, developed in collaboration with Memorial Sloan Kettering Cancer Center, assists oncologists by providing evidence-based treatment recommendations. Watson for Genomics analyses extensive genomic, clinical and pharmacological data to identify potential treatment strategies to target genetic alterations in a patient's tumour.[3]

Niramai Health Analytics, an Indian startup based in Bangalore, has created an affordable and non-invasive method for screening breast cancer by utilizing body heat tracking technology integrated with artificial intelligence known as Thermalytix. Its SMILE-100 System has also obtained authorization from the US FDA for its distinctive breast cancer screening solution that is radiation-free, non-contact, and precise. This system empowers healthcare providers to enhance their decision-making process for breast cancer screening and diagnosis by allowing them to visualize areas of high thermal activity as hotspots on thermal imaging. This particular technique has the ability to identify cancer cells a full five years prior to when mammography and other more intrusive tests can do so. This method utilizes a non-contact and portable technology that costs just one-tenth of the price of traditional mammography.[4]

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[2] *Using AI to Prevent Blindness*, GOOGLE HEALTH, https://health.google/caregivers/arda/ (last visited Nov. 1, 2024).

[3] *Apollo Hospitals Adopts IBM Watson for Oncology and IBM Watson for Genomics to Help Physicians Make Data-Driven Cancer Care Decisions*, IBM NEWSROOM (May 22, 2018), https://in.newsroom.ibm.com/2018-05-22-Apollo-Hospitals-Adopts-IBM-Watson-for-Oncology-and-IBM-Watson-for-Genomics-to-Help-Physicians-Make-Data-Driven-Cancer-Care-Decisions.

[4] Sudip Bhattacharya et al., *Expanding the Horizon for Breast Cancer Screening in India Through Artificial Intelligent Technologies - A Minireview,* 4 Front. Digit. Health 1082884 (2022), https://doi.org/10.3389/fdgth.2022.1082884

A study conducted in the U.S. highlights significant racial bias in a widely used predictive algorithm for healthcare management, demonstrating that at a given similar risk score, Black patients are considerably sicker than White patients. The bias arose due to the algorithm's reliance on healthcare costs as a proxy for healthcare needs. If medical AI systems exhibit racial bias, patients from certain racial backgrounds may be denied access to healthcare or receive delayed diagnoses or misdiagnoses, negatively taking hold of their health outcomes and quality of life. This study shows how the use of ostensibly effective but flawed proxies can perpetuate and even exacerbate existing racial inequities in healthcare access and intervention.[5]

The integration of Artificial Intelligence, specifically multimodal models like GPT-4V, into medical decision-making presents significant risks that warrant thorough evaluation. Despite achieving a higher multi-choice accuracy when compared to medical professionals, GPT-4V frequently demonstrated flawed rationales, particularly in image comprehension. This inconsistency raises concerns about relying on AI to make accurate medical judgments, as correct decisions based on incorrect reasoning may lead to inappropriate clinical actions. Furthermore, while GPT-4V performs well in recalling medical information, it demonstrates a lack of sound reasoning, especially in complex clinical scenarios, thereby underscoring the limitations of AI technology. [6]

As the advancements of AI technologies progress, there is a growing concern about the accountability for inaccuracies that could occur as a result of the lack of transparency in AI systems. The intricate algorithms utilized by AI, often referred to as "black boxes," can obscure the processes through which decisions are made, making it difficult to trace culpability back to the developers or operators. This gives rise to significant ethical and legal concerns regarding who is liable when AI systems err in clinical settings, especially given that patients are vulnerable during their interactions with healthcare providers. The phenomenon of "ever-widening" accountability gaps prompts alarms regarding not only the moral framework within society but also the foundational principles of legal liability. Establishing clear governance

[5] Ziad Obermeyer, Brian Powers, Christine Vogeli, Sendhil Mullainathan, *Dissecting racial bias in an algorithm used to manage the health of populations*, 366 Science, 447-453 (2019) https://doi.org/10.1126/science.aax2342

[6] Qiao Jin et al., *Hidden flaws behind expert-level accuracy of multimodal GPT-4 vision in medicine,* 7 npj Digit. Med., 190 (2024). https://doi.org/10.1038/s41746-024-01185-7

frameworks that delineate responsibilities and ensure patient safety is crucial, as current regulations may not adequately address these emerging challenges. Taking proactive measures to address these can help mitigate the risks associated with AI, paving the way for more accountable and transparent healthcare practices.[7]

1.9 Chapterisation

Chapter 1: Introduction

Chapter 2: Advancements in AI Technologies for Healthcare

Chapter 3: Ethical Implications of AI in Medical Decision-Making

Chapter 4: Legal Frameworks Governing AI in Healthcare

Chapter 5: International Perspectives on AI in Healthcare

Chapter 6: Conclusion

[7] Nithesh Naik et al., *Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility?*, 9 Front. Surg. 862322 (2022). https://doi.org/10.3389/fsurg.2022.862322

CHAPTER 2

ADVANCEMENTS IN AI TECHNOLOGIES FOR HEALTH CARE

2.1 Components and AI Methodologies relevant to healthcare

A wide range of key AI technologies and components are driving transformative changes in healthcare, playing a pivotal role in advancing patient care, optimising clinical processes, and enhancing overall healthcare outcomes. AI is a collection of subfields, including machine learning (ML), neural networks, deep learning (DL), and natural language processing (NLP), each contributing to the intelligence of various applications.[8]

Machine Learning (ML) is a subset of AI that enables computers to learn from data and examples without being explicitly programmed with instructions. Instead, it recognises patterns in the data and predicts outcomes. Machine learning encompasses different types. In supervised learning, algorithms are trained using a labelled dataset, wherein the correct answers are provided and are then utilised to make predictions. Conversely, unsupervised learning does not depend on labelled data; instead, it identifies patterns within the unlabelled dataset. Semi-supervised learning falls between the two, employing a small, labelled dataset for learning and subsequently applying those insights to a larger, unlabelled dataset.

In the field of healthcare, ML models are used for predictive analytics, such as the identification of patients at risk of diseases like diabetes, cardiovascular diseases or cancer by examining their medical records, genetic markers, and lifestyle factors. Machine learning models are also capable of analysing genomic data, lifestyle factors, and real-time health metrics to suggest the most optimal treatment for each patient. Beyond patient care, healthcare institutions can employ machine learning to streamline healthcare operations. Predictive models can

[8] Vidhate S V*, An Overview: Artificial Intelligence and Technology in Enhancing Quality of Health*, 12(11) IJCRT, d6 (2024).

potentially aid hospitals in the management of resources, including staffing, equipment, and bed availability, by forecasting patient admissions.[9]

Deep learning is a specialised and advanced subset of machine learning that utilises multilayered artificial neural networks to analyse large, raw, and unstructured datasets to understand complex relationships akin to the functioning of the human brain. Deep learning models have demonstrated potential in the field of medical imaging, where they can analyse radiology scans, detect abnormalities, and recommend potential diagnoses with a significant level of accuracy. Beyond imaging, deep learning is also being employed for drug discovery, in which models are capable of predicting the interactions between molecules, thereby accelerating the process of recognising potential treatments. Notably, deep learning models used in drug discovery are increasingly attracting the attention of regulatory agencies. It can be now seen that the US Food and Drug Administration (FDA) has begun acknowledging AI-based platforms under its Digital Health Innovation Action Plan, marking a shift towards regulatory support for AI-driven innovations in drug development. Additionally, deep learning algorithms are utilised in personalised medicine to analyse patient data and recommend tailored treatment plans based on individual health profiles.

Natural language processing (NLP) allows AI systems to understand, process, analyse, and generate human language in a way that is both meaningful and beneficial. In the field of healthcare, NLP technology has the potential to harness relevant insights and concepts from unstructured data like medical notes, research papers, and patient histories. By extracting meaningful and valuable insights from this data, NLP helps healthcare providers make better decisions, improve patient care, and streamline administrative tasks.

[9] *Harnessing the Power of Machine Learning in Predictive Analytics for Health,* https://www.grgonline.com/post/harnessing-the-power-of-machine-learning-in-predictive-analytics-for-health (last visited December 18, 2024).

2.2 Applications of AI

Applications of AI technologies can offer substantial improvements in healthcare across various domains, including diagnostics, treatment, operational efficiency and public health initiatives. AI-powered tools can perform on par or better than humans in various tasks with great accuracy, speed, and precision, addressing the critical shortage of physicians in developing nations.[10] A key motivator for adopting AI applications is the cost reductions that AI can bring to the healthcare system. These applications are particularly beneficial in underserved regions, where access to specialists is limited. Moreover, the capability of AI to analyse large datasets can uncover complex patterns and relationships, potentially leading to breakthroughs in medical research and improving patient care.

2.2.1 AI-based Diagnostic Systems

Over the past couple of years, AI has expanded substantially in the domain of medical diagnostics, thereby enabling medical researchers and doctors to provide flawless clinical practice. Traditional diagnostic methods often heavily depend on physician clinical experience and manual review, which can be time-consuming and subject to variability between observers. In contrast, the AI systems can process complex, multidimensional clinical and genomic datasets in real time, thereby reducing inter-observer variability, expediting decision-making, delivering consistent results, and minimising diagnostic delays.

One of the most eminent applications of AI in healthcare is in medical imaging, where it is integrated into diagnostic techniques such as X-rays, CT scans, MRIs, and histopathology slides to identify patterns that may be difficult to detect with the human eye. AI supports multiple stages of the imaging workflow, including image acquisition, pre-processing, interpretation, and follow-up. During acquisition, AI can optimise scan parameters and ensure that images meet diagnostic quality standards, reducing the need for repeat scans and minimising patient exposure to radiation. Once images are obtained, AI algorithms can automatically organise and categorise them, highlight regions of interest, and flag potential abnormalities for further review. These systems can detect abnormalities such as tumours, fractures, haemorrhages and infections. It is also equally impactful in non-imaging diagnostics

[10] Supra 1

such as laboratory test results, genomic sequences, and patient-reported symptoms. AI thus not only enhances diagnostic precision but also reduces reporting time and assists in prioritising urgent cases.

Google's DeepMind has developed an advanced AI system capable of diagnosing a range of eye diseases, including age-related macular degeneration, glaucoma, retinal vein occlusion, diabetic retinopathy, and other vision-threatening conditions, by analysing optical coherence tomography (OCT) scans.[11]

Aidoc, an FDA-approved AI imaging technology, have created AI tools that assist radiologists by automatically flagging critical abnormalities such as intracranial haemorrhages, pulmonary embolisms, spinal fractures, and free air in the abdomen. A notable study by Cedars-Sinai Medical Center found that Aidoc's AI-augmented radiological worklist triage solution reduced the length of stay for patients with intracranial haemorrhages by 1.3 days (11.9%) and pulmonary embolisms (PE) by 2.07 days (26.3%).[12]

Enlitic, a US-based medical imaging startup, uses AI algorithms designed to detect tumours in human lungs from Computed Tomography (CT) scans.[13]

Epic Systems' AI-powered Epic Sepsis Model (ESM) can be deployed in hospital settings to continuously monitor patient data, which alerts clinicians when a patient's risk of sepsis increases, allowing for timely intervention and potentially reducing mortality rates.[14]

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[11]Rishi Reddy Kothinti, *Artificial Intelligence in Disease Prediction: Transforming Early Diagnosis and Preventive Healthcare*, 9(5) IJNRD (2024).

[12]Michael Petry et al., *Decreased Hospital Length of Stay for ICH and PE after Adoption of an Artificial Intelligence-Augmented Radiological Worklist Triage System*. Radiol Res Pract. 1 (2022). https://doi.org/10.1155/2022/2141839

[13]Oleksandr Maidaniuk, *AI and Medical Imaging: Transforming Diagnosis & Care* (Apr. 12, 2024), https://intellias.com/using-ai-in-medical-imaging-to-augment-radiologists-efforts/

[14]John Cull, *Epic Sepsis Model Inpatient Predictive Analytic Tool: A Validation Study, 5*(7) CCE, e0941 (2023). https://doi.org/10.1097/CCE.0000000000000941

2.2.2 Drug Discovery and Development

Drug discovery and development have always been a complex process, often requiring extensive time and significant financial investment. However, artificial intelligence is fundamentally transforming this field within the healthcare system by significantly accelerating research efforts. AI-driven algorithms rapidly analyse massive biomedical datasets, identifying novel drug targets and predicting potential drug candidates more quickly and accurately than traditional methods. This reduces both time and cost in the drug discovery pipeline. It helps researchers understand diseases better, identify potential drug candidates, and predict how these drugs interact with the human body.

AI can be applied effectively in different areas of drug discovery and development, including drug design, drug screening, poly-pharmacology, personalised medicine and drug repurposing.[15]

In drug discovery, AI helps in drug design by identifying the most promising molecular structures that could become effective drugs. It can predict how a molecule will interact with a disease target, thus reducing the lab's need for trial-and-error. Additionally, AI models also help optimise the drug's safety, stability, and absorption in the body. This shortens the design cycle and lowers the risk of failure. Insilico Medicine, a biotechnology company, used AI to design a novel drug candidate for pulmonary fibrosis, a chronic and fatal lung disease that leads to a gradual and irreversible decline in lung function. The entire process took less than 18 months, a timeline that typically spans several years using traditional methods.

AI is also helpful in drug development, which includes testing how safe and effective a new drug is**.** It can simulate how a drug might interact with human cells, tissues, and organs using sophisticated computational models. These simulations help researchers predict a drug's behaviour, potential toxicity, and therapeutic effects before it ever enters a lab or clinical trial. Predicting drug toxicity during preclinical stages can decrease the failure rate and enhance the

[15] Debleena Paul et al., *Artificial intelligence in drug discovery and development,* 26(1), DruDis, 80–93. (2021). https://doi.org/10.1016/j.drudis.2020.10.010

efficiency of drug discovery.[16] It allows for the modification or elimination of unsafe compounds early in the pipeline, improving the chances that only the most promising and safest drugs move forward. By doing so, AI can significantly reduce the need for early-stage animal testing, saving time and resources while also addressing ethical concerns.

AI also advances the field of polypharmacology by enabling the intentional design of drugs that act on multiple biological targets, which is often necessary for treating complex diseases such as cancer, neurological disorders, and metabolic conditions. In addition to identifying beneficial multi-target interactions that enhance therapeutic effectiveness, AI can help minimise harmful off-target effects that may cause side effects or toxicity. This dual capability allows researchers to pursue a more strategic form of polypharmacology, allowing them to design drugs that are not only broadly effective but also selectively safe.

AI significantly enhances clinical trial design and execution by identifying the right patients for the trial. This not only accelerates recruitment but also improves the quality and diversity of trial populations, which leads to more reliable results. Additionally, AI helps optimise trial protocols by simulating various trial scenarios and identifying the most efficient designs, including the best dosage levels, timelines, and endpoints. During the trial itself, AI enables real-time monitoring of patient responses, which allows for early detection of adverse events and adaptive adjustments to the trial if needed. By making clinical trials more targeted, dynamic, and data-driven, AI ultimately reduces development time and brings effective treatments to market more quickly.

AI can aid in drug repurposing or repositioning, which is the process of identifying new therapeutic uses for existing drugs beyond their original indications. It provides significant advantages in terms of reduced development time and costs, particularly in addressing unmet medical needs in rare diseases.[17] BenevolentAI, a UK-based company, used its AI platform to

[16] Ashfaq Ur Rehman et al., *Role of artificial intelligence in revolutionizing drug discovery,* FMRE (2024). https://doi.org/10.1016/j.fmre.2024.04.021

[17] Lucas Cortial et al., *Artificial intelligence in drug repurposing for rare diseases: a mini-review. Front. Med*, *11*, 1404338. (2024). https://doi.org/10.3389/fmed.2024.1404338

identify the rheumatoid arthritis drug baricitinib as a potential treatment for COVID-19, leading to emergency use authorisation.[18]

AI also plays a major role in advancing personalised medicine by analysing patient-specific data such as genomics, proteomics, and clinical records to tailor treatments. It helps researchers to design drugs that improve efficacy and minimise adverse effects by matching therapies to individual genetic and disease profiles.

2.2.3 Precision Medicine

Currently, most medical care is guided by the expected response in an average patient; however, the concept of an "average patient" does not accurately reflect individual variability. It is essential to move away from the one-size-fits-all paradigm towards developing more precise methods to prevent and treat diseases.

AI serves a pivotal role in precision medicine and offers the potential for tailoring healthcare interventions for individuals based on their analysis of data, including disease profiles, diagnostic or prognostic information, or treatment responses. It takes into account the genomic variations as well as contributing factors of medical treatment, such as age, gender, geography, race, family history, immune profile, metabolic profile, microbiome, and environmental vulnerability.[19]

By identifying the intricate patterns within these data, AI can assist in predicting how a patient will respond to certain therapies, thereby enabling physicians to make more accurate decisions. The objective of precision medicine is to utilise individual biology rather than population biology at all stages of a patient's medical journey. The advantages of precision medicine

[18]Yadi Zhou, Fei Wang, Jian Tang et al., *Artificial intelligence in COVID-19 drug repurposing*, 2(12) The Lancet Digital Health, e667-76 (2020). https://doi.org/10.1016/S2589-7500(20)30192-8

[19] Emmanuel Fombu, *Predictive Medicine: Artificial Intelligence and Its Impact on Healthcare Business Strategy* (1st ed. Business Expert Press 2020).

include reduced healthcare costs, reduced adverse drug response, and enhanced effectiveness of drug action.

A compelling example of AI's role in precision medicine is seen in the treatment of medulloblastoma, the most common paediatric malignant brain tumour. Traditionally managed as a single disease, medulloblastoma is now recognised to consist of biologically distinct molecular subgroups, such as WNT, SHH, Group 3, and Group 4, each with unique genetic profiles, clinical outcomes, and therapeutic responses. This stratification was made possible through AI-assisted analysis of hundreds of tumour exomes. By identifying these subgroups, clinicians are now able to tailor therapies based on tumour biology, thus facilitating the delivery of the right treatment, at the right dosage requirements, to the right cohort of paediatric patients. For example, treatment intensity can be reduced in WNT-positive patients, who generally have excellent prognoses, while therapy may be intensified in Group 3 and Group 4 patients, who are at higher risk of relapse. In the SHH subgroup, AI has aided in uncovering age-specific variations and mutation patterns, such as TP53 mutations in older children, which help guide risk-adapted treatment decisions within this group.[20]

2.2.4 Personalised medicine

Personalised medicine marks a significant transformation in healthcare that focuses on customising medical treatment to the individual traits, preferences, and circumstances of each patient, moving beyond the traditional one-size-fits-all model. Personalised medicine extends beyond the biological subtyping of diseases and incorporates a holistic understanding of the individual. Al provides personalised treatment by analysing the individual's medical history, genetic makeup, response to treatments, environmental exposures, lifestyle factors, psychosocial context, and personal values.[21] This level of personalisation has the potential to enhance treatment efficacy and reduce adverse reactions, leading to better patient

[20] Kevin B. Johnson et al., *Precision Medicine, AI, and the Future of Personalized Health Care.* CTS, 14(1), 86–93 (2021). https://doi.org/10.1111/cts.12884

[21] Sushanta Kumar Das et al., *AI in Indian healthcare: From roadmap to reality,* 2 Intelligent Pharmacy 329–334 (2024). https://doi.org/10.1016/j.ipha.2024.02.005

experiences.[22] This approach acknowledges that effective healthcare must treat the individual as a whole, not just their disease.

For instance, in managing and treating chronic conditions like diabetes or hypertension, AI can help customise diet plans, optimise the timing and dosage of medication for individual patients, and tailor activity levels to a patient's daily routine and adherence patterns.

