



THE LAW FOR AI IN HEALTHCARE

Man Teng Iong



ROUTLEDGE

The Law for AI in Healthcare

This book presents a timely overview of how artificial intelligence (AI) is transforming modern healthcare. Combining legal, ethical and practical viewpoints, it explores the impact of AI on patients, clinicians, healthcare organisations and regulators in the European Union, the United Kingdom and the United States.

It delves into the fundamentals of clinical AI systems, explaining how they function and make decisions. It also addresses practical concerns such as safety, fairness, transparency and patient trust. Drawing on real-world examples, such as AI-assisted diagnosis, clinical decision-support tools and machine-learning programmes in hospitals, this book highlights the challenges of aligning law and policy with rapid technological advancements. Key topics explored include bias in medical algorithms, accountability for automation errors and the importance of patient autonomy and data rights for digitally enabled care.

The book will appeal to students, policymakers, practitioners and anyone looking to understand the future law of AI in healthcare.

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To my children Meng Hin Iong and Seng Hong Iong, and to my wife Iao Man Hong, without whom this book would have been completed earlier



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Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
AD	Advance Directive
AI	artificial intelligence
AMA	American Medical Association
API	application programming interface
AR	augmented reality
CAG	Confidentiality Advisory Group
CDS	clinical decision support
CE	Conformité Européenne (European Conformity)
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CT	computed tomography
DPA	Data Protection Act
DPIA	Data Protection Impact Assessment
DPO	Data Protection Officer
EDPB	European Data Protection Board
EHRC	Equality and Human Rights Commission
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration
FTC	Federal Trade Commission
GDPR	General Data Protection Regulation
GMLP	Good Machine Learning Practice
HHS	Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
ICO	Information Commissioner's Office
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IG	Information Governance
IMDRF	International Medical Device Regulators Forum
IRB	Institutional Review Board
ISO	International Organization for Standardization
LGBTQ+	Lesbian, Gay, Bisexual, Transgender, Queer, and Questioning, and all other sexual orientations and gender identities not listed

MDCG	Medical Device Coordination Group
MDR	Medical Devices Regulations
MHRA	Medicines and Healthcare products Regulatory Agency
ML	Machine Learning
MRI	magnetic resonance imaging
NICE	National Institute for Health and Care Excellence
NHS	National Health Service
NHSX	National Health Service X (NHS England as host)
OCR	Office for Civil Rights
ONC	US Department of Health and Human Services' Office of the National Coordinator for Health Information Technology
PCCP	Predetermined Change Control Plan
PHI	personal health information
PMA	Pre-Market Approval
PMS	Post-Market Surveillance
PMSR	Post-Market Surveillance Report
PSUR	Periodic Safety Update Report
QMS	Quality Management System
RCTs	randomised controlled trials
TPO	treatment, payment, or healthcare operations
UK	United Kingdom
UNESCO	United Nations Educational, Scientific and Cultural Organization
US	United States
VR	virtual reality
XR	extended reality



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Part I

Foundations (Comparative, Concise, Consistent)



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1 Introduction

Why AI in Healthcare Needs Law and Ethics

Abstract

Artificial intelligence (AI) is heavily embedded in the realm of healthcare, and has vast potential to establish a more efficient route for diagnoses and clinical treatments in healthcare, as well as to enhance patient outcomes. At the same time, AI systems raise unique issues of ethics and law, like threats to patient privacy, algorithmic bias, opacity of decision-making and uncertainty of responsibility in the case of harm caused. This introductory chapter argues that law and ethics are not just marginal to healthcare AI but are fundamental modes of governance that will determine the limits on whether such technologies can be adopted in a manner that will be safe and trustworthy. Rather than offering either a technical overview of the applications of AI or a detailed regulatory analysis, the chapter seeks to lay out a unifying thematic argument: the integration of AI into healthcare alters the traditional understandings associated with professional judgment, patient autonomy and responsibility as well as generating a demand for robust legal and ethical guardrails. Using an illustrative example of AI-assisted clinical triage as a means of understanding the implications of failures in the domains of transparency, oversight and validation, this chapter shows how failures in these areas can directly translate to patient harm. It further discusses the interactions between ethical values (such as beneficence, non-maleficence, autonomy and justice) on the one hand and legal tools (such as data protection, medical device regulations and liability regimes) on the other hand for building trust in AI-enabled health systems. By placing these issues in the broader movements of European Union, United Kingdom and United States governance approaches, the chapter lays the conceptual groundwork for the more granular discussions of data governance, consent, fairness, liability and institutional oversight of AI-driven healthcare in the rest of the book.

AI is changing healthcare at an incredible pace from more accurate diagnosis to personalising treatment. In fields like medical imaging and predictive analytics, for example, AI systems are in a position to crawl through tremendous modes of data to look out for medical patterns or signs of disease beyond human capacity. These innovations promise huge benefits – faster diagnosis, better care and potential improvement for the patient. However, the same qualities of AI that make it so powerful raise some of the most troubling ethical and legal questions. AI

algorithms use data to learn and make their autonomous or semi-autonomous decisions that can have life-and-death implications for medical decision-making, with no direct involvement from a human. This reality envisions us to pose and critically evaluate this question: how do we make such systems safe, fair and accountable? Robust legal and ethical governance is not a choice but instead a top priority to ensure the integration of AI's application in healthcare in a way that protects the patient and ensures public trust. In this introductory chapter, I report the compelling case for legal and ethical oversight of healthcare AI as the foundation for its adoption in a way that is safe and trustworthy.