2.2.5 Patient monitoring and care delivery

AI technologies excel in continuous patient monitoring within inpatient settings by tracking vital signs such as heart rate, blood pressure, respiratory rate, activity levels, and behavioural patterns. These systems establish personalised baselines for each patient, enabling the early detection of deviations such as irregular heart rhythms, respiratory distress, or unusual movement. When such anomalies occur, AI algorithms can promptly identify and alert healthcare providers, allowing timely intervention before conditions deteriorate. In addition, AI is highly effective in remote patient monitoring (RPM) through the analysis of data from wearable devices, smart sensors, and telehealth platforms.

By processing vast volumes of patient data, AI can identify trends and evaluate responses to treatment, enabling the development of personalised care plans. These systems can recommend adjustments to medications, lifestyle changes, and follow-up schedules, ensuring that treatment remains responsive to each patient's ongoing needs.

In hospital settings, AI platforms such as LookDeep Health use computer vision to continuously monitor patients through video analysis. These systems identify behaviours linked to fall risk, patient isolation, and unsupervised movement. In a real-world deployment across 11 hospitals covering more than 1,000 patient-days, the platform showed high accuracy

[22] Adithya V Sabu, *Artificial Intelligence in Healthcare,* 8(3) IJNRD d473 (2023).

in recognising patient activities, allowing staff to respond quickly and help prevent falls and other incidents.[23]

2.2.6 Clinical Decision Support

Artificial Intelligence plays a crucial role in the domain of clinical decision-making by mimicking human cognitive functions such as reasoning, learning, and pattern recognition. The integration of AI into Clinical Decision Support Systems (CDSS) enhances clinicians' decision-making, treatment efficacy, and patient outcomes. AI-powered CDSS operate on a foundation of medical knowledge, algorithms, and patient data, aiming to bridge the gap between vast medical information and timely, informed clinical decisions. From diagnostic support to personalised treatment recommendations, risk prediction, and the facilitation of clinical documentation, AI-powered CDSS revolutionises traditional approaches, thus becoming a vital asset in modern medicine.[24] It can reduce healthcare costs and promote evidence-based practices.

AI-powered Clinical Decision Support Systems improve diagnosis by using deep learning to analyse medical images such as X-rays, MRIs, and pathology slides. For instance, researchers at Stanford University developed an AI system to assist in diagnosing skin cancer. The system uses deep learning, specifically convolutional neural networks (CNNs), to analyse dermoscopic images of skin lesions and distinguish between benign and malignant cases. It was trained on a dataset of over 130,000 images; the AI achieved dermatologist-level accuracy of 86.6 per cent in a clinical trial involving more than 1,000 images. In addition to matching expert diagnostic performance, the system delivers results within seconds, significantly faster than the average 11.9 seconds taken by human dermatologists.[25]

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[23] Paolo Gabriel et al., Continuous Patient Monitoring with AI: Real-Time Analysis of Video in Hospital Care Settings, 4 *Front. Imaging* (2025), https://doi.org/10.3389/fimag.2025.1547166.

[24]Malek Elhaddad & Sara Hamam, *AI-Driven Clinical Decision Support Systems: An Ongoing Pursuit of Potential,* 16(4) Cureus e57728 (2024), https://doi.org/10.7759/cureus.57728

[25]Andre Esteva, *Dermatologist-level classification of skin cancer with deep neural networks,* 542(7639) Nature 115–118 (2017). https://doi.org/10.1038/nature21056

AI-powered Clinical Decision Support Systems (CDSS) can recommend personalised treatment plans by integrating diverse patient data, including genetic profiles, comorbidities, and previous responses to therapy. The "AI Clinician" is a reinforcement learning algorithm developed to optimise the treatment of sepsis. It continuously learns from patient data and treatment outcomes to personalise therapy for individual patients. By dynamically adjusting treatment strategies, the system outperformed standard clinical protocols in simulation studies, indicating the potential for improved patient outcomes.[26]

AI-powered Clinical Decision Support Systems (CDSS) excel in predicting health risks and enabling early interventions. By utilising machine learning models and real-time patient data, these systems help clinicians identify individuals at elevated risk, enabling timely and focused medical responses. This risk stratification supports more efficient use of healthcare resources and improves patient care by preventing the progression of potentially serious conditions. Doctor AI, utilising Recurrent Neural Network (RNN) models, has been shown to assist in the early detection of heart failure onset.[27]

AI-powered Clinical Decision Support Systems can greatly help in clinical documentation by incorporating voice recognition and natural language processing capabilities. These systems easily integrate with clinical workflows and enable real-time documentation during patient encounters.

2.2.7 AI-Driven Robots

The use of artificial intelligence with robotics in the healthcare sector offers the potential to enhance patient outcomes and save costs by augmenting human abilities and assisting human healthcare professionals. AI robots are available in many different forms, such as exoskeletons,

[26]Matthieu Komorowski et al., *The Artificial Intelligence Clinician Learns Optimal Treatment Strategies for Sepsis in Intensive Care*, 24 Nat. Med. (2018), https://doi.org/10.1038/s41591-018-0213-5.

[27] Edward Choi et al., *Doctor AI: Predicting Clinical Events via Recurrent Neural Networks*, 56 *JMLR* Workshop & Conf. Proc. (2016).

mobile robots, and humanoid robots.[28] These include robots used for surgical procedures such as laparoscopic operations, robotic assistants for rehabilitation and patient assistance, robots that are integrated into implants and prosthetics, and robots used to assist physicians and other healthcare staff with their tasks.

AI-powered robots can execute surgical procedures with minimal invasiveness, greater precision and consistency, resulting in shorter recovery times and better patient outcomes.[29] The first surgical robots approved by the FDA were the Da Vinci Surgical System in the year 2000 and the ZEUS Robotic Surgical System in 2001, which have been improving over time.[30] Since then, many other surgical robots have been introduced for general laparoscopic surgical procedures, gynaecologic laparoscopic surgical procedures, urologic surgical procedures, orthopaedic surgeries, cardiothoracic surgeries, and neurosurgeries. The current generation of surgical robots is integrating AI into their systems, and in the near future, AI platforms such as Google's DeepMind, IBM Watson and other advanced AI tools are expected to deliver promising surgical interventions. IBM Watson has advanced medical cognitive and NLP capabilities that allow it to effectively respond to surgeon's queries. Further, similar AI platforms assist in real-time blood monitoring, detect physiological responses to pain, and offer navigation support during surgical procedures.

Socially assistive robots (SARs) are emotionally intelligent machines that can provide an alternate source of connection for interventions within health and social care.[31] It can give exclusive patient care by communicating with patients in a way that they respond emotionally. The different response types include interaction, communication, companionship, and emotional connection. Companies such as Blue Frog Robotics have developed BUDDY, and

[28]David B Olawade et al., *Artificial intelligence in healthcare delivery: Prospects and pitfalls,* Journal of Medicine, Surgery, and Public Health 3 (2024). https://doi.org/10.1016/j.glmedi.2024.100108

[29]Stephanie Ness*, Influence of AI: Robotics in Healthcare*, 17(5), AJRCOS 222-237 (2024). https://doi.org/10.9734/ajrcos/2024/v17i5451

[30] Yeisson Rivero-Moreno et al., *Robotic Surgery: A Comprehensive Review of the Literature and Current Trends*, 15(7) Cureus e42370 (2023). https://doi.org/10.7759/cureus.42370

[31] Bethany Nichol et al. *Exploring the impact of socially assistive robots on health and wellbeing across the lifespan: An umbrella review and Meta-analysis, 153* International Journal of Nursing Studies (2024). https://doi.org/10.1016/j.ijnurstu.2024.104730

the National Institute of Advanced Industrial Science and Technology, or AIST, have developed PARO and augmented the concept of companion robots to enhance safety, combat loneliness, and promote well-being. Judicious use of SARs in the healthcare system guarantees outstanding patient care, flawless medical procedures, and a safe atmosphere for patients and medical professionals.[32]

Wearable robotic devices are a game-changer for people with mobility challenges, offering support and guidance for their limb movements. They are especially beneficial for those individuals who are trying to recover from strokes, spinal cord injuries, or musculoskeletal issues. A project called ExoNet, developed by the University of Waterloo, merges computer vision with deep learning artificial intelligence to enable autonomous control of robotic exoskeletons. The development allows the robot to think and control itself without human intervention.[33]

AI-enabled cleaning and disinfection robots also play a role in transforming hygiene standards in healthcare environments by providing efficient and data-driven sanitation solutions. These autonomous systems use advanced sensors, AI algorithms, and real-time data processing to navigate complex hospital settings and guarantee thorough disinfection of surfaces. They reduce the need for manual cleaning, lower reliance on a large cleaning staff, and limit human exposure to pathogens.

Several healthcare facilities are trying to adopt AI-enabled cleaning and disinfection robots to meet strict hygiene protocols. Akara Robotics, a Dublin-based startup, has provided AI-enabled UV disinfection robots to a UK NHS hospital, where they are making their mark in the hospital's clinical decision unit, wards, and operating theatres. The robots use advanced AI

[32] Niyati Deo & Ashish Anjankar, *Artificial Intelligence with Robotics in Healthcare: A Narrative Review of its Viability in India*, 15(5) Cureus e39416 (2023). https://doi.org/10.7759/cureus.39416

[33] Angelica Marie Sanchez, *Taking a step towards self-walking robotic exoskeletons,* Waterloo News (Jan 6, 2022) https://uwaterloo.ca/news/global-impact/taking-step-towards-self-walking-robotic-exoskeletons

algorithms and a proprietary physics engine to autonomously navigate and deliver an exact dose of germ-killing treatment based on programmed cleaning instructions.[34]

AI-driven robots can efficiently handle tasks such as advanced patient monitoring, routine checkups, medical diagnosis, and streamlining hospital logistics and operations. Moxi is an AI-powered robot developed by Diligent Robotics to help hospital staff by performing non-patient-facing tasks. These tasks include delivering lab samples, obtaining medications, and transporting supplies, allowing nurses to focus more on patient care. Moxi integrates with hospital electronic health record systems to carry out tasks automatically based on clinical documentation and staff requests.[35]

AI-driven robotics also enables telemedicine and remote healthcare services, extending medical expertise to areas with limited access to healthcare facilities. It can be controlled by healthcare professionals from anywhere in the world, allowing them to interact and provide consultations to patients without being physically present. This ensures exclusive patient care and creates safer working conditions, reducing the risk of infection for healthcare providers.

2.2.8 AI-Powered Chatbots and Virtual Assistants

Chatbots and virtual assistants are tools that are designed to engage in either voice or text-based conversations and provide a range of services to facilitate communication with patients, healthcare providers, and other stakeholders.

Chatbots are typically used for specific tasks, such as answering patient questions, providing appointment reminders, or assisting with symptom checks based on predefined rules or limited AI. They may be integrated into websites, patient portals, or messaging platforms for quick interactions. Virtual assistants utilise advanced AI to offer a more comprehensive, multi-functional approach. It can understand complex patient queries, handle voice-based interactions, and integrate with multiple healthcare systems, offering a higher level of

[34] Akara, https://www.akara.ai/disinfection-robot (last visited Jan. 24, 2025)
[35] *Moxi*, https://www.diligentrobots.com/moxi/ (last visited May 1, 2025).

personalisation and functionality than chatbots. They can help with patient triage, medication management, managing health data, scheduling appointments, providing reminders, and even offering virtual consultations or managing chronic conditions through continuous monitoring.

Ada is an AI-driven symptom assessment tool that has been developed and optimised by clinicians. With over 14 million users and 35 million symptom assessments conducted, Ada ranks among the most popular symptom assessment applications available in the market.[36] Ada's chatbot is built on a rich medical knowledge base that encompasses information from clinical guidelines, scientific research, and expert insights. This helps to ensure that the recommendations offered are grounded in an evidence-based approach. Ada assists in analysing the symptoms and provides a list of possible conditions by employing a step-by-step approach that enables users to input the symptoms, allows follow-up questions to clarify the symptoms, and utilises the patient's medical history to refine the analysis. In addition to the symptoms, Ada also takes into account other factors such as age, sex, geographical location and lifestyle, thereby ensuring that the user receives a personalised health insight that is unique to their profile. Based on the assessment conducted, Ada offers recommendations regarding the subsequent steps, including self-care measures, and indicates whether the individual needs to consult a doctor immediately or later based on the symptoms and details about potential diagnosis. Ada is designed and maintained by healthcare professionals and doctors, thus ensuring both reliability and accuracy.[37]

Infermedica specialises in symptom assessment with AI-powered virtual triage, helping users to identify potential health conditions and navigate their healthcare options effectively. Infermedica facilitates the streamlining of patient intake processes and enhances access to care. The technology is clinically validated, performs accurately, and is designed to support healthcare providers in optimising workflows while enhancing patient engagement and satisfaction.[38]

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[36] Ada, https://ada.com/ (last visited Jan. 25, 2025)

[37]Dhivya Sudeep, *Next-Gen Patient Support: AI Chatbots in Healthcare*, 13(11) IJSR, 1425 (2024). https://dx.doi.org/10.21275/SR241124072157

[38] Infermedica, https://infermedica.com/ (last visited Jan. 25, 2025)

Woebot is a fully automated chatbot that employs artificial intelligence to deliver the users with accessible, on-demand support for mental well-being. Woebot engages users through interactive conversations based on concepts from Cognitive Behavioural Therapy (CBT) and other therapeutic approaches. NLP techniques are utilised by Woebot to build a human-like conversation interface to deliver services to patients, including psychological monitoring, psychological pattern analysis and psychological status improvement.[39] It offers tools for mood tracking, mindfulness practice, and emotional regulation, aiding individuals in the effective management of symptoms of anxiety and depression. While it does not replace clinical care, Woebot serves as a valuable adjunctive tool to clinical care. A randomised controlled trial conducted among college students evaluated the effectiveness of the Woebot in giving Cognitive Behavioural Therapy (CBT) and found that the Woebot notably decreased depressive symptoms.[40]

Similarly, Wysa is an AI-based, emotionally intelligent mobile chatbot designed for building mental resilience and promoting mental well-being through a text-based conversational interface.[41] It employs evidence-based self-help practices such as cognitive behavioural therapy, dialectical behaviour therapy, positive behaviour support, behavioural reinforcement, mindfulness, and guided micro actions, as well as tools to assist users in developing emotional resilience skills.[42]

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[39] Duckki lee, *AI-based Healthcare Chatbot*, 10(2) IRJET (2023).

[40]Kathleen Kara Fitzpatrick et al., *Delivering cognitive behavior therapy to young adults with symptoms of depression and anxiety using a fully automated conversational agent (Woebot): a randomized controlled trial*, 4(2) JMH (2017). https://doi.org/10.2196/mental.7785

[41] Raquel Simões de Almeida & Tiago Pereira da Silva, *AI Chatbots in Mental Health: Are We There Yet?*, Digital Therapies in Psychosocial Rehabilitation and Mental Health 226, 243 (IGI Global, 2020), https://doi.org/10.4018/978-1-7998-8634-1.ch011.

[42] Becky Inkster et al., *An Empathy-Driven, Conversational Artificial Intelligence Agent (Wysa) for Digital Mental Well-Being: Real-World Data Evaluation Mixed-Methods Study*, 6(11) JMIR mHealth and uHealth e12106 (2018). https://doi.org/10.2196/12106

2.2.9 Electronic Health Records

Electronic Health Records (EHRs) serve as digital repositories of patient health information in hospitals or health centres and mostly describe the periodic care provided to them. It could include identifying information, personal data like age and weight, medical history, diagnoses, drugs and allergies, immunisation records, laboratory results, radiological pictures, vital signs, and billing information.[43] EHRs are designed to support comprehensive documentation and enable continuous monitoring of a patient's health status over time.

While EHRs have greatly improved the accessibility and centralisation of patient data, they also introduce significant challenges, including data overload, fragmented documentation, inconsistent data entry, and usability issues for clinicians. AI helps in overcoming these challenges and unlocks the full potential of EHR systems in delivering efficient, accurate, and patient-centred healthcare.

One of the primary contributions of AI in EHRs is the automation of unstructured clinical data extraction from disparate sources such as physician notes, discharge summaries, referral letters, radiology and pathology reports, and even patient-generated health data. This data is then processed and interpreted by AI, which then structures and categorises it into meaningful clinical concepts such as symptoms, diagnoses, medications, and treatment regimen plans. This transformation enhances the usability of EHR data for clinical decision-making and minimises the need for clinicians to interpret manual data. Consequently, this reduces the cognitive and administrative burden on healthcare providers, helping to mitigate physician burnout and allowing greater attention to be directed toward patient care.

AI algorithms can triage patient queues, assign resources, and schedule tasks by considering factors such as clinical urgency, patient history, and resource availability. This capability enhances clinical workflow optimisation, expedites the delivery of healthcare, reduces wait times, and improves overall operational efficiency.

[43] Hamidreza Esmaeili & Mohebali Rahdar, *Artificial Intelligence and its Role in Electronic Patient Record*, 8(4) JPHR 333-343 (2023). https://doi.org/10.30491/hpr.2024.454379.1424

In addition, AI tools can cross-reference information from a wide range of sources, including patient history records, clinical terminology services, and third-party databases, to identify potential discrepancies, detect fraud, and ensure data integrity. These features also facilitate smart billing, automated medical coding, and real-time insurance eligibility verification, thereby improving revenue cycle management and lowering claim denials.

Atrium Health, a healthcare network in North Carolina employing around 70,000 staff, deployed Microsoft's DAX™ Copilot to streamline its administrative processes. The solution enables the automated creation of draft clinical summaries from in-person exams or telehealth patient conversations that can be quickly reviewed and finalised in the EHR system. As a result, clinicians save up to 40 minutes per day, and 84% of them report an improved documentation experience.[44]

2.2.10 Hospital operations and resource management

Artificial intelligence is transforming hospital operations and resource management by introducing data-driven automation, predictive analytics, and real-time optimisation, helping to address longstanding challenges such as increasing patient volumes, staffing shortages, and fragmented data systems that have traditionally been labour-intensive and inefficient.[45]

Predictive analytics embedded in hospital management platforms can forecast patient influx and thereby manage bed occupancy based on historical data, seasonal trends, and patient demographics. As a result, hospitals can proactively manage bed allocation, reduce overcrowding, eliminate supply overstocking, and minimise patient wait times. It can also support workforce planning by predicting variations in hospital admissions and discharges, helping to identify peak periods and fluctuations in patient volume. Additionally, AI can assist

[44] *Atrium Health: AI Solution Improved Documentation Experience for Almost 85% of Physicians,* Atrium Health News (Oct. 10, 2023). https://atriumhealth.org/about-us/newsroom/news/atrium-health-ai-solution-improved-documentation-experience

[45] Bishan Nandy, *The impact of artificial intelligence on hospital operations: A comprehensive analysis*, Express Healthcare (Aug. 24, 2024) https://www.expresshealthcare.in/news/the-impact-of-artificial-intelligence-on-hospital-operations-a-comprehensive-analysis/445342/

in recruitment by analysing staffing needs and optimising hiring processes. AI-driven solutions can also be applied to enhance the efficiency of operating room scheduling by minimising idle time, reducing delays, and maximising surgical throughput. It does so by analysing historical surgical durations, patient preparation intervals, surgeon availability, and equipment utilisation patterns.

LeanTaaS's iQueue is an AI-driven platform designed to optimise hospital operations across multiple domains. iQueue for Inpatient Flow uses predictive modelling to predict patient admissions and discharges, improving bed management and cutting down on patient placement delays. iQueue for Operating Rooms enhance surgical scheduling, increases case volumes, and improves utilisation of staff and equipment. iQueue for Infusion Centers leverages AI to streamline appointment scheduling and resource allocation, enabling centres to safely accommodate more patients while minimising wait times.[46]

Johns Hopkins Hospital in the United States implemented an AI-driven system called the GE Healthcare Command Centre, which uses real-time data and predictive analytics to monitor patient movement, anticipate bottlenecks, and coordinate care across departments. The system has led to a 38% improvement in bed assignment time, an 83% reduction in the operating room holds, a 46% increase in the acceptance of complex patient transfers, and a 43-minute improvement in ambulance dispatch time, clearly demonstrating how AI can significantly enhance hospital capacity management.[47]

2.2.11 Population Health Management (PHM)

Population health management (PHM) aims to improve health outcomes across entire communities by monitoring and coordinating health interventions. Artificial intelligence supports PHM by analysing large and varied datasets, including electronic health records

[46] LeanTaaS https://leantaas.com/ (last visited Jan 31, 2025)

[47] *Johns Hopkins Capacity Command Center Creates a New Center of Gravity*, (last visited Jan 31, 2025) https://www.gehccommandcenter.com/outcomes/johns-hopkins-capacity-command-center-creates-a-new-center-of-gravity

(EHRs), demographic details, behaviour patterns, and social factors, to spot trends, predict risks, and guide proactive care strategies. AI can detect emerging health threats, enable preventive care, and support timely, targeted interventions.[48] Integrating data on socioeconomic status, environmental conditions, and access to care allows AI to highlight and address health disparities, promoting more equitable outcomes for underserved or high-need populations.

AI can also stratify patients by their risk of developing chronic conditions, experiencing complications, or requiring hospitalisation. In times of limited resources or staffing shortages, it helps health systems prioritise efforts such as deploying community health workers, delivering vaccines, or organising screening programmes in areas where they are most needed.

Geo Health AI is a novel geospatial population health AI algorithm that acts as a powerful tool for understanding and addressing geographic disparities in population health. It could be applied to a range of population health challenges, including identifying geographic hotspots for chronic illness, forecasting areas vulnerable to infectious disease outbreaks, determining optimal locations for new healthcare facilities, targeting public health interventions toward underserved communities, and evaluating how environmental conditions influence health outcomes.[49]

Mount Sinai Health Systems, a hospital network in New York City, has developed an AI model that uses algorithms to mine data and detect patients who may be at risk for unexpected hospital admissions among the system's 500,000-patient population health programme and develop predictive modelling features. The system can enable clinical pathways and protocols to be redesigned to intervene proactively in the highest-risk cases and thereby help reduce unnecessary admissions.[50]

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[48] Priya Jeyaraj & T.S.A. Narayanan, *Role of Artificial Intelligence in Enhancing Healthcare Delivery*, 11(12) *Int'l J. Innovative Sci. & Mod. Eng'g* (Dec. 2023), https://doi.org/10.35940/ijisme.A1310.12111223

[49]Ganesh Ramalingam, Leaveraging AI for Public Health Management, 10(4) IJSRET 1224 (2024).

[50]*Icahn School of Medicine at Mount Sinai to establish world-class center for artificial intelligence: : Hamilton and Amabel James Center for Artificial Intelligence and Human Health*, Newswise, (Jun. 11, 2019) https://www.newswise.com/articles/icahn-school-of-medicine-at-mount-sinai-to-establish-world-class-center-for-artificial-intelligence-hamilton-and-amabel-james-center-for-artificial-intelligence-and-human-health

NextGen Healthcare provides population health management tools that support disease trend analysis and predictive modelling for potential outbreaks.[51]

Organisations like Gavi have used AI to optimise vaccine delivery routes and cold chain logistics in Africa and South Asia by analysing population density and health system capacity. This has improved immunisation coverage in hard-to-reach areas and reduced outbreaks in challenging environments.[52]

Collectively, these examples bring out the critical role artificial intelligence can play in mitigating public health inequities when aligned with well-designed and thoughtful outreach strategies. By leveraging real-time data and predictive modelling, AI enables health systems and policymakers to pinpoint at-risk populations, optimise service delivery, and deploy interventions where they are most urgently needed. This encourages a move from reactive to proactive public health governance. For policymakers, the integration of AI into national health infrastructure offers a strategic opportunity to advance equity-focused health policies, strengthen epidemic preparedness, and enhance resource allocation in underserved regions.

[51]Nextgen, https://www.nextgen.com/solutions/value-based-care/population-health (last visited Feb. 1, 2025)

[52]Gautam Chamarthy et al., *Artificial Intelligence in public health: A case study*, 20(01) WJBPHS 364–377 (2024). https://doi.org/10.30574/wjbphs.2024.20.1.0783

CHAPTER 3

ETHICAL IMPLICATIONS OF AI IN MEDICAL DECISION-MAKING

3.1 Introduction

The operation of artificial intelligence in medical decision-making raises important ethical issues that need to be tackled to protect patient welfare, ensure fairness, and maintain trust in our healthcare systems. As AI technologies become more pragmatic and widespread, they hold the potential to transform diagnosis, treatment planning, and patient monitoring, improving outcomes and efficiency. Beyond benefits in high-income settings, AI has the ability to democratise medical expertise and globalise healthcare by extending advanced diagnostic and treatment tools to remote and underserved areas. While these advancements bring exciting possibilities, they also spark a host of complex questions around autonomy, transparency, explainability, bias, accountability, and preservation of human values in care.

3.2 Patient Autonomy and Informed Consent

Respect for patient autonomy is a central tenet of medical ethics. As Raanan Gillon articulates in *Philosophical Medical Ethics*, autonomy is "the capacity to think, decide and act (on the basis of such thought and decision) freely and independently." This concept underpins the right of persons to determine decisions about their own bodies and medical treatment in accordance with their values, beliefs, goals and preferences.

Within the clinical context, respect for autonomy serves as a safeguard against coercion, paternalism, and informational neglect. It ensures that patients are neither compelled to undergo unwanted procedures nor subjected to medical interventions without a comprehensive understanding of their nature and implications. This obligation manifests in the doctrine of *informed consent*, which requires healthcare professionals to give patients complete, clear, and comprehensible information about any proposed intervention, including its purpose, benefits, potential risks, and reasonable alternatives. Patients must then voluntarily agree to the course of action, retaining the right to refuse or withdraw consent at any time.

Integrating artificial intelligence into medical decision-making brings both opportunities and challenges to the principle of patient autonomy. On one hand, AI-enabled systems can empower patients by providing personalised health information and enhancing their capacity to make informed decisions. For instance, in the management of chronic conditions such as diabetes, AI-driven platforms can analyse data from wearable devices and continuous glucose monitors to offer real-time, individualised recommendations regarding diet, physical activity, and medication adjustments. Such tools may encourage greater patient engagement and shared decision-making, fostering a sense of control and active participation in care.

However, the deployment of AI in clinical settings also introduces significant ethical complexities, particularly in relation to informed consent and the inherent opacity of many AI systems, which can impair patient autonomy. These systems often generate recommendations through complex machine learning algorithms that lack interpretability even for their developers, making it challenging for both clinicians and patients to understand how specific diagnoses or treatment recommendations are generated. For example, Corti's algorithms, which are used to detect cardiac arrests during emergency calls, operate as a black box since even the system's creator cannot fully explain how it arrives at its conclusions.[53] As a result, both clinicians and patients may struggle to interpret or evaluate AI-generated recommendations, leading to uncertainty in clinical decision-making. For healthcare professionals, this lack of transparency can be troubling, while for patients, it may obscure the extent to which AI has influenced their care. This restricts their ability to fully understand the reasoning behind a recommendation, which in turn affects their ability to give genuinely informed and meaningful consent to treatment.[54]

[53] Sara Gerke et al., *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, in Artificial Intelligence in Healthcare 205 (Adam Bohr & Kaveh Memarzadeh eds., Academic Press 2020), https://doi.org/10.1016/B978-0-12-818438-7.00012-5.

[54] Shinae Yu et al., *The Ethics of Using Artificial Intelligence in Medical Research*, 39(4) *Kosin Med. J.* 229 (2024), https://doi.org/10.7180/kmj.24.140.

Furthermore, over-reliance on AI recommendations by both clinicians and patients may inadvertently erode patient autonomy. A key concern is the emergence of *automation bias*, where clinicians may place undue trust in AI-generated outputs, even when these conflict with patient-centric considerations. When AI consistently presents a specific treatment as optimal based on statistical or clinical efficiency, clinicians might default to that option without adequately considering a patient's personal values, beliefs, goals or preferences. dynamic can reduce the patient's role to passive compliance rather than active deliberation. Additionally, AI systems may prioritise objective metrics, such as survival rates or cost-effectiveness, at the expense of more subjective but equally important considerations, such as quality of life or psychological well-being.

Moreover, the integration of AI into clinical practice may reduce the emphasis on the doctor-patient relationship, which is founded on empathy, trust, and communication. This shift raises concerns about the potential devaluation of human clinical competence.[55] As AI-generated recommendations increasingly guide clinical decisions, their growing influence may pressure physicians to follow algorithmic suggestions, diminishing confidence in their own judgment diminishing confidence in their own judgment or deskilling them. Patients may also begin to view AI as the primary decision-maker, leading to reduced trust in their doctors. Subsequently, there is a threat to the shared decision-making and the autonomy of patients and doctors.[56]

3.3 Bias, Equity and Fairness

Bias in AI refers to systematic and repeatable errors that result in unfair, prejudiced and discriminatory outcomes for certain groups of patients, particularly for minority and underserved populations.[57] Numerous cases have shown how biases in algorithms can lead to injustice in terms of racial origins, skin tone, age, gender, or disability, as these systems often

[55] Nandita Sharma & Divya Gupta, *Artificial Intelligence in Medicine: Navigating Ethical Challenges*, 1(1) JEFI (2023), https://doi.org/10.56450/JEFI.2023.v1i01.010.

[56] Adewunmi Akingbola et al., *Artificial Intelligence and the Dehumanization of Patient Care*, 3 *J. Med., Surgery & Pub. Health* (2024), https://doi.org/10.1016/j.glmedi.2024.100138.

[57] Ariana Mihan et al., *Mitigating the Risk of Artificial Intelligence Bias in Cardiovascular Care*, 6(10) *Lancet Digit. Health* (2024), https://doi.org/10.1016/S2589-7500(24)00155-9.

reflect and amplify existing societal inequalities embedded in historical healthcare data. These biases can emerge at multiple stages of the AI lifecycle, including data collection, model development, validation, and deployment. If the training datasets are not representative of the diverse patient populations, the AI systems may generate skewed predictions that favour certain groups over others.[58] Moreover, the design of AI algorithms can introduce biases in decisions made during development, such as which variables to include and how to weigh them, which may reflect the implicit biases. Human annotation biases can occur if healthcare professionals' implicit prejudices influence how data is labelled, and these prejudices may become embedded in the AI system's decision-making process.[59] Further, AI systems often fail to account for broad-ranging social determinants of health, such as income, education, and environment, which can result in incomplete or biased assessments.[60] These disparities are not only seen in performance but also in potential or actual clinical benefits, causing inequitable care.

The National Liver Offering Scheme (NLOS) in the United Kingdom uses an algorithm to allocate livers for transplantation. However, this algorithm has been criticised for systemic biases, particularly against younger patients. Despite the aim of reducing waiting list deaths, the algorithm has prolonged waits for younger patients, raising fairness concerns.[61]

Similarly, in the United States, a widely used healthcare algorithm was found to systematically underestimate the health needs of Black patients. The algorithm predicted future healthcare costs based on historical data, but because Black patients typically incur lower healthcare costs, the algorithm did not identify them as high-risk despite having more severe health conditions.[62]

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[58] Natalia A. Norori et al., *Addressing Bias in Big Data and AI for Health Care: A Call for Open Science*, 2(10) *Patterns* 100347 (2021), https://doi.org/10.1016/j.patter.2021.100347.

[59] *Navigating AI Bias in Healthcare: Challenges and Solutions*, Foresee Medical Blog (Sept. 3, 2024), https://www.foreseemed.com/blog/ai-bias-in-healthcare.

[60] James L. Cross et al., *Bias in Medical AI: Implications for Clinical Decision-Making*, 3(11) *PLOS Digit. Health* e0000651 (2024), https://doi.org/10.1371/journal.pdig.0000651.

[61] Arvind Narayanan & Sayash Kapoor, *Does the UK's Liver Transplant Matching Algorithm Systematically Exclude Younger Patients?*, AI Snake Oil (Nov. 12, 2024), https://www.aisnakeoil.com/p/does-the-uks-liver-transplant-matching.

[62] Supra 5

A study titled *Poor Warfarin Dose Prediction with Pharmacogenetic Algorithms that Exclude Genotypes Important for African Americans* gave a clear demonstration that its widely used pharmacogenetic algorithms for warfarin dosing perform poorly in African Americans because they fail to consider critical genetic variations.[63]

Another prominent example of algorithmic bias relates to gender disparities in cardiovascular care. Cardiovascular disease (CVD) is a leading cause of mortality worldwide, yet its manifestation and progression differ between men and women. However, many clinical risk assessment tools, such as those developed from the Framingham Heart Study conducted in Massachusetts, United States, have historically been based on datasets dominated by male patients. As a result, these models often fail to account for sex-specific risk factors and atypical symptom presentations, such as fatigue, breathlessness, or nausea, which are more commonly reported by women experiencing cardiac events. As a result, women are more likely to be misdiagnosed or experience delays in treatment, contributing to higher morbidity and mortality. A study conducted in the Netherlands by Maas and Appelman (2010) explicitly criticises the male-centric approach in cardiovascular diagnostics. They emphasised the urgent need to recalibrate risk assessment tools by incorporating sex-specific variables and developing models trained on more representative populations, thereby improving diagnostic accuracy and treatment efficacy for female patients.[64]

To mitigate bias in AI healthcare systems, it is essential to ensure that training datasets are inclusive and representative of diverse patient populations. This includes accounting for factors such as race, ethnicity, gender, socioeconomic status, and geographic location. Additionally, bringing together diverse stakeholders in the development and validation of AI algorithms can aid in identifying and tackling potential biases. Regular audits and evaluations of AI systems are also crucial to ensure that they operate fairly and equitably.

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[63]Katarzyna Drozda et al., *Poor Warfarin Dose Prediction with Pharmacogenetic Algorithms That Exclude Genotypes Important for African Americans,* 25(2) Pharmacogenetics & Genomics 73, 81 (2015), https://doi.org/10.1097/FPC.0000000000000108.

[64] A.H.E.M. Maas & Y.E.A. Appelman, *Gender Differences in Coronary Heart Disease*, 18(12) *Neth. Heart J.* 598 (2010), https://doi.org/10.1007/s12471-010-0841-y

3.4 Transparency and Explainability

Transparency and explainability are key ethical principles when it comes to creating and using AI-based tools in healthcare. These principles play a critical role in building trust and improving cooperation among stakeholders in the healthcare system.

Transparency in AI refers to the openness with which information about the AI system, including its design, intended use, training data sources, underlying algorithm, functioning, limitations and performance metrics, is shared with the stakeholders such as healthcare professionals, patients, regulatory bodies, and developers. Explainability is a closely related concept, which is the ability of the AI system to provide a clear, understandable and meaningful explanation for its outputs or recommendations. It enables users to assess, question, and contextualise those decisions.[65]

Many AI models operate as "black boxes," and their internal decision-making processes are not readily interpretable even by their developers. Many believe that if providers cannot figure out how an AI system produces its outputs, then they cannot determine if the system is biased or inaccurate. This lack of transparency can result in erosion of trust. In healthcare contexts where decisions directly impact diagnoses, treatments, or prognoses, this opacity undermines the principle of informed consent. Patients must be aware of and understand the role of AI in their care in order to make autonomous and informed choices about their treatment.

Furthermore, a lack of explainability can reduce the willingness of healthcare providers to trust or adopt AI systems, regardless of their demonstrated accuracy. Clinicians are professionally and legally responsible for the care they provide, and they may hesitate to rely on tools whose reasoning they cannot understand or justify. This is especially important in cases of adverse outcomes, where it is necessary to trace back and evaluate the reasoning behind clinical

[65] Isla Chen, Transparency and Explainability in AI: Making Intelligent Systems Accountable, Hakia (Feb. 15, 2023), https://www.hakia.com/transparency-and-explainability-in-ai-making-intelligent-systems-accountable.

decisions. Many scholars also argue that the explainability of AI algorithms is necessary to detect biases in an AI-generated health recommendation.[66]

IBM Watson for Oncology was developed in collaboration with Memorial Sloan Kettering Cancer Center and marketed as an AI system capable of recommending personalised cancer treatments. However, it faced widespread criticism as the system often produced treatment recommendations that were clinically inappropriate or not supported by established guidelines. IBM Watson's decision-making process was not transparent to the end-users, and many clinicians could not understand how or why specific treatments were suggested. Eventually, it was pulled back from several hospitals.[67]

To address these ethical challenges, several strategies can be employed to enhance the transparency and explainability of AI systems in healthcare. One way to tackle this is by using explainable AI (XAI) techniques. These methods are designed to make the decision-making processes of AI models clearer and interpretable. Additionally, involving clinicians and patients in the development and evaluation of AI systems can ensure that these technologies align with clinical needs and ethical standards.

3.5 Privacy and Data Protection

Privacy is a fundamental human right recognised in various international frameworks, including Article 12 of the *Universal Declaration of Human Rights* and Article 8 of the *European Convention on Human Rights*. It is also recognised under Article 21 of the *Constitution of India*, which guarantees the right to life and personal liberty. Within the healthcare context, privacy refers to the individual's right to control access to their personal health information and to determine how such information is collected, stored, and shared. This

[66] Alex John London, *Artificial Intelligence and Black-Box Medical Decisions: Accuracy Versus Explainability*, 49(1) *Hastings Ctr. Rep.* 15 (2019), https://doi.org/10.1002/hast.973.

[67] Casey Ross & Ike Swetlitz, *IBM's Watson Supercomputer Recommended 'Unsafe and Incorrect' Cancer Treatments, Internal Documents Show*, STAT (July 25, 2018), https://www.statnews.com/2018/07/25/ibm-watson-recommended-unsafe-incorrect-treatments/

right serves as a cornerstone of ethical medical practice and is vital to maintaining trust between patients and healthcare providers.

In today's digital era, data is often viewed as a valuable asset. The advent of artificial intelligence in healthcare has transformed the way medical data is collected, analysed, and utilised. AI systems rely on access to vast and diverse datasets in order to function accurately and effectively. These datasets often include sensitive information such as electronic health records, genetic profiles, diagnostic images, biometric identifiers, insurance details, and real-time data from wearable devices. While these systems can enhance clinical decision-making, this process inherently increases the risk of breaches in privacy and confidentiality. These breaches can result in significant harm, including identity theft, unauthorised surveillance, discrimination, and a breakdown of trust in healthcare systems.

A notable example is the data breach in 2020 involving Babylon Health, a digital health platform, where a software flaw resulted in some users inadvertently gaining access to video recordings of other patients' consultations.[68] In 2020, Hackers and experts discovered vulnerabilities in the Indian government application of Aarogya Setu, putting the personal health data of 90 million Indian users at risk.[69] These incidents show the vulnerabilities that can be associated with AI-driven healthcare systems.

Project Nightingale is a collaboration set up in 2018 between Google and Ascension, a large non-profit healthcare provider in the United States. Under this project, Google gained access to a vast amount of personal health data from Ascension's patients, including lab results, diagnoses, hospitalisation records, and other medical information. This data was transferred to Google's cloud services without patient notification or consent, raising concerns about transparency and patient autonomy. The partnership was conducted under the premise that

[68] Leo Kelion, *Babylon Health Admits GP App Suffered a Data Breach*, BBC (June 10, 2020), https://www.bbc.com/news/technology-52986629.