I. The Dual Promise and Peril of AI in Healthcare

AI's promise to improve medicine is accompanied by a need to be able to control the associated risks. On the one hand, AI-powered tools can be used to enhance clinical decision-making – a good example of this is their ability to analyse radiographs or lab results faster or more accurately than a clinician in some cases.¹ On the other hand, these tools can go wrong in unforeseeable ways, or even make existing problems in healthcare worse if left unchecked. Patient privacy is an area of great concern. Effective AI solutions require large amounts of health data to be used to train algorithms – which contains personal sensitive information. Without proper governance, such data could be used in violation of patient confidentiality, or for nefarious purposes. Data protection legislation like the European Union's General Data Protection Regulation (GDPR) and the United States' Health Insurance Portability and Accountability Act (HIPAA) are strict laws regarding how medical data is handled and AI systems must comply with these laws to allow the data of patients to remain safe.² Data security and obtaining consent for data use by AI's data-hungry operations is an ethical and legal imperative, failure to which could undermine public trust and thus violate the fundamental rights of patients.

Another major issue is algorithmic bias and fairness. AI systems in healthcare may inadvertently reproduce or even exacerbate healthcare disparity with regard to treatment outcome.³ If an AI tool is trained with historical or unrepresentative data, then it may work poorly for some populations – for example, an under-diagnosis of diseases in some minority populations, because they were underrepresented in the training data. Studies have brought to light some egregious examples: one commercial health algorithm relied on cost of care as a proxy for need, which caused far fewer Black patients to be flagged for extra care than White patients who were just as sick, because of historical deficiencies in access to healthcare for people of

1 Thomas Davenport and Ravi Kalakota, 'The Potential for Artificial Intelligence in Healthcare' (2019) 6(2) *Future Healthcare Journal* 94–98. See also Robert Kaczmarczyk et al., 'Evaluating Multimodal AI in Medical Diagnostics' (2024) 7(1) *npj Digital Medicine* 205.

2 Tuan Pham, 'Ethical and Legal Considerations in Healthcare AI: Innovation and Policy for Safe and Fair Use' (2025) 12(5) *Royal Society Open Science* 241873.

3 *ibid.*

color.⁴ Such cases are an example of how bias in AI can mean inequitable care, at odds with another key principle of medical ethics – justice. Addressing the biases necessitates careful oversight in the selection of the dataset, model design and performance auditing. Indeed, many AI models are “black boxes” where the decision-making process is opaque even to the individuals who created them.⁵ This opacity makes it hard to see why an AI is making a mistake or to correct its behaviour, making it essential to have measures in place for carefully overseeing and ensuring accountability in the development and deployment of AI technologies.⁶ Ethical principles of fairness and equity require that AI tools are made and controlled to meet the needs of all groups of patients effectively, instead of reinforcing inequalities.

Perhaps the thorniest problem is accountability. When an AI informs or automates a clinical decision, who is to blame when something goes wrong? Consider a scenario where the AI-based diagnostic system does not flag a life-threatening condition, or on the other hand, a false alarm is generated by the system thereby causing unnecessary invasive procedures. In traditional care, the duty of care of a treating physician and his or her potential liability for negligence are well established.⁷ AI complicates this picture. If, for example, a machine learning program misdiagnosed a patient, responsibility might be, more or less, shared between the people who wrote the software code, the hospital that implemented the system and the clinicians using it. Current malpractice and product liability legislation is being challenged by these circumstances, as it is unclear whether an AI should be considered like a medical device, a service or an extension of the clinical team.⁸ Legal scholars point out that healthcare AI has not been tested in court to any significant extent,⁹ but the lack of precedent of clear liability patterns means there isn't much certainty for providers or patients when it comes to liability. With no clear-cut rules, there is a risk that patients suffering due to faulty AI will have a hard time getting redress, or on the other hand that too many fears of liability will stifle beneficial innovation. There needs to be a balanced approach – one that offers the avenues to compensate patients when AI does harm, while also bringing clear obligations for the developers and users. As the European Commission has observed, it is important to create a strong framework for victims to be able

4 Irene Dankwa-Mullan, ‘Health Equity and Ethical Considerations in Using Artificial Intelligence in Public Health and Medicine’ (2024) 21 *Preventing Chronic Disease* 240245.

5 *ibid.*

6 *ibid.*

7 Ibrahim Habli, Tom Lawton and Zoe Porter, ‘Artificial Intelligence in Health Care: Accountability and Safety’ (2020) 98(4) *Bull World Health Organ* 251–256.

8 Nadia de la Houssaye et al., ‘Healthcare AI in the United States – Navigating Regulatory Evolution, Market Dynamics, and Emerging Challenges in an Era of Rapid Innovation’ (2025) 15 *National Law Review* 275.

9 W Nicholson Price II, Sara Gerke and I. Glenn Cohen, ‘Liability for Use of Artificial Intelligence in Medicine’ in Barry Solaiman and I. Glenn Cohen (eds), *Research Handbook on Health, AI and the Law* (Edward Elgar 2024) 150–166.