[69] Yuthika Bhargava, *Hacker 'Sees' Security Flaws in Aarogya Setu*, The Hindu (May 7, 2020), https://www.thehindu.com/news/national/ethical-hacker-robert-baptiste-elliot-alderson-sees-security-flaws-in-aarogya-setu/article31515292.ece.

Google would act as a "business associate" of Ascension, as defined by HIPAA regulations, which allows certain data sharing without patient consent. However, the scale of data involved and the lack of patient awareness led to public outcry and government scrutiny. In response to this, the United States Department of Health and Human Services put in place an inquiry into the project to assess its compliance with HIPAA and the implications for patient privacy.[70] This example illustrates the ethical risks of large-scale health data use, particularly when commercial entities are involved, and patient awareness is lacking. Patients may not be fully aware that their data is being used for commercial purposes and may not have consented to such uses. This lack of transparency can take the edge off trust in healthcare systems and AI technologies. Ethically, it is imperative that patients are informed about the potential commercial uses of their data and that they have the opportunity to opt-out if they choose.

In an effort to safeguard privacy, healthcare providers and researchers often anonymise patient data before using it to train AI models. Anonymisation involves removing personally identifiable information (PII) to prevent individual patients from being identified. However, research has demonstrated that anonymised data can, at times, be re-identified, especially when combined with other datasets.

In 2019, the University of Chicago Medicine partnered with Google to share patient data for research purposes. A former patient filed a lawsuit against both institutions, alleging that his medical records were shared without his consent and that they weren't adequately de-identified. The data included doctor's notes and timestamps, which, according to the complaint, could potentially be re-identified using advanced data-mining techniques. In 2023, the Seventh Circuit Court of Appeals sustained the dismissal of the lawsuit, ruling that the plaintiff had not demonstrated economic harm or a violation of a property interest in his medical information. The court also noted that the data-sharing arrangement complied with HIPAA regulations and did not amount to a breach of privacy rights. However, the lawsuit raised concerns about the

[70] Aimee Picchi, *Google's "Project Nightingale" Faces Government Inquiry Over Patient Privacy*, CBS News (Nov. 13, 2019), https://www.cbsnews.com/news/googles-project-nightingale-faces-government-inquiry-over-patient-privacy/.

adequacy of de-identification processes and the transparency of data-sharing practices in AI-driven healthcare initiatives.[71]

A study conducted by Université Catholique de Louvain in collaboration with Imperial College London found that 99.98% of individuals in an anonymised healthcare dataset could be re-identified using just 15 demographic attributes.[72] These findings call into question the reliability of traditional anonymisation techniques and highlight the need for more advanced de-identification and data protection strategies.

It is essential that there should be proper data minimisation techniques by limiting the collection and retention of patient data to what is strictly necessary for the intended AI application. Transparent policies must govern the purposes for which data is collected, how it will be used, and who will have access to it, with patients being adequately informed and their consent obtained wherever possible. Furthermore, access to sensitive health data should be restricted through role-based permissions, two-factor authentication, and comprehensive audit trails to ensure accountability and prevent misuse. Clear lines of responsibility should be established among healthcare providers, AI developers, and third-party vendors to swiftly address and remedy any breaches or inappropriate use of data.

3.6 Accountability and Liability

As AI systems become more autonomous and influential in clinical settings, determining accountability and liability in cases of error or patient harm has grown increasingly complex.

Traditionally, accountability in healthcare has been relatively straightforward, where clinicians and healthcare institutions may share liability for systemic failures. However, with AI, the lines of responsibility blur as there are new actors, such as developers, vendors and data providers in the field.

[71] Dinerstein v. Google LLC, No. 20-3134 (7th Cir 2023)

[72] Luc Rocher et al., *Estimating the Success of Re-Identifications in Incomplete Datasets Using Generative Models*, 10(1) *Nat. Comm.* 3069 (2019), https://doi.org/10.1038/s41467-019-10933-3.

When an AI system provides a recommendation or makes a decision that leads to patient harm, it is often unclear whether the liability should rest with the healthcare provider, the developer of the AI system, or the institution deploying the technology. This ambiguity is exacerbated by the "black box" nature of many AI algorithms, which may produce outcomes without offering a clear explanation of their internal logic, making it difficult for clinicians, regulators, or even the developers themselves to trace how a specific decision was made.[73]

From an ethical standpoint, the degree of autonomy granted to an AI system, the level of human oversight involved, the foreseeability of harm, and the quality of the system's design and deployment are all factors that significantly influence where responsibility should rest.[74] When AI is used purely as a decision-support tool, providing suggestions that clinicians are expected to interpret and potentially override, then the clinician remains the final decision-maker and, accordingly, bears the primary responsibility. In this model, the doctrine of vicarious liability may apply, with institutions or supervising clinicians held accountable for errors made by or in conjunction with AI systems. For instance, if a clinician ignores evidence or overrides an accurate AI recommendation for unjustified reasons, responsibility may rightly fall on the clinician.

However, as AI systems are increasingly deployed in high-stakes, semi-autonomous or autonomous contexts such as robotic surgery or automated triage systems, the burden of accountability may reasonably shift towards developers and manufacturers, particularly when harm results from design flaws or system malfunctions that were not foreseeable by end-users. Also, if a developer releases an AI tool with known limitations or without adequate testing, then it may be ethically justifiable to hold the developer or manufacturer accountable for the resulting harm.

[73] Clara Cestonaro et al., *Defining Medical Liability When Artificial Intelligence Is Applied on Diagnostic Algorithms: A Systematic Review*, 10 *Front. Med.* 1305756 (2023), https://doi.org/10.3389/fmed.2023.1305756.

[74] *Ibid*

Legal frameworks are still catching up to these developments. Current malpractice and product liability laws in most jurisdictions are not well-equipped to handle situations where the fault is distributed across multiple stakeholders, including software vendors, hospital administrators, and data engineers.

In November 2023, a lawsuit was charged against UnitedHealthcare for its use of the nH Predict algorithm, which denied and overrode claims to elderly patients for extended care that had been approved by their doctors. The system also carried a staggering 90% error rate, sparking debate about whether liability lies with the insurer who implemented the system, the developers who created the algorithm, or the physicians who failed to question its output. Although not yet adjudicated conclusively, such cases highlight the murky nature of accountability in AI-assisted healthcare.[75]

To address these challenges proactively, there is a growing consensus on the need for a clear delineation of roles and responsibilities in the use of AI in medical decision-making. Healthcare institutions must implement explicit policies and protocols governing the deployment, monitoring, and oversight of AI systems. Developers should be obligated to follow stringent safety and transparency standards, including continuous post-deployment monitoring and risk reporting. Additionally, implementing measures like mandatory liability insurance, compensation programs for patients affected by AI-related mistakes, and transparent incident reporting systems can help ensure that no patient is left without recourse in the event of harm.

[75] Brendan Pierson, Lawsuit Claims UnitedHealth AI Wrongfully Denies Elderly Extended Care, Reuters (Nov. 15, 2023), https://www.reuters.com/legal/lawsuit-claims-unitedhealth-ai-wrongfully-denies-elderly-extended-care-2023-11-14/.

CHAPTER 4

LEGAL FRAMEWORK GOVERNING ARTIFICIAL INTELLIGENCE IN HEALTHCARE

4.1 Introduction

India's large and diverse population places significant pressure on its healthcare system. Persistent issues such as uneven distribution of medical resources, limited infrastructure in rural areas, shortage of skilled professionals, and escalating healthcare costs have long hindered the delivery of equitable and effective medical services. The advent of AI in healthcare has emerged as a transformative force for improving patient outcomes and operational efficiency.

The growing interest in AI is not merely technological but also strategic, as healthcare providers and policymakers seek innovative solutions to bridge systemic gaps and democratise access to quality care. These include AI-enabled imaging tools, clinical decision support systems, predictive analytics for public health, and virtual health assistants. These innovations hold particular relevance in India, where technological interventions can extend healthcare access to underserved regions and mitigate the strain on overburdened institutions.

Despite this momentum, the legal and regulatory framework governing AI in healthcare in India remains in a formative stage, characterised by a patchwork of sectoral regulations, ethical guidelines, and emerging policy initiatives. Laws such as the Information Technology Act, 2000, and the Medical Devices Rules, 2017, along with domain-specific policies and guidelines issued by bodies like the Medical Council of India (now superseded by the National Medical Commission) and the National Health Policy, 2017, by the Ministry of Health and Family Welfare (MoHFW), provide some structure but were not conceived with AI technologies in mind. As a result, critical issues of data privacy, algorithmic accountability, patient safety, liability in case of AI errors, and ethical concerns raised by AI systems remain insufficiently addressed.

In 2018, the National Institution for Transforming India (NITI Aayog), the Indian government's apex public policy think tank, released the *National Strategy for Artificial Intelligence* (NSAI), articulating a vision to position India as a major global leader in the field of artificial intelligence.[76] It was promoted under the concept of *AI for All* and emphasises the adoption of AI in key sectors such as healthcare, agriculture, education, smart cities, and smart mobility.[77] It outlined a set of recommendations to promote AI adoption, such as the promotion of research through the establishment of Centres of Research Excellence (COREs). It emphasised the importance of skilling and reskilling initiatives to set up the workforce for the demands of an AI-driven economy. The strategy also prioritised facilitating the adoption of AI technologies through AI solutions in various sectors and recognised the need to formulate responsible AI guidelines.

In response to the growing importance of ethics in AI deployment, NITI Aayog expanded its efforts by releasing a two-part policy framework in 2021. The first part of this framework, published in February 2021 under the title "*Principles for Responsible AI*", outlines principles such as Safety & Reliability, Equality, Inclusivity & Non-discrimination, Privacy & Security, Transparency, Accountability, and Protection and reinforcement of positive human values.[78] The second part of this framework, published in August 2021 under the title "*Operationalising Principles for Responsible AI"*, focused on translating ethical principles into actionable measures. It proposed a risk-based approach to AI regulation, recommending that the degree of regulatory scrutiny be proportionate to the potential harm posed by a given AI application. It also advocated for policy tools such as regulatory sandboxes, controlled deployments, and the encouragement of ethics-by-design practices. It recognised the need for necessary actions by both government and private sectors, in collaboration with research institutes, to ensure regulatory and policy interventions, targeted capacity building, and compliance with relevant AI standards.[79]

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[76] *National Strategy for Artificial Intelligence*, NITI Aayog (June 2018), https://www.niti.gov.in/sites/default/files/2023-03/National-Strategy-for-Artificial-Intelligence.pdf

[77] Rahul Kailas Bharati, *Navigating the Legal Landscape of Artificial Intelligence: Emerging Challenges and Regulatory Framework in India, SSRN Electronic Journal*. (2024).http://dx.doi.org/10.2139/ssrn.4898536

[78] *Principles for Responsible AI*, NITI Aayog (Feb. 2021) https://www.niti.gov.in/sites/default/files/2021-02/Responsible-AI-22022021.pdf

[79] *Operationalizing Principles for Responsible AI*, NITI Aayog (Aug. 2021), https://www.niti.gov.in/sites/default/files/2021-08/Part2-Responsible-AI-12082021.pdf.

Complementing these policy efforts, the government launched the National Digital Health Mission (NDHM) in 2020, rebranded as the Ayushman Bharat Digital Mission (ABDM) in 2021. ABDM is set out by the National Health Authority (NHA) under the MoHFW and seeks to build a federated digital health ecosystem across India. Key components include the Ayushman Bharat Health Account (ABHA), electronic health records, and a consent-based data-sharing framework. These initiatives, while broader in scope, establish the digital infrastructure and interoperability standards essential for ethical and secure AI integration in healthcare. Additionally, the NHA promotes innovation through public-private partnerships and regulatory sandboxes that support responsible AI development.

In caution to increasing concerns about data privacy in the digital age, the Indian government recently laid out the Digital Personal Data Protection Act, 2023, to guard individuals' personal data in the digital space, which in turn affects the development and use of AI. This legislation sets out a comprehensive framework for the processing of personal data, focusing on individual rights, consent, and the responsibilities of data fiduciaries. In the healthcare sector, this translates into stronger protections for sensitive health information. Although not specific to artificial intelligence, the Act addresses data privacy concerns that are integral to AI applications, making certain that personal data used in AI systems is handled responsibly and in a secure manner.[80]

Recognising these gaps, the Indian Council of Medical Research (ICMR) released the Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare in 2023. They emphasise core ethical values such as autonomy, safety, equity, accountability, and data integrity. The ICMR guidelines also highlight the need for rigorous validation of AI tools, transparency in algorithmic decision-making, and mechanisms for human oversight. Importantly, they establish expectations for informed consent, risk mitigation, and continuous monitoring, offering a foundation for ethically responsible innovation.

[80] Ankit Singh, *The AI Regulatory Landscape in India: What to Know*, AZoRobotics (Feb. 26, 2025), https://www.azorobotics.com/Article.aspx?ArticleID=742.

4.2 Existing Legal and Regulatory Frameworks

4.2.1 Information Technology Act, 2000 and rules

The Information Technology Act, 2000 (IT Act) serves as the foundational legal framework for regulating electronic governance, digital communication, and cyber-related offences in India.[81] Although enacted prior to the rise of artificial intelligence (AI) technologies, several provisions in the IT Act apply to AI-related activities, particularly in sectors such as healthcare, where vast amounts of sensitive personal data are processed using digital platforms. The IT Act is supplemented by the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 (SPDI Rules), which governs the collection, storage, processing, and transfer of sensitive personal data or information. These can include health records, medical history, physical and mental health conditions, genetic information and biometric information.[82]

Section 43A of the IT Act mandates that any body corporate handling sensitive personal data or information must implement reasonable security practices. It enables compensation for data privacy breaches resulting from negligent handling of sensitive personal data. This means that AI systems or platforms processing data must ensure robust data protection measures and comply with this provision to avoid legal repercussions.[83]

Section 72 of the IT Act penalises any person who, in the exercise of powers conferred under the Act, secures access to electronic records, documents, correspondence, or other digital information and discloses such material without the consent of the person concerned. The provision addresses breaches of confidentiality and privacy by imposing criminal liability in cases where information obtained lawfully under the Act is subsequently misused. It holds particular relevance in public healthcare contexts, where authorised personnel may access sensitive patient data through state-managed digital systems or health information exchanges.

[81] *Information Technology Act, No. 21 of 2000*, https://www.indiacode.nic.in/bitstream/123456789/13116/1/it_act_2000_updated.pdf.

[82] Dipika Jain, *Regulation of Digital Healthcare in India: Ethical and Legal Challenges*, 11(6) Healthcare 9 (2023), https://doi.org/10.3390/healthcare11060911

[83] *Regulating AI in India: Challenges, Initiatives, and Path to Future Success*, K. Singhania & Co (Mar. 13, 2025), https://singhanialaw.com/regulating-ai-in-india-challenges-initiatives-and-path-to-future-success/.

The penalty for breach under this section is imprisonment for a term which may extend to two years or a fine which may extend to one lakh rupees or both.[84]

Section 72A of the IT Act provides protection against unauthorised disclosure or access gain of information by service providers or intermediaries with the intention of causing wrongful loss or gain and without the consent of the data subject. This section is particularly relevant in today's healthcare environment, where third-party vendors, including AI developers, cloud service providers, and telemedicine platforms, handle sensitive health information. However, its scope is limited as it applies only when there is a contractual relationship, which may not cover all real-world data-sharing scenarios. The penalty under Section 72A is imprisonment for a period which may extend to three years or a fine which may extend to five lakh rupees or both.

The forthcoming Digital India Act aims to replace the Information Technology Act, 2000, thereby modernising the legal framework governing India's digital ecosystem. [85]Although still in draft form, the forthcoming legislation is anticipated to introduce specific provisions addressing emerging technologies, including artificial intelligence. It is expected to address algorithmic accountability, user rights, and digital safeguards while establishing a regulatory body for oversight.

4.2.2 Medical Devices Rules, 2017

The Medical Devices Rules, 2017 (MDR 2017) are drawn up under the Drugs and Cosmetics Act, 1940, which is the parent legislation empowering the regulation of drugs, cosmetics, and medical devices in India.[86]

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[84] Anisha Gupta, *Healthcare Data*, in *State of Data Regulation in India: A Compendium* (B.P. Mishra ed., 2020), https://cis.pubpub.org/pub/laws-and-enacted-statutes-healthcare-data/release/5.

[85] Nibedita Basu & Rhishikesh Dave, Comparative Analysis of Laws in AI, 5 SDGs Review. (2024), https://doi.org/10.47172/2965-730X.SDGsReview.v5.n03.pe05575.

[86] Medical Devices Rules, 2017, https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTg4NQ.

The Medical Devices Rules, 2017, is administered by the Central Drugs Standard Control Organisation (CDSCO) and primarily regulates medical devices distributed or used within the country for their safety, quality, and performance. In February 2020, it was clarified in Gazette Notification S.O. 648(E) published by CDSCO that the definition of medical device also includes any software or accessory intended for medical use.[87] This expansion allows AI-based software used for medical purposes to be regulated as a medical device.

MDR 2017 has a dedicated risk-based classification system for medical devices, aligning closely with the international standards of the FDA and the European MDR. Medical Devices are designated into four classes based on their intended use and associated risk: Class A (low risk), Class B (moderate risk), Class C (high risk), and Class D (very high risk). This classification determines the grade of regulatory scrutiny, documentation, and clinical evidence required for approval. High-risk devices (Classes C and D) fall under CDSCO's direct oversight, while lower-risk devices (Classes A and B) are managed by State Licensing Authorities and Notified Bodies. It mandates the submission of detailed information on the software design and development process and evidence of the validation as used in the finished device. Moreover, the introduction of Unique Device Identification (UDI) requirements under MDR 2017 enhances traceability, post-market surveillance, and compliance audits. This is especially important for healthcare providers, as patient safety depends on the reliability of these tools.

While MDR 2017 laid the foundation for regulating software-based medical devices, it was largely designed for traditional, hardware-based devices. To address this regulatory gap, the CDSCO in 2021 issued a specific guidance document for the risk-classification of Software as a Medical Device (SaMD).[88] Software as a Medical Device (SaMD) is software intended to be used for one or more medical purposes that perform without being part of a hardware medical device. This guidance provides a risk-based classification of SaMD based on its intended purpose and potential impact on health outcomes, which aligns with the framework of the

[87] Shambhavi Naik & Bharath Reddy, *A Framework for the Governance of AI in Healthcare for India: An Exploratory Model*, *Indian J. Med. Ethics* (2025), https://doi.org/10.20529/IJME.2025.037.

[88] Bruno Gretler, *Navigating the Regulatory Landscape of Fast-Growing Markets: India*, Congenius (Mar. 25, 2025), https://congenius.ch/regulatory-landscape-india/.

International Medical Device Regulators Forum (IMDRF). It is categorised into low-risk (Class A), low-moderate risk (Class B), moderate-risk (Class C), and high-risk (Class D) devices. Class A SaMDs do not directly interpret or interfere with the patient clinical data. Class B SaMDs usually provide the patient with real-time information on the patient's parameters but do not provide any clinical diagnosis. Class C SaMDs provide a diagnosis of disease conditions as well as a direct analysis of the patient's physiological activity. In India, the CDSCO has not yet identified any SaMDs with high risk to patients.[89] The CDSCO functions as the licensing authority for Class C and Class D SaMDs, and in the case of Class A and Class B SaMDs, the State Licensing Authority is the licensing authority.[90] The CDSCO guidance clarifies regulatory expectations for SaMD developers and harmonises Indian practice with global standards, thereby facilitating international collaboration and market access.

4.2.3 Telemedicine Practice Guidelines, 2020

Telemedicine is "the provision of health services by health professionals, where distance is a critical factor, using information and communication technologies to exchange valid information for the purposes of diagnosis, treatment and prevention of disease or injury, research and evaluation, and to facilitate the continuing education of health professionals, with the aim of safeguarding the health of individuals and communities.

The *Telemedicine Practice Guidelines, 2020*, were issued by the Ministry of Health and Family Welfare and are included as Appendix 5 of the *Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002*. These guidelines provide a legal and ethical framework for the conduct of telemedicine consultations in India, delineating the responsibilities of registered medical practitioners (RMPs) and setting standards for the use of digital platforms in clinical interactions.[91]

[89] Freyr Solutions, *Regulation of Software as Medical Device (SaMD) in India*, https://www.freyrsolutions.com/blog/regulation-of-software-as-medical-device-samd-in-india (last visited Apr. 18, 2025).

[90] MedDev Experts, *CDSCO Registration for Software as Medical Device (SaMD)*, https://medicaldevicelicense.com/cdsco-registration-for-software-samd/ (last visited Apr. 18, 2025).

[91] *Telemedicine Practice Guidelines* (2020), https://esanjeevani.mohfw.gov.in/assets/guidelines/Telemedicine_Practice_Guidelines.pdf

A significant aspect of the 2020 Guidelines is their explicit stance on the use of Artificial Intelligence (AI) and Machine Learning (ML) in telemedicine platforms. The guidelines explicitly prohibit telemedicine platforms based on AI or ML from independently counselling patients or prescribing medicines. The Guidelines specify that only RMPs are entitled to counsel or prescribe medicines, and they must engage directly with the patient.[92] This ensures that clinical responsibility and accountability remain with qualified human practitioners, not with automated systems.

While the use of autonomous AI in clinical decision-making is restricted, the guidelines do allow AI, Internet of Things (IoT) devices, and data science-based decision-support tools to assist RMPs in evaluating, diagnosing, and managing patients. Such technologies may augment clinical decision-making, but final prescription or counselling must rest with the RMP.

Additionally, these platforms are required to implement robust grievance redressal mechanisms to effectively address any issues or concerns raised by patients. This ensures accountability and builds patient trust in the system, especially when AI is used as part of the service delivery process.

It is important to note that although the Indian Medical Council (IMC) was replaced by the National Medical Commission (NMC), the Telemedicine Practice Guidelines, 2020, remain in effect. The NMC had issued updated *Registered Medical Practitioner (Professional Conduct) Regulations, 2023*, which included revised Guidelines for Practice of Telemedicine. However, these new regulations were put in abeyance following considerable backlash from stakeholders, including medical professionals and pharmaceutical companies.[93] As a result, the 2002 IMC Regulations, along with the 2020 Telemedicine Practice Guidelines, currently continue to govern the ethical and professional standards for telemedicine practice in India.

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[92] Damodharan Dinakaran *et al.*, *Telemedicine Practice Guidelines of India, 2020: Implications and Challenges*, 63(1) *Indian J. Psychiatry* 97 (2021), https://doi.org/10.4103/psychiatry.IndianJPsychiatry_476_20.

[93] Shouryendu Ray & Vatsala Poddar, *National Medical Commission Professional Conduct Guidelines: A Knee-Jerk Approach to Medical Regulation*, *Bar & Bench* (Sept. 17, 2023), https://www.barandbench.com/columns/nmc-professional-conduct-guidelines-a-knee-jerk-approach-to-medical-regulation.

4.2.4 Digital Personal Data Protection Act, 2023

The increasing digitisation of healthcare data has allowed for a wide variety of advancements in clinical care, ranging from telemedicine and electronic health records to AI-driven diagnostics and personalised treatment planning. However, this transformation has simultaneously raised significant concerns about data privacy and security. The use of digitisation in healthcare, in particular, relies on vast volumes of sensitive personal data, which is often stored on cloud servers or processed through distributed computing systems, thus introducing new layers of risk related to unauthorised access, data breaches, and misuse.

India introduced its comprehensive data privacy law, the Digital Personal Data Protection Act (DPDP Act), in August 2023, aiming to protect individuals' digital personal data.[94] Influenced by the European General Data Protection Right (GDPR), the Act seeks to achieve a balance between protecting individual autonomy and informational privacy and ensuring the lawful processing of digital personal data.

The law applies to the processing of digital personal data, where the personal data is collected in digital form or non-digital form and digitised later. It is not applicable to personal data processed by an individual for any personal or domestic purpose and personal data which is made or caused to be made available publicly.

The law outlines the rights of data principals, obligations of data fiduciaries, and penalties for data breaches and introduces a special category called significant data fiduciaries. Data principal is the individuals to whom the personal data is related. A Data Fiduciary is any person who determines the purpose and processing of personal data.[95] A Significant Data Fiduciary (SDF) is designated by the Central Government based on various factors such as the volume and sensitivity of the data processed, potential risk, etc.

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[94] *Digital Personal Data Protection Act, 2023* (No. 22 of 2023), https://www.meity.gov.in/static/uploads/2024/06/2bf1f0e9f04e6fb4f8fef35e82c42aa5.pdf

[95] Subhajit Saha & Surjashis Mukhopadhyay, A New Age of Data Privacy Laws in India: Review of Digital Personal Data Protection Act, 2023, 10(1) IIJLS (2024), https://doi.org/10.60143/ijls.v10.i1.2024.114.

The DPDP Act emphasises a consent-centric regime for the processing of personal data. It ensures that personal data can only be collected and processed with the explicit and informed consent of the individual. It also mandates verifiable consent from parents or legal guardians for children and persons with disabilities. It also specifies certain circumstances where consent is not required for the processing of personal data. These include scenarios where the data principal has voluntarily given their personal data and has not objected to its use for a specific purpose, as well as in cases of natural disasters, medical emergencies, employment-related matters, and for the provision of government services and benefits.

The DPDP Act allows the processing of personal data only for lawful purposes and restricts data collection to what is necessary. The data can be erased when the specified purpose for which it was collected and processed is no longer served. The Data Principal have the right to withdraw consent at any time, following which the data fiduciary is obligated to stop processing and erase the personal data unless its retention is required under law.[96] However, the withdrawal of consent may result in the inability to access certain goods or services that rely on the processing of that data. Thus, the data principal must bear the practical consequences arising from such withdrawal. The Act grants Data Principals the right to request correction, completion, updating, and erasure of their personal data for which consent was previously given. These rights and obligations are reflective of the constitutional principles set out in the landmark K.S. Puttaswamy v. Union of India[97] decision, where the Supreme Court of India asseverated the fundamental right to privacy as intrinsic to the right to life and personal liberty under Article 21 of the Constitution.

In the healthcare context, it means that there should be clear and transparent communication between the healthcare providers and patients. They must get explicit and informed consent from patients before collecting, using, or sharing their sensitive personal health information. This requirement equally applies to AI-based healthcare systems, which must also secure valid consent prior to processing any health-related data. Healthcare organisations must also ensure

[96] Varun Kumar & Ishika Mittal, *The Digital Personal Data Protection Act, 2023: Overview of the Impact on Data Fiduciaries and the Obligations Placed*, *SCC Times* (Mar. 11, 2024), https://www.scconline.com/blog/post/2024/03/11/the-digital-personal-data-protection-act-2023-overview-of-the-impact-on-data-fiduciaries-and-the-obligations-placed/.

[97] (2017) 10 SCC 1

that they only collect data that is important for the provision of healthcare services and medical research. Further, they must also specify the purpose for which they are using the patient's data. It is essential that the use of a patient's data is explained in a clear and understandable manner, thereby ensuring that patients are fully informed and aware of their data protection rights.

Data fiduciaries must implement safety and security measures at technical and organisational levels to prevent any unauthorised access, use, disclosure, alteration, and destruction. It can include measures like encryption, obfuscation, data masking, maintaining access controls, conducting security audits, etc. This means that healthcare providers, including AI-based healthcare systems, must have powerful security measures to protect patient information.

Additionally, entities designated as Significant Data Fiduciaries by the government must appoint a Data Protection Officer to ensure compliance. When a data fiduciary experiences a data breach where personal information is compromised, they are legally obligated to notify the Data Protection Board of India (DPBI) and the affected Data Principals, thereby ensuring transparency and accountability.

The data principal has a right of grievance redressal by approaching the appropriate data fiduciary or consent manager for not fulfilling their obligations or any kind of omission in protecting the personal data. This is laid down in Section 13 of the DPDP Act, 2023. As per Section 14 of the DPDP Act, 2023, the data principal also has a right to nominate the individuals who will assume the responsibility and authority of the data principal after the death of the data principal.[98]

[98] Anurag Sourot & Deepali Kushwaha, *Critical Analysis of the Digital Personal Data Protection Act, 2023*, 7(2) IJLLR (2025), https://www.ijllr.com/post/critical-analysis-of-the-digital-personal-data-protection-act-2023.

It also prescribes the quantum of penalties applicable for various breaches of the Act. For instance, a penalty of up to Indian Rupees 250 crore may be levied for failure to execute reasonable security safeguards to prevent personal data breaches. Non-compliance with the requirement to notify the DPBI and the affected Data Principals of a personal data breach may attract a penalty of up to Indian Rupees 200 crore.[99]

As AI continues to integrate itself more deeply into India's healthcare landscape, the DPDPA marks a foundational shift in how personal data is regulated, yet it leaves key challenges unaddressed. One of the most pressing concerns lies in the Act's over-reliance on individual consent. While this strengthens individual autonomy, it poses practical difficulties in the context of AI systems, which often involve continuous data processing, real-time analytics, and evolving use cases that may not be foreseeable at the time of initial data collection. This could lead to procedural burdens and fragmented consent management, making it challenging to deploy AI at scale in clinical settings. The legislation lacks AI-specific safeguards such as requirements for algorithmic transparency, fairness audits, or impact assessments, creating a regulatory gap for high-risk, opaque decision-making in healthcare. Furthermore, the Act exempts publicly available data from its ambit, creating a loophole for the unregulated use of health-related information scraped from open sources. Another fact is that much of the obligations and enforcement mechanisms remain to be culled out and are dependent upon the delegated legislations and subsequent enactments. This regulatory uncertainty poses significant compliance challenges for data fiduciaries, especially in high-risk domains like healthcare. While the designation of Significant Data Fiduciaries introduces a risk-based approach, the lack of sector-specific thresholds for what constitutes "significant" in healthcare further adds to the ambiguity. The real-world implementation of this legislation is likely to be influenced by shifting political priorities, economic considerations, and lobbying from industry stakeholders, potentially diluting its efficacy.

[99] Ishwar Ahuja & Sakina Kapadia, *Digital Personal Data Protection Act, 2023 – A Brief Analysis*, *Bar & Bench* (Aug. 22, 2023), https://www.barandbench.com/view-point/digital-personal-data-protection-act-2023-a-brief-analysis.

4.2.5 ICMR Ethical Guidelines for Application of AI in Biomedical Research and Healthcare (2023)

The Indian Council of Medical Research (ICMR) released a guiding document titled '*Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare*' in 2023 through the DHR-ICMR Artificial Intelligence Cell.[100]

The guidelines articulate ten overarching principles that are patient-centric and are intended to serve as a guide for stakeholders, including creators, developers, technicians, clinicians, researchers, ethics committees, sponsors, and funding organisations.[101]

i) Autonomy

Humans must retain full control of any matters related to medical decision-making. The inference of AI technology on the patient's autonomy should not be done under any circumstances. The guideline advocates for the integration of the "Human in the Loop" (HITL) model in AI, i.e., if the necessity arises, healthcare professionals are empowered to override AI decisions.[102] If a decision taken by a physician and AI technology is different, both options should be presented before the patient.

[100] *Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare* (2023), https://www.icmr.gov.in/icmrobject/uploads/Guidelines/1724842648_ethical_guidelines_application_artificial_intelligence_biomed_rsrch_2023.pdf.

[101] Madhavi Bhargava et al., *Artificial Intelligence in Biomedical Research and Publications: It Is Not About Good or Evil but About Its Ethical Use*, 49(6) *Indian J. Cmty. Med.* 777 (2024), https://doi.org/10.4103/ijcm.ijcm_560_24.

[102] Tithishri Kundu & Mainak Bardhan, *Artificial Intelligence in Neurology, Ethics, Recent Guideline, and Law—An Indian Perspective*, 16 *Frontiers in Neurology* (2025), https://doi.org/10.3389/fneur.2025.1515041.

Consent should be obtained from the patient before using AI in research projects and evaluation programs, and they should be informed of all the benefits and physical, psychological and social risks associated with it. The patient or participant has the right to refuse consent to use AI Technologies and should not face any coercion from the government, sponsor, researcher, healthcare professional, or any other stakeholder.

Over-dependency on AI is discouraged, as it can negatively impact the patient-clinician relationship and undermine the patient's autonomy.

ii) Safety and risk minimisation

All the stakeholders have a responsibility to ensure the safety of a participant and verify that AI-based systems operate reliably and securely. This includes implementing a robust set of control measures to prevent unintended or deliberate misuse of sensitive health data. It must be ensured that such data is completely anonymised and delinked from the global technology. These safeguards should be subject to review by the Ethics Committee (EC) and relevant regulatory authorities. Moreover, the EC and other stakeholders must ensure that any deployment of AI systems in healthcare is supported by a favourable benefit-risk assessment.

iii) Trustworthiness

A trustworthy AI-based solution should also be able to provide accurate analysis of health data. It should also be lawful, ethical, reliable and valid from technical and social perspectives, explainable based on scientific plausibility, transparent, and independent of a physician's views or decision.

Sufficient information about AI technologies must be documented and published in an adequate platform before deploying them to ensure the input of public consultation and debate regarding design, usage, safety, security, etc.

iv) Data privacy

As per ICMR guidelines, privacy and personal data protection must be at all stages of development and deployment of AI-based technologies. It must prevent unauthorised access, modification, or loss of personal data, particularly since health-related data is of a sensitive nature. ICMR suggests the anonymisation of patients' data, especially since such data can be presented as metadata and non-image data. The application of AI to personal data must not unreasonably curtail people's real or perceived liberty. The ICMR acknowledges that the Information Technology Act, 2000 (and the rules thereunder) and the Digital Personal Data Protection Act, 2023, will be binding on the AI Guidelines.

v) Accountability and Liability

As per the ICMR, AI technologies must be subjected to scrutiny and regular audits by the concerned authorities to ensure optimum functioning, and such audit reports have to be made public. Further, the health sector representatives should be involved in all stages of the development and deployment of such AI technologies.

Automation is a major benefit of employing AI-based solutions. Nevertheless, there are inherent risks of misinterpretation in the clinical setting with full automation, and hence, it should always be appropriately supervised. The adoption of the HITL helps in the optimal sharing of accountability for those who are involved in the development and deployment of AI-based algorithms. The legal responsibility for AI usage needs to be properly defined before it is deployed for clinical or public use. If the harm is caused by functionality, the designer, developer, or manufacturer may be held accountable, and if the harm is due to defective implementation of technology, then the end-user or organisation may be held accountable.

vi) Optimisation of data quality

Since AI is a data-driven technology, the outcomes largely depend upon the data used for training and testing the AI. If the dataset is skewed or of poor quality or has inappropriate and inadequate data representations, it may lead to biases, discrimination, errors and suboptimal functioning of the AI technology.

Therefore, it is necessary that before deploying AI technologies, the chances for biases must be considered, identified and thoroughly scrutinised. If there is any allegation of discrimination or evidence of bias in an AI system, the operation of such a system must be discontinued, and appropriate corrective measures must be adopted.

vii) Accessibility, Equity and Inclusiveness

AI developers and concerned authorities should endeavour to provide equal opportunity and access to AI technology among different user groups, thereby ensuring fairness in the distribution of AI technology. Special consideration should be given to those groups that are socially and economically disadvantaged. Further, ICMR suggests the use of local languages in the user interface to overcome language-related accessibility barriers and narrow the digital divide.

viii) Collaboration

The field of artificial intelligence in healthcare is inherently data-driven, requiring access to large, well-curated datasets for any meaningful use of AI for health. This can only be achieved by fostering collaboration across multiple levels. It encourages interdisciplinary, international collaboration and assistance involving different stakeholders. However, it is essential to ensure that no ill effect comes upon the patients whose data may be used to build or test the algorithms during prospective trials of AI technologies. Such activities should adhere to Indian laws, regulations and guidelines.

ix) Non-Discrimination and Fairness Principles

AI-based technologies should be designed for universal usage in order to avoid potential biases and inaccuracies in the algorithms and maintain quality. There should not be any discrimination against individuals or groups based on race, age, caste, religion, or social status. AI developers should give special attention to groups like children, women, ethnic minorities, persons with disabilities, etc., to promote and protect the equality of individuals.

In case of unfortunate events or accidents, there should be appropriate forums for grievance redressal available for the victims. There must also be a provision for people to raise problems about its technical, functional, or ethical misuse. It should also be ensured that the whistleblower's identity is protected.

x) Validity

Before application, it has to be ensured that the AI technology undergoes rigorous clinical and field validation to ensure that there is safety and efficacy for the patients or participants.[103]

The guidelines further provide elaborate guiding principles for the development phase, validation phase, and clinical and other health-related deployment. Hospitals and research institutions must be clear about the use of data collected during the development phase of AI technologies. They should ensure that the data collected doesn't inflict harm or discrimination on the user or patients. A feedback mechanism should exist through which users and physicians can communicate concerns or suggestions to the developers. Further, there should be provisions for removing/modifying the data from the databases in case the user or patients choose to opt-out at any stage. The validation phase verifies whether the developed AI technology is a valid

[103] Rishikaa, *The Indian Council of Medical Research Released the Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare*, Saikrishna & Associates, https://www.saikrishnaassociates.com/the-indian-council-of-medical-research-released-the-ethical-guidelines-for-application-of-artificial-intelligence-in-biomedical-research-and-healthcare/ (last visited Apr. 19, 2025).

solution for a clinical condition. Validation of AI technology is to be done by a multidimensional, multi-sectoral team comprising clinical, data science, statistical, engineering, public health and epidemiological experts. The deployment phase is the last phase and must be dealt with utmost care. Health professionals should have a fair idea of the functional basis of AI technology before its deployment. Health professionals should communicate about the potential lacunae and limitations of the AI technology to the patient/participant prior to deployment. If the use of AI technology causes any adverse event or injury, then the user/participant has the right to receive appropriate compensation from the stakeholders.[104]

The ICMR guidelines also suggest ethical review procedures in medical AI. It states that the Ethics committee is responsible for examining and assessing scientific rigour and ethical aspects of health research. It should ensure that the proposal is scientifically sound and weighs in all the potential risks and benefits. ECs should also consider including legal experts who have experience in IT and medical law, data scientists and computer scientists with expertise in AI technology.

The ICMR has taken a timely intervention in recognising the ethical implications of AI in the healthcare sector and the need to regulate it. These guidelines are patient-centric and highlight the potential threats from the use and misuse of AI-based solutions in healthcare. Given that the development and deployment of AI in healthcare remains at a nascent stage, these place a strong emphasis on ensuring human intervention and oversight throughout all stages of its design, implementation, and use.

Despite providing a robust ethical framework, the ICMR guidelines have certain limitations. The ICMR guidelines are descriptive in nature rather than prescriptive in nature. They lack detailed, actionable steps for operationalising these principles in real-world scenarios. This can lead to variability in interpretation and application across institutions.

[104] Kamya Pandey, Summary: Ethical Guidelines for AI Released by Indian Council of Medical Research, *Medianama* (May 5, 2023), https://www.medianama.com/2023/05/223-icmr-ai-guidelines-summary-key-ideas/.

While the guidelines stress accountability and liability, they do not fully resolve complex questions regarding legal responsibility in cases where AI systems make erroneous or harmful decisions. These guidelines are also insufficient on specific issues such as algorithmic transparency and explainability. The absence of explicit guidelines on these matters may lead to uncertainties regarding the AI systems in clinical decision-making processes.

The governance mechanisms for AI oversight in healthcare remain at a nascent stage, posing challenges for consistent and effective regulation. These guidelines require regular and timely updates to remain relevant, effective, and capable of addressing emerging ethical, legal, and technical complexities. Without such revisions, they risk lagging behind the rapid and continuous advancements in AI technologies.

CHAPTER 5

INTERNATIONAL PERSPECTIVES ON AI IN HEALTHCARE

5.1 Introduction

As Artificial Intelligence continues to transform the global healthcare landscape, many countries are increasingly recognising the urgent need to establish robust legal and regulatory frameworks. The rapid integration of AI technologies into medical diagnostics, treatment planning, patient care, and health system management has highlighted significant concerns around data privacy, safety, accountability, and ethical use. The global AI in healthcare market is experiencing unprecedented growth. It was valued at approximately USD 26.69 billion in the year 2024 and is projected to reach approximately around USD 613.81 billion by the year 2034, growing at a compound annual growth rate (CAGR) of 36.83%.[105] In response to this surge, governments and international bodies are actively developing and refining legal structures to make sure that the use of AI in healthcare is both effective and aligned with public interest.

5.2 Legal Frameworks for AI in Healthcare Across Countries and Institutions

Regulating AI in healthcare is an intricate task that involves striking a balance between fostering scientific innovation and protecting human rights and safety. Different countries may adopt various approaches to AI regulation, reflecting their unique values and priorities. For instance, jurisdictions such as the European Union and China have AI-specific laws, while others, including the United Kingdom, United States and Australia, are initially assessing how existing technology-neutral laws can be applied to AI.[106]

[105] Artificial Intelligence Market Size Projected to Hit USD 3,680.47 Bn by 2034, Globe Newswire (Nov. 7, 2024) https://www.globenewswire.com/news-release/2024/11/07/2976909/0/en/Artificial-Intelligence-Market-Size-Projected-to-Hit-USD-3-680-47-Bn-by-2034.html

[106] David Egan & Jieni Ji, *AI in healthcare: legal and ethical considerations in this new frontier, International Bar Association* (Feb. 11, 2025). https://www.ibanet.org/ai-healthcare-legal-ethical

5.2.1 European Union

The European Union (EU) began shaping its approach to AI by issuing non-binding guidelines, including the *"Ethics Guidelines for Trustworthy AI"* and the *"Policy and Investment Recommendations",* both published in 2019. The *Ethics Guidelines for Trustworthy AI* outlined seven key requirements: human oversight, technical robustness and safety, privacy and data governance, transparency, diversity and non-discrimination, societal and environmental well-being, and accountability. The *Policy and Investment Recommendations* set out strategic priorities aimed at enhancing Europe's competitiveness in AI while promoting its ethical and responsible use.

The regulatory journey took a significant turn in 2021 with the introduction of the *Medical Device Regulation (MDR)* and the *In Vitro Diagnostic Medical Device Regulation (IVDR).* These frameworks modernised the EU's approach to medical device oversight by incorporating specific provisions for Software as a Medical Device (SaMD). Under the MDR, AI-driven medical devices are classified depending on the level of risk they may pose to patients and users, particularly with respect to their intended use in diagnosis or treatment. The IVDR complements this by regulating diagnostic AI tools that analyse biological samples.

As part of its digital strategy, the European Union (EU) proposed the world's first comprehensive legal framework for artificial intelligence, the *Artificial Intelligence Act (AI Act)*, in 2021.[107] This landmark regulation was formally adopted in 2024 and is set to be enforced in phases over the coming years. Unlike previous sector-specific laws, the AI Act is a horizontal framework that applies across all sectors, including healthcare. The Act ensures that AI systems used in the EU are safe, transparent, traceable, and non-discriminatory.

[107] *EU AI Act: First Regulation on Artificial Intelligence* (June 8, 2023), https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence.

The AI Act takes a risk-based approach, categorising and regulating AI systems according to the level of potential harm they may cause.

AI systems that have an unacceptable risk are strictly prohibited. This includes systems that manipulate human behaviour subliminally or exploit vulnerabilities of specific groups, such as children or persons with disabilities, real-time remote biometric identification in public spaces for law enforcement, and social scoring systems that rate individuals' trustworthiness based on behaviour or personality traits. However, certain uses, including law enforcement, psychological treatment, or medical therapies involving behavioural analysis, may be permitted under narrowly defined lawful conditions.

AI systems classified as high-risk must meet strict requirements and are subjected to human oversight. This includes systems that evaluate consumer creditworthiness, assist in hiring or managing employees, or employ biometric identification. All high-risk AI systems must undergo conformity assessments before entering the EU market and are subject to ongoing monitoring throughout their lifecycle. Providers must establish risk management systems, register in a central EU database, and submit post-market surveillance reports. Furthermore, affected individuals have the right to file complaints with national supervisory authorities.

Limited-risk AI systems involve applications such as AI chatbots or decision support tools that pose lower risks to user's rights or safety. These systems are primarily subject to transparency obligations, such as notifying users when they are interacting with an AI. While not subject to strict pre-market controls, developers must still ensure compliance with EU consumer protection and product safety laws.

Minimal-risk AI systems include tools like AI-enabled email filtering or inventory management. These pose no obligations under the AI Act, although developers are encouraged to adhere to voluntary codes of conduct and best practices.[108]

[108] Felix Busch et al., Navigating the European Union Artificial Intelligence Act for Healthcare, 7 *npj Digit. Med.* (2024), https://doi.org/10.1038/s41746-024-01213-6.

The AI Act also addresses general-purpose AI models, including generative AI systems such as ChatGPT. These models, even if not high-risk themselves, can pose systemic risks depending on their scale and capabilities. Under the AI Act, foundation models are required to meet specific transparency requirements, such as disclosing that content is AI-generated, implementing safeguards to prevent the generation of illegal content, and publishing summaries of copyrighted data used in training to ensure compliance with EU copyright law. Models classified as high-impact or systemic risk, like advanced iterations of GPT models, must undergo rigorous testing and documentation, and report any serious incidents to the European Commission.

If an AI system does not fall within one of these categories, it would not be under the scope of the AI Act. However, it would still need to comply with the General Data Protection Regulation (GDPR). The GDPR remains central to protecting individuals' rights when personal data is involved in AI processing. It governs how personal health data, often used to train or operate AI systems, is collected, processed, stored, and shared.

Under the GDPR, data processing must be based on clear legal grounds, with informed, explicit, and freely given consent when applicable. The burden of proof lies on the data controller, who must demonstrate that valid consent has been obtained. The GDPR also guarantees transparency and access rights: patients have the right to access their health data and must be informed of how their data is used, including the right to withdraw consent at any time. Data must be provided in an intelligible format using plain language. Although the regulation affirms the right to access data, it allows for administrative fees to be charged if repeated requests are made, potentially limiting free access in practice.

5.2.2 United Kingdom

The United Kingdom does not yet have a dedicated statutory framework specifically regulating artificial intelligence. However, it seeks to apply and adapt existing legislation to AI applications.

Even though regulations such as the UK Medical Device Regulations 2002 (UK MDR) were not originally designed with modern machine learning or generative AI in mind, they are increasingly being interpreted to encompass software-based technologies, including AI-driven systems.

In 2021, the Medicines and Healthcare Products Regulatory Agency (MHRA) initiated a dedicated reform initiative titled the *Software and AI as a Medical Device (SaMD/AIaMD) Change Programme* to ensure the UK MDR is fit for purpose for AIaMD.[109] It is structured around two core workstreams: the first addresses overarching reforms to regulate the full lifecycle of Software as a medical device, covering areas such as cybersecurity, post-market surveillance, and data protection. The second workstream focuses specifically on AI-related issues such as adaptive algorithms, bias mitigation, and the explainability and interpretability of AI models. Mirroring GDPR principles, the Data Protection Act regulates the use of personal data, ensuring privacy and security in AI applications.

Although the UK has not introduced horizontal, AI-specific legislation akin to the European Union's AI Act, it has signalled its regulatory direction through a number of high-level policy papers and governmental statements. Notably, in March 2023, the UK government set out a policy paper on *'A pro-innovation approach to AI regulation'*, which outlines a light-touch, flexible regulatory model. It introduces five cross-sectoral principles intended to guide the regulation and development of AI: (i) safety, security and robustness; (ii) appropriate transparency and explainability; (iii) fairness; (iv) accountability and governance; and (v) contestability and redress. These principles are non-statutory and are to be interpreted by existing regulators, such as the MHRA in healthcare, the Competition and Markets Authority (CMA), and the Office of Communications (Ofcom).[110]

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[109] *Software and AI as a Medical Device Change Programme roadmap, Medicines & Healthcare products Regulatory Agency, U K Government (June 14, 2023)* https://www.gov.uk/government/publications/software-and-ai-as-a-medical-device-change-programme/software-and-ai-as-a-medical-device-change-programme-roadmap

[110] *AI Regulation: A Pro-Innovation Approach,* Department for Science, Innovation and Technology and Office for Artificial Intelligence, U K Government (Mar. 29, 2023), https://www.gov.uk/government/publications/ai-regulation-a-pro-innovation-approach.

The UK's House of Commons Innovation and Technology Committee released an interim report on 31 August, 2023, examining different approaches to regulating AI in the UK. The report suggested that the government propose a 'tightly focused AI Bill' in the upcoming parliamentary session to establish the UK as a global leader in AI governance.

In August 2023, the Department for Science, Innovation and Technology (DSIT), alongside the Office for AI, published a further white paper reaffirming the UK's commitment to a decentralised, regulator-led strategy rather than a comprehensive AI law. Despite this, the House of Commons Innovation and Technology Committee, in an interim report dated 31 August 2023, recommended the introduction of a "tightly focused AI Bill" in the forthcoming parliamentary session. The report argued that such legislation could help position the UK as a leader in global AI governance, particularly in high-impact sectors such as healthcare. However, to date, the UK government has not proposed any specific legislation on AI.

5.2.3 United States

In the United States, there is no singular, dedicated regulatory pathway for AI-based healthcare technologies, but the Food and Drug Administration (FDA) has sought to adapt its existing frameworks to address the distinct challenges presented by AI and machine learning systems.

In April 2019, the FDA introduced the "Proposed Regulatory Framework for Modifications to AI/ML-based Software as a Medical Device (SaMD)". This proposal placed the onus on developers to ensure the real-world performance of their AI systems, requiring them to notify the FDA of any changes affecting performance or input data.[111] The framework also stipulated that any alteration in the intended use of an AI system would necessitate a new approval process. Building upon this, the FDA released the "AI/ML-based SaMD Action Plan" in January 2021, outlining five key actions to oversee AI/ML-based medical devices based on the Total Product Life Cycle (TPLC). These actions included the establishment of Good Machine Learning Practices (GMLPs), a patient-centric approach emphasising transparency, methods to mitigate algorithmic bias, and initiatives for real-world performance monitoring. The GMLPs

[111]H. Benjamin Harvey & Vrushab Gowda, *How the FDA Regulates AI*, 27(1) *Acad. Radiol.* (2020), https://doi.org/10.1016/j.acra.2019.09.017.

encompassed aspects such as ensuring data relevance to clinical problems, maintaining consistency in data collection, planning for modifications, defining appropriate boundaries in datasets, and ensuring transparency in AI algorithms and their outputs.

The Federal Food, Drug, and Cosmetic Act, as amended by the 1976 Medical Device Amendments, provides the statutory basis for regulating software-based medical technologies, including autonomous AI systems. Further clarification came with the 21st Century Cures Act in 2016, with the definition of medical devices explicitly encompassing AI-based tools, placing them under the FDA's regulatory jurisdiction. The FDA categorises devices into three classes—Class I (low risk), Class II (moderate risk), and Class III (high risk)—with regulatory controls increasing with risk level. As of December 2024, the FDA had approved 1,016 AI- and machine-learning-enabled medical devices, underscoring the expanding role of AI in clinical practice.

Alongside the FDA, other federal agencies have also engaged with AI governance in healthcare. The Office of the National Coordinator for Health Information Technology (ONC) oversees the Health Data, Technology, and Interoperability Certification Programme (HTI-1 Rule), which sets requirements for the safe and interoperable use of AI-based decision support tools in electronic health records. This ensures that such tools can function reliably within complex healthcare information ecosystems.

In parallel, the Federal Trade Commission (FTC) has issued general principles for the use of AI and algorithms, particularly in relation to consumer protection. In April 2020, the FTC outlined five guiding principles for organisations: transparency about AI use, clear explanation of automated decisions, fairness in outcomes, robustness of data and models, and organisational accountability for compliance and non-discrimination. Though not healthcare-specific, these guidelines reinforce broader ethical standards relevant to AI use in medicine.[112]

[112] Harmon L. (Monty) Cooper et al., *Recent FTC Guidance on the Use of Artificial Intelligence and Algorithms in the Age of COVID-19*, 37(8) The Computer & Internet Lawyer (2020).

In October 2022, the White House published the "Blueprint for an AI Bill of Rights", proposing five foundational principles: protection from unsafe or ineffective systems, safeguards against algorithmic discrimination, preservation of data privacy, transparency in automated decisions, and the availability of human alternatives. This blueprint serves as a policy roadmap for the ethical development and use of AI technologies, including in healthcare.[113] The Biden administration reinforced these principles in October 2023 through an Executive Order on the Safe, Secure, and Trustworthy Development and Use of AI.[114] The order directed various federal agencies, including the Department of Health and Human Services (HHS), to set out standards and oversight mechanisms for AI applications. The FDA and the Centers for Medicare & Medicaid Services (CMS) were tasked with advancing strategies for AI adoption in healthcare. Key provisions include the implementation of the AI Bill of Rights and the formation of the Office of the Chief AI Officer to coordinate these initiatives. The Executive Order also highlighted themes such as risk management, equity, innovation, and transparency. However, as an executive action, it lacks the permanence of statutory law and may be subject to revision or repeal under future administrations.

5.2.4 China

Over the past few years, China has progressively built its regulatory system for AI use in healthcare, mainly under the direction of the National Medical Products Administration and the National Health Commission, with contributions from other agencies such as the Cyberspace Administration of China (CAC). This evolving framework aligns with broader national strategies, particularly the Healthy China 2030 Initiative, which emphasises improving healthcare quality, accessibility, and innovation. As part of this effort, China has published several guidelines for AI-driven medical devices, data protection, cybersecurity, and ethical governance, ensuring that AI applications in healthcare are safe, effective, and aligned with national priorities.

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[113] *White House Releases Long-Awaited "AI Bill of Rights" Document*, EPIC (Oct. 4, 2022). https://epic.org/white-house-releases-long-awaited-ai-bill-of-rights-document/

[114] *Biden Administration Announces Artificial Intelligence Executive Order*, Global Policy Watch (Oct. 31, 2023) https://www.globalpolicywatch.com/2023/10/biden-administration-announces-artificial-intelligence-executive-order/

In 2019, the NMPA issued a *Technical Guideline on AI-aided Software*, which highlighted the characteristics of deep learning technology, controls for software data quality, valid algorithm generation, and methods to assess clinical risks. It also clarified that for AI software, version naming rules should cover algorithm-driven and data-driven software updates and should list all typical scenarios for major software updates.[115] This document laid the groundwork for subsequent regulatory measures by addressing the unique threats of AI in medical applications.

In 2021, the NMPA released the *Guidelines for the Classification and Definition of AI Medical Software Products*. These guidelines provided a framework for classifying AI medical devices based on their intended use, usage scenarios, and core functions of the product.[116] They also addressed the safety and effectiveness of AI algorithms and standardised naming conventions for medical software products.

In 2022, the regulatory landscape expanded with the *Guidelines for the Registration and Review of AI Medical Devices,* which standardised submission requirements and technical review processes and the *Guidelines for the Registration and Review of Medical Device Software*, which focused on the quality management of Software. The *Guidelines for the Registration and Review of Medical Device Cybersecurity* established standards for the cybersecurity of medical devices, taking into consideration the entire product lifecycle. In addition to the cross-speciality guidance of AI applications in healthcare, guidelines for specific medical applications of AI, such as the *Guidelines for the Registration Review of Pulmonary Nodule CT Image Assisted Detection Software* and the *Guidelines for the Registration and Review of Diabetic Retinopathy Fundus Image Aided Diagnosis Software* were also issued.[117]

[115] Filippo Pesapane et al., Legal and Regulatory Framework for AI Solutions in Healthcare in EU, US, China, and Russia: New Scenarios after a Pandemic, 1(4) Radiation (2021). https://doi.org/10.3390/radiation1040022

[116] Nicholas Chan, *Use of Artificial Intelligence in Healthcare Industry in Mainland China,* Triage Health Law (Sept. 25, 2023). https://www.triagehealthlawblog.com/life-sciences/use-of-artificial-intelligence-in-healthcare-industry-in-mainland-china/

[117] Felix Busch et al., *AI regulation in healthcare around the world: what is the status quo?*, medRxiv (2025). https://doi.org/10.1101/2025.01.25.25321061

In 2023, *Interim Measures for the Administration of Generative AI Services* were issued by the Cyberspace Administration of China (CAC), in collaboration with six other national regulatory bodies. These measures aim to regulate public-facing generative AI services, emphasising ethical governance, transparency, and risk mitigation. They outlined principles such as adherence to laws, respect for social morality, and avoidance of content that could harm national security or public interests. The regulations also call for safeguards against algorithmic bias based on ethnicity, religion, gender, age, occupation, and other factors, while requiring AI systems to respect IP rights and business ethics to avoid unfair competition and the unauthorised disclosure of trade secrets. Furthermore, generative AI must uphold individual rights, ensuring it does not harm the physical or mental well-being of users. To enhance accountability, developers are required to use legally obtained data, respect personal information rights by securing user consent, and strive to ensure the authenticity, accuracy, objectivity, and diversity of training data.

In 2024, the NMPA released the draft *Medical Device Administration Law* for public consultation. This draft law presents the first overarching regulatory framework in China for the entire life cycle of medical devices, including research and development (R&D), manufacturing, distribution, and use. It remains to be seen whether this law will also apply to AI-based medical devices, potentially replacing previous administrative regulations with limited legal authority.

Apart from AI-specific guidelines related to healthcare, the regulation of personal data, particularly sensitive health information, is governed by the *Personal Information Protection Law (PIPL)*. This law establishes strict requirements for the processing of personal data, including the need for explicit consent from individuals, clear limitations on data usage, and stringent rules regarding data localisation and cross-border data transfers.

5.2.5 Australia

Australia's legal and ethical framework for the use of Artificial Intelligence in healthcare is still developing, relying largely on existing legislation, while efforts to establish AI-specific regulations continue. Among the foundational legal instruments, the Privacy Act 1988 plays a critical role by regulating the handling of personal information, including sensitive health data, by both government agencies and certain private sector organisations. Although not directly aimed at AI technologies, the Online Safety Act 2021 provides a broader regulatory context for digital platforms operating in Australia, particularly in relation to telehealth and mobile health services.

Recognising the increasing significance of artificial intelligence, the Australian Government published the AI Ethics Framework in November 2019 through the Department of Industry, Science, Energy and Resources (DISER), in partnership with CSIRO's Data61. This framework outlines eight core ethical principles designed to guide the responsible development and use of AI in a way that is safe, secure, and reliable. Although these principles are voluntary, they serve as an important reference point for industry stakeholders and are particularly relevant in healthcare, where AI-driven decisions can have profound and direct effects on human lives. The framework emphasises that AI systems should be developed to benefit all people, society, and the environment. They should be grounded in human-centred values, respecting human rights, dignity, and individual autonomy. Fairness is another core tenet, requiring AI to be inclusive and accessible while avoiding unfair bias or discrimination. The principles also stress the importance of privacy and data protection, mandating that AI systems uphold privacy rights and maintain strong data security. AI technologies must function reliably and safely, operating in accordance with their intended purpose. Their operations and decision-making processes should be transparent and explainable to users and stakeholders. The principle of contestability ensures that when AI systems have significant impacts on individuals, communities, or the environment, there must be a timely and accessible process for challenging or reviewing decisions. Finally, accountability is identified as a cornerstone of trustworthy AI, necessitating that clear lines of responsibility are established for those involved in the development and

deployment of AI technologies and that human oversight remains integral to system governance.[118]

On the regulatory side, the Therapeutic Goods Administration (TGA) amended the Therapeutic Goods (Medical Devices) Regulations 2002 to specifically address Software as a Medical Device (SaMD). To clarify these amendments, an associated guideline titled Regulatory Changes for Software-Based Medical Devices was published in 2021. These reforms introduced a risk-based classification system for software-based medical devices, aligning Australia's regulatory framework more closely with international standards, particularly the European Union's Medical Device Regulation (EU MDR). Under this system, software devices are categorised based on their intended purpose and the potential risk they pose to patient safety. This risk-based approach ensures that higher-risk devices undergo more rigorous regulatory scrutiny. [119]

The revised regulations also explicitly require software-based medical devices to implement robust cybersecurity measures and to manage data effectively throughout the Software's lifecycle. Additionally, manufacturers must ensure that the version and build number of the Software are clearly identifiable and accessible to users, thereby enhancing traceability and accountability. Importantly, the TGA has identified certain categories of Software that are either excluded from regulation or considered exempt under specific conditions. Excluded categories include low-risk consumer health products, telehealth enablers, electronic medical records, population-level analytics tools, and laboratory information management systems. In some cases, Software such as Clinical Decision Support Systems (CDSS) may be exempt from full regulatory oversight if they meet specific criteria established by the TGA. This demonstrates that the TGA acknowledges the importance of regulating AI-driven medical devices at the national level while also striving for alignment with international standards, prioritising SaMDs with high-risk factors that have a high impact on patient safety.

[118] Australia's AI Ethics Principles Department of Industry, Science and Resources, Australia, (last visited 24 Apr. 2025), https://www.industry.gov.au/publications/australias-artificial-intelligence-ethics-principles/australias-ai-ethics-principles

[119] Kavitha Palaniappan et al., *Global Regulatory Frameworks for the Use of Artificial Intelligence (AI) in the Healthcare Services Sector,* 12(5) Healthcare (2024). https://doi.org/10.3390/healthcare12050562

5.3 Global Guidelines and Contributions related to AI in Healthcare

5.3.1 WHO Guidelines

The World Health Organisation (WHO) is a key player in promoting ethical, safe, and effective AI use in global healthcare. The WHO has been active in addressing AI's role in healthcare through initiatives like the WHO Global Strategy on Digital Health, which is a comprehensive framework developed to guide countries in leveraging digital technologies to strengthen health systems and achieve universal health coverage.

The WHO guidance on *Ethics & Governance of Artificial Intelligence for Health*, released in 2021, outlines six consensus principles to ensure that AI in healthcare is developed and implemented ethically. These principles emphasise the importance of protecting human autonomy and ensuring that AI supports, rather than replaces, human decision-making. They also highlight the need for AI to promote human well-being and safety, with transparency and accountability in decision-making processes. Additionally, the guidelines stress the importance of equity and inclusiveness, ensuring that AI does not exacerbate health disparities but instead benefits all populations. AI systems should also be adaptable and sustainable, meeting evolving health needs while fostering long-term societal benefits. Lastly, the principles call for the protection of privacy and data security, ensuring that individuals' health information remains confidential and secure. These guidelines aim to create a framework where AI in healthcare serves the public good while minimising potential risks.[120]

In 2024, the WHO released guidance on the *ethics and governance of large multi-modal models (LMMs)*. LMMs are capable of processing and generating diverse data types and are increasingly applied in areas like diagnosis, patient education, administrative tasks, medical training, and drug research. It also highlights risks such as misinformation, algorithmic bias, and cybersecurity vulnerabilities. The guidance emphasises the need for inclusive stakeholder engagement in the development and deployment of LMMs.

[120] *Ethics and governance of artificial intelligence for health,* (28 June 2021). https://www.who.int/publications/i/item/9789240029200

Key recommendations include establishing ethical standards, ensuring human rights protections, and implementing mandatory post-release audits to safeguard public health interests.[121]

5.3.2 OECD AI Principles

The Organisation for Economic Cooperation and Development (OECD) first introduced its *AI Principles* in May 2019, establishing them as the first intergovernmental standards for artificial intelligence. These principles were endorsed by 42 countries with the objective of promoting the use of AI that is innovative and trustworthy and respects human rights and democratic values.[122]

In May 2024, the OECD updated these principles to address the rapid advancements in AI technologies, particularly the emergence of general-purpose and generative AI. The updated principles now include enhanced provisions on AI system safety, information integrity, responsible business conduct, transparency and responsible disclosure, environmental sustainability, and international cooperation for trustworthy AI. By following OECD AI Principles, policymakers are better equipped to steer the development and application of AI to maximise its benefits and minimise its risks. This approach is essential for unlocking AI's potential to drive economic advancement, improve social well-being, and support environmental sustainability while protecting individuals and societal values.

5.3.3 Global Partnership on Artificial Intelligence (GPAI)

The Global Partnership on Artificial Intelligence (GPAI) is indeed a collaborative initiative designed to bring together experts from various sectors, including industry, academia, government, and civil society, to promote the responsible development of AI.

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[121] *WHO releases AI ethics and governance guidance for large multi-modal models* (18 January, 2024). https://www.who.int/news/item/18-01-2024-who-releases-ai-ethics-and-governance-guidance-for-large-multi-modal-models

[122] *AI Principles*, https://www.oecd.org/en/topics/sub-issues/ai-principles.html (last visited May 1, 2025).

One of its key goals is to foster the development of methodologies that demonstrate how AI can be leveraged to tackle global challenges, including crises such as pandemics or climate change.[123]

GPAI is a multilateral initiative, and its members include OECD countries along with other countries involved in the partnership. The goal is to promote AI that is human-centric, safe, secure, and trustworthy, aligning with the principles outlined in the OECD's Recommendation on AI. These principles focus on ensuring AI is developed and deployed ethically and responsibly, benefiting societies while minimising risks.

5.3.4 G20 AI Principles

The G20, comprising the world's major economies, endorsed a set of Principles on Artificial Intelligence in 2019, adapted from the OECD's AI Principles. These principles are intended to guide the responsible development and deployment of AI technologies, including those used in sensitive domains such as healthcare. While the principles are non-binding, they represent a global consensus on the importance of developing human-centred, ethical, and trustworthy AI systems.

5.3.5 UNESCO Recommendation on the Ethics of Artificial Intelligence

The UNESCO Recommendation on the Ethics of Artificial Intelligence, adopted in November 2021, serves as a comprehensive global framework aimed at guiding the responsible development and deployment of AI across all 194 member states of UNESCO.[124] At its core, the Recommendation upholds the safeguard of human rights and dignity, guaranteeing that AI systems are designed and utilised in ways that respect the fundamental rights of individuals. This includes the need for transparency in AI systems, allowing stakeholders and users to understand how decisions are made by AI and ensuring that these processes are accessible**.**

[123] *Global Partnership on Artificial Intelligence,* https://www.oecd.org/en/about/programmes/global-partnership-on-artificial-intelligence.html (last visited May 1, 2025).

[124] *Ethics of Artificial Intelligence*, UNESCO, https://www.unesco.org/en/artificial-intelligence/recommendation-ethics (last visited May 1, 2025).

The Recommendation stresses the importance of fairness in AI, advocating for systems that are free from biases based on race, gender, ethnicity, or other personal characteristics, thus promoting equitable outcomes for all users. It also underscores the principle of accountability, calling for mechanisms to ensure that AI developers, users, and stakeholders can be held responsible for the outcomes of AI systems, particularly when they impact people's lives in critical sectors like healthcare.Another key component of the Recommendation is the emphasis on human oversight. It acknowledges that while AI technologies hold vast potential, they must remain under human control to safeguard ethical standards and ensure decisions made by AI systems align with human values and well-being.

Furthermore, the UNESCO Recommendation advocates for ethical data governance, ensuring that healthcare data, often sensitive and personal, is handled with the highest standards of privacy and security. It promotes a holistic approach to AI deployment, ensuring that AI solutions are inclusive and accessible, especially for marginalised or vulnerable populations.

5.3.6 Bletchley Declaration (AI Safety Summit)

The Bletchley Declaration was adopted on November 1, 2023, during the inaugural AI Safety Summit hosted by the United Kingdom at Bletchley Park. This landmark agreement brought together 28 countries, including India, China, the United States, the United Kingdom, alongside the European Union, in a unified effort to address the global risks posed by advanced artificial intelligence technologies.[125] The declaration acknowledges that the rapid advancement of frontier AI systems, particularly those with general-purpose capabilities, carries the potential for catastrophic risks not just to individuals, but to global society, security, and stability. The signatory nations of the Bletchley Declaration have agreed to work together in an open and inclusive way to support the development of AI that is safe, trustworthy, responsible, and focused on human needs. The declaration focuses on the risks of frontier AI by promoting shared understanding, identifying common safety concerns, and supporting risk-based policies tailored to each country.

[125] *Britain publishes 'Bletchley Declaration' on AI safety,* Reuters (November 1, 2023) https://www.reuters.com/technology/britain-publishes-bletchley-declaration-ai-safety-2023-11-01/

CHAPTER 6

CONCLUSION AND SUGGESTIONS

6.1 Introduction

The expeditious evolution of artificial intelligence has led to profound changes across various sectors, with healthcare emerging as one of its most promising yet ethically complex frontiers. As AI becomes increasingly embedded in medical decision-making, it challenges long-standing norms, responsibilities, and safeguards within clinical practice. Questions surrounding patient autonomy, informed consent, data privacy, transparency, and accountability have become more intricate with the adoption of AI-driven tools. The absence of a dedicated legal framework to govern these developments reveals a critical gap between technological progress and the regulatory mechanisms meant to ensure ethical and equitable practice. This growing disconnect calls for comprehensive, sector-specific legislation that upholds core ethical principles, protects patient rights, and establishes clear accountability mechanisms, especially in high-stakes clinical settings shaped by opaque algorithmic decision-making.

6.2 Conclusion

The first chapter, titled 'Introduction', provides a comprehensive overview of the study's foundation. It constitutes an introduction, statement of problem, scope and delimitation, research objectives, research questions, hypothesis, research methodology, literature review and chapterisation. The introduction establishes the foundational premise that while Artificial Intelligence (AI) holds a revolutionary capacity to improve healthcare delivery, it also raises significant ethical and legal complexities. These include concerns related to patient autonomy, informed consent, transparency of AI decision-making, explainability, legal ambiguity around liability, and the risk of algorithmic bias. The research's objectives are focused on evaluating ethical dilemmas and assessing the adequacy of current legal frameworks, and the same is framed into the research problems. The scope is limited to the ethical and legal impacts of AI integration on both healthcare professionals and patients and does not delve into the technical details or specific applications of AI systems. The research methodology adopted is doctrinal legal research drawing from legislation, case law, scholarly articles, and authoritative texts to

form the conjecture. The literature review further supports the discussion by incorporating real-world examples and academic insights.

The second chapter presents a comprehensive exploration of the advancements in artificial intelligence technologies and how they are transforming the healthcare landscape. It begins by outlining the key artificial intelligence methodologies relevant to the field, including machine learning, deep learning, and natural language processing. The chapter details a broad range of applications, such as artificial intelligence-based diagnostic systems and artificial intelligence-enabled drug discovery, that accelerate the development of new treatments and approaches in precision and personalised medicine tailored to individual genetic and lifestyle characteristics. It highlights artificial intelligence's role in continuous patient monitoring, as well as how clinical decision support systems enhance the accuracy and speed of medical decisions made. AI-driven robots can also contribute to surgeries, patient assistance, cleaning, and managing logistics, while AI chatbots and virtual assistants enhance patient communication and streamline administrative functions. Integration of AI with electronic health records boosts data management, documentation, and workflow efficiency. Furthermore, AI transforms hospital operations by optimising resource allocation, scheduling, and patient flow and supports population health management by analysing diverse data sources to predict risks, target interventions, and ensure equitable access to care across communities.

The third chapter critically examines the ethical implications arising from the use of artificial intelligence in medical decision-making, focusing on the balance between technological advancement and core ethical principles in healthcare. It opens by discussing how AI poses significant ethical dilemmas concerning patient autonomy, as opaque AI systems may impair informed consent and diminish the doctor-patient relationship. It also underscores the risks of algorithmic bias, illustrating how underrepresentation in training datasets and socio-structural inequities can lead to discriminatory outcomes that disproportionately harm marginalised groups, undermining fairness and equity. Transparency and explainability emerge as foundational values for sustaining trust and accountability, especially since the "black box" nature of many AI models inhibits clinical interpretability and informed patient decision-making. In the realm of privacy and data protection, the chapter highlights the tension between the data-hungry nature of AI and the individual's right to control sensitive health information,

bringing attention to high-profile breaches and the shortcomings of anonymisation, thus stressing the need for stringent data governance. Then, it scrutinises the evolving question of accountability in AI-mediated harm, revealing the challenges posed by fragmented responsibility among developers, clinicians, and institutions and calling for robust legal and ethical frameworks to ensure transparency, redress, and just compensation in cases of AI-related errors.

The fourth chapter explores the evolving legal framework governing the integration of artificial intelligence in India's healthcare sector. It outlines how existing laws, including the Information Technology Act of 2000 and the Medical Devices Rules of 2017, provide foundational but limited regulatory coverage for AI-driven tools, particularly with regard to data protection, liability, and patient safety. The chapter details key policy developments such as NITI Aayog's National Strategy for AI and the Ayushman Bharat Digital Mission, which aim to facilitate AI adoption through digital infrastructure and responsible innovation. The Telemedicine Practice Guidelines, 2020 reaffirm the necessity of human oversight by restricting AI from independent clinical action. The Digital Personal Data Protection Act of 2023, while instrumental in protecting personal health data, is not AI-specific and relies primarily on a consent-based model, which poses practical challenges in dynamic AI systems. The ICMR's 2023 Ethical Guidelines are also examined, offering patient-centric principles like autonomy, data privacy, fairness, and accountability while highlighting the need for human oversight, transparent validation, and ethical governance. However, it remains advisory in nature and lacks legal enforceability.

The fifth chapter discusses the evolving legal and ethical landscape surrounding the deployment of artificial intelligence in healthcare. This chapter compares the regulatory models adopted by key jurisdictions, including the European Union, the United Kingdom, the United States, China, and Australia, and also examines the contributions of major international organisations like the WHO, OECD, GPAI, G20, UNESCO, and initiatives such as the Bletchley Declaration. Countries and international organisations are taking varied regulatory approaches based on their socio-political priorities and technological capabilities. The European Union is at the forefront with a comprehensive legal structure through its AI Act, GDPR, and Medical Device Regulation, applying a risk-based model to ensure transparency

and patient protection. The United Kingdom has adopted a principles-based, regulator-led approach without enacting specific AI legislation, favouring flexible, sector-specific adaptations of existing laws. The United States integrates AI into healthcare through the FDA's evolving SaMD regulatory frameworks, the AI Bill of Rights, and executive directives. China, under national strategies like Healthy China 2030, has introduced detailed technical guidelines and lifecycle regulations overseen by multiple agencies, complemented by the Personal Information Protection Law. Australia emphasises alignment with international standards through its Therapeutic Goods Administration (TGA) framework, supported by a voluntary AI Ethics Framework that foregrounds human-centred design and risk stratification. Beyond national efforts, global institutions such as the World Health Organisation advocate for ethically grounded AI governance, emphasising human autonomy, transparency, and inclusivity, while the OECD's AI Principles promote trustworthy and sustainable development. Multilateral efforts such as the Global Partnership on Artificial Intelligence (GPAI), the G20 AI Principles, and UNESCO's Ethics of AI Recommendation further reinforce commitments to fairness, accountability, and human oversight. The Bletchley Declaration of 2023, signed by major global powers, marks a historic consensus on managing the existential and societal risks posed by frontier AI technologies.

The sixth chapter, titled 'Conclusions and Suggestions', begins with an introduction that sets the stage for the culmination of the research study. This is followed by a comprehensive summary of the main findings from each of the earlier chapters. The key elements of the study are synthesised into a cohesive and concise analysis, offering a clear analysis. The chapter then transitions into a set of well-founded recommendations, which are drawn from the in-depth analysis conducted throughout the research. These recommendations act as a roadmap, presenting a potential course of action that ought to be taken into account for addressing the complex legal and ethical dimensions associated with the use of artificial intelligence in medical decision-making.

With this in mind, the hypothesis for the study can be inferred as

1. AI in healthcare offers significant benefits in improving medical decision-making and patient outcomes, but it also raises ethical challenges that compromise patient autonomy, privacy and informed consent.

2. Existing legal frameworks are insufficient to address the unique challenges presented by AI in medical decision-making.

The findings of the study affirm both hypotheses. The research consistently highlights how AI enhances diagnostic precision, streamlines clinical workflows, and enables more proactive and personalised care, confirming its significant potential to improve medical decision-making and patient outcomes. However, these benefits also bring along some substantial ethical concerns. The opacity of AI systems often hampers transparency and informed consent, while their data-intensive nature raises unresolved issues regarding privacy and control over personal health information. Furthermore, reliance on algorithmic outputs may reduce opportunities for patient preferences and shared decision-making, which ultimately compromises patient autonomy. The analysis also reveals that current legal and regulatory frameworks remain underdeveloped in addressing the specific complexities introduced by AI. While some regulations provide general protections, they fall short in terms of AI-specific accountability, transparency standards, and mechanisms to ensure fairness and equity in clinical contexts. The absence of enforceable, sector-specific legal provisions contributes to ongoing uncertainty and gaps in safeguarding patient rights, thereby confirming the inadequacy of existing legal structures in governing AI in healthcare.

The research, as developed across the chapters, engages each research question with specific analysis and contextual grounding. Ethical challenges such as autonomy and informed consent are critically examined through real-world examples and doctrinal analysis, illustrating how opaque algorithmic systems complicate shared decision-making and clinical trust. The study's exploration of algorithmic bias reveals how disparities in training data and system design contribute to unequal outcomes, particularly for marginalised populations, reinforcing the need for inclusive model development and evaluation. Legal analysis reveals that existing Indian and comparative frameworks provide limited recourse for AI-specific harms, with regulatory

instruments remaining fragmented, generalised, or advisory in nature. Discussions on decision-making authority and human oversight demonstrate that while AI can assist, it cannot fully replace clinical judgment, especially in complex or value-laden situations. The examination of global regulatory approaches underscores the importance of adaptability and international cooperation in creating norms that ensure equitable AI governance. The research collectively highlights that while AI has the potential to revolutionise healthcare, its deployment must be matched by legal, ethical, and procedural safeguards that uphold patient dignity, prevent systemic discrimination, and ensure accountability across all levels of implementation.

6.3 Suggestions

6.3.1 Dedicated legislation for AI technologies

It is imperative to establish a clear, dedicated and enforceable regulatory framework specifically addressing AI in healthcare. India's existing medical device and data protection laws provide a foundational basis; however, the unique challenges posed by AI, such as algorithmic opacity, dynamic learning systems, and autonomous decision-making, necessitate bespoke regulations. These should mandate rigorous pre-deployment validation of AI systems and ongoing post-market surveillance. Such regulations should be developed collaboratively by interdisciplinary experts, including technologists, legal scholars, medical practitioners, and ethicists, ensuring a balanced approach that fosters innovation while safeguarding public interests. A centralised regulatory authority or specialised division within existing health regulators could be tasked with AI oversight, ensuring consistent implementation across jurisdictions.

The legal framework should try to contextualise the doctrine of informed consent in light of AI's role in clinical decision-making. Clinicians should be legally obligated to disclose the involvement of AI systems when such tools significantly influence medical decisions. This includes informing patients about the nature of the AI system, its general functioning, data sources, known limitations, and the possibility of embedded biases. Such enhanced transparency would protect patient autonomy and foster trust. Informed consent processes should also be calibrated and stratified according to the risk level of the AI application, with

more detailed disclosure mandated for high-stakes decisions involving diagnoses, prognoses, or life-sustaining treatment choices.

Additionally, in cases of errors or harm caused by AI-driven decisions, liability parameters should clarify responsibilities across AI developers, healthcare providers, and institutions, incorporating the principle of human oversight to prevent abdication of medical accountability.

Moreover, the legislative framework must be technologically agnostic yet future-proof, adaptable to rapid advancements in AI architectures and capable of responding to emerging threats such as generative AI or synthetic data misuse.

6.3.2 Algorithmic Impact Assessments

To safeguard against the ethical, clinical, and societal risks posed by AI systems in medical decision-making, Algorithmic Impact Assessments should be done as a mandatory legal requirement prior to the deployment of high-stakes AI applications in healthcare. Drawing inspiration from established regulatory mechanisms such as Environmental Impact Assessments (EIAs) and Social Impact Assessments (SIAs), Algorithmic Impact Assessments would serve as structured, anticipatory evaluations designed to assess potential risks, biases, and societal consequences of AI systems before they are permitted for clinical use. These assessments would ensure that AI tools closely align with basic ethical principles such as fairness, transparency, and accountability while being sensitive to the specific demographic, epidemiological, and infrastructural realities of India's healthcare ecosystem. It must also include a comprehensive bias audit and fairness analysis, ensuring that algorithmic decisions do not disproportionately harm or exclude vulnerable groups. This would shift regulatory oversight from a reactive to a preventive mode, allowing ethical concerns and design flaws to be identified and mitigated early in the AI development cycle.

6.3.3 Imposing Explainability Thresholds

Given the life-and-death nature of many AI-driven medical interventions, India should explore imposing "explainability thresholds" as a legal requirement. Any AI system that significantly affects patient outcomes must meet a minimum standard of interpretability. These thresholds would function as regulatory benchmarks, mandating that any AI model deployed in clinical decision-making, particularly in domains involving invasive procedures, risk stratification, or life-sustaining interventions, must provide clinically relevant rationales for its conclusions. AI systems that cannot achieve explainability must be legally restricted to an advisory role.

Moreover, the degree of explainability required should be proportional to the risk associated with the AI system's output. This implies a tiered model of compliance: low-risk AI applications, such as administrative triaging or appointment scheduling, might be subject to minimal explainability requirements, while high-risk applications, such as autonomous diagnostic imaging or ICU admission prioritisation, must meet stringent interpretability standards before deployment.

6.3.4 Capacity building and awareness programs

In India, where technological adoption in healthcare is often fragmented and accompanied by infrastructural and educational disparities, capacity building must be prioritised as both a policy and institutional imperative.

Training initiatives should equip clinicians with the knowledge to interpret AI outputs critically, integrate them appropriately into clinical workflows, identify algorithmic biases and communicate AI-informed decisions transparently to patients. Such training should ideally be incorporated into medical curricula, Continuing Medical Education modules, and specialist workshops endorsed by regulatory bodies such as the National Medical Commission (NMC). Policymakers must also be conversant with AI's capabilities and limitations to legislate effectively, while public awareness campaigns can build trust and alleviate apprehensions about AI in healthcare. Establishing interdisciplinary centres of excellence focused on AI ethics, law, and medicine could catalyse research and policy innovation tailored to the nation's needs.

6.4 Other Recommendations

- India could develop a voluntary "Ethical AI Certification" system similar to the BIS standards or FSSAI marks that may be administered by a neutral third-party regulatory body. This certification would assess AI systems based on criteria such as fairness, explainability, patient safety, and alignment with Indian ethical norms.

- A rapid response tribunal may be set up to provide fast-track mediation, compensation, and oversight for patients adversely affected by AI-based medical decisions. It could function at state levels and be composed of judges, medical professionals, data scientists, and bioethicists.

- Fostering multistakeholder collaboration and international cooperation is essential. India should actively participate in global AI governance forums, learn from global frameworks and adapt them according to the national needs.

BIBLIOGRAPHY

STATUTES AND REGULATIONS

1] Artificial Intelligence Act, 2021

2] Constitution of India, 1950

3] Digital Personal Data Protection Act, 2023

4] Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare, 2023

5] Information Technology Act, 2000

6] Medical Devices Rules, 2017

7] Telemedicine Practice Guidelines, 2020

8] UK Medical Device Regulations 2002

BOOKS

1] Adam Bohr & Kaveh Memarzadeh, Artificial Intelligence in Healthcare (Academic Press 2020)

2] António Marques & Ricardo Queirós, *Digital Therapies in Psychosocial Rehabilitation and Mental Health* (IGI Global, 2020)

3] Bernard Nordlinger, Cédric Villani & Daniela Rus, *Healthcare and Artificial Intelligence* (Springer, 2020)

4] Dr. Janak Gunatilleke, *Artificial Intelligence in Healthcare: Unlocking Its Potential* (1st ed. 2022).

5] Emmanuel Fombu, *Predictive Medicine: Artificial Intelligence and Its Impact on Healthcare Business Strategy* (1st ed. Business Expert Press 2020).

6] Michael F. Byrne, *AI in Clinical Medicine: A Practical Guide for Healthcare* (1st ed. 2023, Wiley-Blackwell).

ARTICLES

1] Alex John London, *Artificial Intelligence and Black-Box Medical Decisions: Accuracy Versus Explainability*, 49(1) *Hastings Ctr. Rep.* 15 (2019), https://doi.org/10.1002/hast.973.

2] Anurag Sourot & Deepali Kushwaha, *Critical Analysis of the Digital Personal Data Protection Act, 2023*, 7(2) IJLLR (2025), https://www.ijllr.com/post/critical-analysis-of-the-digital-personal-data-protection-act-2023.

3] Ashfaq Ur Rehman et al., *Role of artificial intelligence in revolutionizing drug discovery,* FMRE (2024). https://doi.org/10.1016/j.fmre.2024.04.021

4] Bethany Nichol et al. *Exploring the impact of socially assistive robots on health and wellbeing across the lifespan: An umbrella review and Meta-analysis, 153* International Journal of Nursing Studies (2024). https://doi.org/10.1016/j.ijnurstu.2024.104730

5] Clara Cestonaro et al., *Defining Medical Liability When Artificial Intelligence Is Applied on Diagnostic Algorithms: A Systematic Review*, 10 *Front. Med.* 1305756 (2023), https://doi.org/10.3389/fmed.2023.1305756.

6] Damodharan Dinakaran *et al.*, *Telemedicine Practice Guidelines of India, 2020: Implications and Challenges*, 63(1) *Indian J. Psychiatry* 97 (2021), https://doi.org/10.4103/psychiatry.IndianJPsychiatry_476_20.

7] David B Olawade et al., *Artificial intelligence in healthcare delivery: Prospects and pitfalls,* Journal of Medicine, Surgery, and Public Health 3 (2024). https://doi.org/10.1016/j.glmedi.2024.100108

8] David Egan & Jieni Ji, *AI in healthcare: legal and ethical considerations in this new frontier, International Bar Association* (Feb. 11, 2025). https://www.ibanet.org/ai-healthcare-legal-ethical

9] Debleena Paul et al., *Artificial intelligence in drug discovery and development,* 26(1), DruDis, 80–93. (2021). https://doi.org/10.1016/j.drudis.2020.10.010

10] Dhivya Sudeep, *Next-Gen Patient Support: AI Chatbots in Healthcare*, 13(11) IJSR, 1425 (2024). https://dx.doi.org/10.21275/SR241124072157

11] Felix Busch et al., *AI regulation in healthcare around the world: what is the status quo?*, medRxiv (2025). https://doi.org/10.1101/2025.01.25.25321061

12] Felix Busch et al., Navigating the European Union Artificial Intelligence Act for Healthcare, 7 *npj Digit. Med.* (2024), https://doi.org/10.1038/s41746-024-01213-6.

13] Filippo Pesapane et al., Legal and Regulatory Framework for AI Solutions in Healthcare in EU, US, China, and Russia: New Scenarios after a Pandemic, 1(4) Radiation (2021). https://doi.org/10.3390/radiation1040022

14] Ganesh Ramalingam, Leaveraging AI for Public Health Management, 10(4) IJSRET 1224 (2024).

15] H. Benjamin Harvey & Vrushab Gowda, *How the FDA Regulates AI*, 27(1) *Acad. Radiol.* (2020), https://doi.org/10.1016/j.acra.2019.09.017.

16] Hamidreza Esmaeili & Mohebali Rahdar, *Artificial Intelligence and its Role in Electronic Patient Record*, 8(4) JPHR 333-343 (2023). https://doi.org/10.30491/hpr.2024.454379.1424

17] Isla Chen, Transparency and Explainability in AI: Making Intelligent Systems Accountable, Hakia (Feb. 15, 2023), https://www.hakia.com/transparency-and-explainability-in-ai-making-intelligent-systems-accountable.

18] James L. Cross et al., *Bias in Medical AI: Implications for Clinical Decision-Making*, 3(11) *PLOS Digit. Health* e0000651 (2024), https://doi.org/10.1371/journal.pdig.0000651.

19] Kavitha Palaniappan et al., *Global Regulatory Frameworks for the Use of Artificial Intelligence (AI) in the Healthcare Services Sector,* 12(5) Healthcare (2024). https://doi.org/10.3390/healthcare12050562

20] Kevin B. Johnson et al., *Precision Medicine, AI, and the Future of Personalized Health Care.* CTS, 14(1), 86–93 (2021). https://doi.org/10.1111/cts.12884

21] Madhavi Bhargava et al., *Artificial Intelligence in Biomedical Research and Publications: It Is Not About Good or Evil but About Its Ethical Use*, 49(6) *Indian J. Cmty. Med.* 777 (2024), https://doi.org/10.4103/ijcm.ijcm_560_24.

22] Malek Elhaddad & Sara Hamam, *AI-Driven Clinical Decision Support Systems: An Ongoing Pursuit of Potential,* 16(4) Cureus e57728 (2024), https://doi.org/10.7759/cureus.57728

23] Nandita Sharma & Divya Gupta, *Artificial Intelligence in Medicine: Navigating Ethical Challenges*, 1(1) JEFI (2023), https://doi.org/10.56450/JEFI.2023.v1i01.010.

24] Natalia A. Norori et al., *Addressing Bias in Big Data and AI for Health Care: A Call for Open Science*, 2(10) *Patterns* 100347 (2021), https://doi.org/10.1016/j.patter.2021.100347.

25] *Navigating AI Bias in Healthcare: Challenges and Solutions*, Foresee Medical Blog (Sept. 3, 2024), https://www.foreseemed.com/blog/ai-bias-in-healthcare.

26] Nithesh Naik et al., *Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility?*, 9 Front. Surg. 862322 (2022). https://doi.org/10.3389/fsurg.2022.862322

27] Niyati Deo & Ashish Anjankar, *Artificial Intelligence with Robotics in Healthcare: A Narrative Review of its Viability in India*, 15(5) Cureus e39416 (2023). https://doi.org/10.7759/cureus.39416

28] Oleksandr Maidaniuk, *AI and Medical Imaging: Transforming Diagnosis & Care* (Apr. 12, 2024), https://intellias.com/using-ai-in-medical-imaging-to-augment-radiologists-efforts/

29] Priya Jeyaraj & T.S.A. Narayanan, *Role of Artificial Intelligence in Enhancing Healthcare Delivery*, 11(12) *Int'l J. Innovative Sci. & Mod. Eng'g* (Dec. 2023), https://doi.org/10.35940/ijisme.A1310.12111223

30] Rahul Kailas Bharati, *Navigating the Legal Landscape of Artificial Intelligence: Emerging Challenges and Regulatory Framework in India, SSRN Electronic Journal*. (2024).http://dx.doi.org/10.2139/ssrn.4898536

31] Rishi Reddy Kothinti, *Artificial Intelligence in Disease Prediction: Transforming Early Diagnosis and Preventive Healthcare*, 9(5) IJNRD (2024).

32] Sara Gerke et al., *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, in Artificial Intelligence in Healthcare 205 (Adam Bohr & Kaveh Memarzadeh eds., Academic Press 2020), https://doi.org/10.1016/B978-0-12-818438-7.00012-5.

33] Shinae Yu et al., *The Ethics of Using Artificial Intelligence in Medical Research*, 39(4) *Kosin Med. J.* 229 (2024), https://doi.org/10.7180/kmj.24.140.

34] Subhajit Saha & Surjashis Mukhopadhyay, A New Age of Data Privacy Laws in India: Review of Digital Personal Data Protection Act, 2023, 10(1) IIJLS (2024), https://doi.org/10.60143/ijls.v10.i1.2024.114.

35] Sushanta Kumar Das et al., *AI in Indian healthcare: From roadmap to reality,* 2 Intelligent Pharmacy 329–334 (2024). https://doi.org/10.1016/j.ipha.2024.02.005

36] Vidhate S V*, An Overview: Artificial Intelligence and Technology in Enhancing Quality of Health*, 12(11) IJCRT, d6 (2024).

37] Yeisson Rivero-Moreno et al., *Robotic Surgery: A Comprehensive Review of the Literature and Current Trends*, 15(7) Cureus e42370 (2023). https://doi.org/10.7759/cureus.42370

WEBSITES

1] Amlan Mohanty & Shatakratu Sahu, *India's Advance on AI Regulation*, Carnegie India (Nov. 21, 2024), https://carnegieendowment.org/research/2024/11/indias-advance-on-ai-regulation

2] Ankit Singh, *The AI Regulatory Landscape in India: What to Know*, AZoRobotics (Feb. 26, 2025), https://www.azorobotics.com/Article.aspx?ArticleID=742.

3] Bishan Nandy, *The impact of artificial intelligence on hospital operations: A comprehensive analysis*, Express Healthcare (Aug. 24, 2024) https://www.expresshealthcare.in/news/the-impact-of-artificial-intelligence-on-hospital-operations-a-comprehensive-analysis/445342/

4] Bruno Gretler, *Navigating the Regulatory Landscape of Fast-Growing Markets: India*, Congenius (Mar. 25, 2025), https://congenius.ch/regulatory-landscape-india/.

5] Ishwar Ahuja & Sakina Kapadia, *Digital Personal Data Protection Act, 2023 – A Brief Analysis*, *Bar & Bench* (Aug. 22, 2023), https://www.barandbench.com/view-point/digital-personal-data-protection-act-2023-a-brief-analysis.

6] *Regulating AI in India: Challenges, Initiatives, and Path to Future Success*, K. Singhania & Co (Mar. 13, 2025), https://singhanialaw.com/regulating-ai-in-india-challenges-initiatives-and-path-to-future-success/.

7] Varun Kumar & Ishika Mittal, *The Digital Personal Data Protection Act, 2023: Overview of the Impact on Data Fiduciaries and the Obligations Placed*, *SCC Times* (Mar. 11, 2024), https://www.scconline.com/blog/post/2024/03/11/the-digital-personal-data-protection-act-2023-overview-of-the-impact-on-data-fiduciaries-and-the-obligations-placed/.

NEWSPAPER

1] Aimee Picchi, *Google's "Project Nightingale" Faces Government Inquiry Over Patient Privacy*, CBS News (Nov. 13, 2019), https://www.cbsnews.com/news/googles-project-nightingale-faces-government-inquiry-over-patient-privacy/.

2] Angelica Marie Sanchez, *Taking a step towards self-walking robotic exoskeletons,* Waterloo News (Jan 6, 2022) https://uwaterloo.ca/news/global-impact/taking-step-towards-self-walking-robotic-exoskeletons

3] Artificial Intelligence Market Size Projected to Hit USD 3,680.47 Bn by 2034, Globe Newswire (Nov. 7, 2024) https://www.globenewswire.com/news-release/2024/11/07/2976909/0/en/Artificial-Intelligence-Market-Size-Projected-to-Hit-USD-3-680-47-Bn-by-2034.html

4] *Biden Administration Announces Artificial Intelligence Executive Order*, Global Policy Watch (Oct. 31, 2023) https://www.globalpolicywatch.com/2023/10/biden-administration-announces-artificial-intelligence-executive-order/

5] Brendan Pierson, Lawsuit Claims UnitedHealth AI Wrongfully Denies Elderly Extended Care, Reuters (Nov. 15, 2023), https://www.reuters.com/legal/lawsuit-claims-unitedhealth-ai-wrongfully-denies-elderly-extended-care-2023-11-14/.

6] *Britain publishes 'Bletchley Declaration' on AI safety,* Reuters (November 1, 2023) https://www.reuters.com/technology/britain-publishes-bletchley-declaration-ai-safety-2023-11-01/

7] Casey Ross & Ike Swetlitz, *IBM's Watson Supercomputer Recommended 'Unsafe and Incorrect' Cancer Treatments, Internal Documents Show*, STAT (July 25, 2018), https://www.statnews.com/2018/07/25/ibm-watson-recommended-unsafe-incorrect-treatments/

8] *Icahn School of Medicine at Mount Sinai to establish world-class center for artificial intelligence: : Hamilton and Amabel James Center for Artificial Intelligence and Human Health*, Newswise, (Jun. 11, 2019) https://www.newswise.com/articles/icahn-school-of-medicine-at-mount-sinai-to-establish-world-class-center-for-artificial-intelligence-hamilton-and-amabel-james-center-for-artificial-intelligence-and-human-health

9] J*ohns Hopkins Capacity Command Center Creates a New Center of Gravity* https://www.gehccommandcenter.com/outcomes/johns-hopkins-capacity-command-center-creates-a-new-center-of-gravity (last visited Jan 31, 2025).

10] Rishikaa, *The Indian Council of Medical Research Released the Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare*, Saikrishna & Associates, https://www.saikrishnaassociates.com/the-indian-council-of-medical-research-released-the-ethical-guidelines-for-application-of-artificial-intelligence-in-biomedical-research-and-healthcare/ (last visited Apr. 19, 2025).

11] *White House Releases Long-Awaited "AI Bill of Rights" Document*, EPIC (Oct. 4, 2022). https://epic.org/white-house-releases-long-awaited-ai-bill-of-rights-document/

12] Yuthika Bhargava, *Hacker 'Sees' Security Flaws in Aarogya Setu*, The Hindu (May 7, 2020), https://www.thehindu.com/news/national/ethical-hacker-robert-baptiste-elliot-alderson-sees-security-flaws-in-aarogya-setu/article31515292.ece.

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