



GUIDELINE OF THE MALAYSIAN MEDICAL COUNCIL

MMC GUIDELINE ON THE ETHICAL USE OF ARTIFICIAL INTELLIGENCE (AI) IN MEDICAL PRACTICE VERSION 1/2025

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1 Preamble

This ethical guideline is an initiative of the Malaysian Medical Council (MMC) to provide registered medical practitioners in Malaysia with a practical approach to integrating ethics in the use of Artificial Intelligence (AI) in their practice.

1.1 Overview

The past decade has seen an exponential increase in the use of AI across all aspects of human life, transforming and revolutionizing almost every industry and everyday human interaction. AI in healthcare has been groundbreaking, reshaping how patients are diagnosed, treated, and monitored. While the benefits of AI in healthcare are undeniable, a debate has ignited over its moral and ethical use. Hence, this guideline on the ethical use of AI in medical practice is important to ensure that AI is used responsibly, is based on evidence, is bias-free, and is designed and deployed to promote equity when utilised by registered medical practitioners in the Malaysian setting.

AI offers the tremendous opportunity of affordability and availability, making healthcare more accessible.

In clinical practice, AI is often considered as “supporting clinical decision-making”.¹ However, incorporating complex and emerging AI into clinical decision-making is novel and set to alter clinical practice monumentally. Patient safety, privacy, and confidentiality alongside professional and reputational safety will be risked, by the absence of professional ethical guidance on the use of AI in clinical practice.

The World Health Organization (WHO) published two reports on the use of AI systems in healthcare. Its 2021 report² emphasises the need to integrate ethical norms in all states of AI and identifies six consensus principles³ to ensure AI works to benefit the public; the 2023 report⁴, sets out regulatory considerations on AI⁵ for health intended as a stakeholder’s

¹ Smith, H., Downer, J., & Ives, J. (2024). Clinicians and AI use: Where is the professional guidance? *Journal of Medical Ethics*, 50(6), 437–441. <https://doi.org/10.1136/jme-2022-108831>

² World Health Organization. (2021). Ethics and governance of artificial intelligence for health. <https://www.who.int/publications/i/item/9789240029200>

³ (1) protect autonomy; (2) promote human well-being, human safety, and the public interest; (3) ensure transparency, explainability, and intelligibility; (4) foster responsibility and accountability; (5) ensure inclusiveness and equity; (6) promote AI that is responsive and sustainable.

⁴ World Health Organization. (2023). Regulatory considerations on artificial intelligence for health. World Health Organization. <https://iris.who.int/handle/10665/373421>

⁵ (1) transparency and documentation; (2) risk management; (3) Intended use and analytical and clinical validation; (4) data quality; (5) privacy and data protection; (6) engagement and collaboration.

resource for manufacturers and registered medical practitioners who wish to use AI-based medical devices in clinical practice.

WHO in early 2024, further published an AI ethics and governance guidance for large multi-modal models (LMMs).⁶ The guidance contains recommendations for governments, technology companies, and healthcare providers to ensure the responsible use of LMMs and safeguard public's health.

As of July 2024, 14 legal jurisdictions⁷ have some form of published laws, guidance, or regulations on AI governance in healthcare albeit at different stages of development. Most of these documents are in line and converge with WHO's key principles.⁸

The WHO documents, however, do not specifically provide details on the ethical obligations of registered medical practitioners using AI.

In the meantime, AI is fast penetrating the Malaysian healthcare domain without much guidance. AI in healthcare is only set to grow under the Ministry of Health's Digital Health Blueprint^{9,10} with the public and private healthcare sectors embracing AI for better patient care. Registered medical practitioners who are set to embrace AI in the clinical care of patients, as such, must be mindful of their ethical obligations. Registered medical practitioners must ensure that AI is harnessed for better patient care and that its use does not cause harm.

1.2 Guiding Principles of the Ethical Use of AI in Medical Practice

This guideline is developed in line with WHO's guidance papers on the ethical use of AI in healthcare, and the Malaysian Principles of Responsible Artificial Intelligence identified by the Ministry of Science, Technology, and Innovation (MOSTI) in their National Guidelines On AI Governance & Ethics.¹¹

1.2.1 Protect autonomy.

It is important to ensure that AI does not interfere with human autonomy. People should still be the primary decision-makers in healthcare and medical settings. Oversight of AI systems needs to be transparent, and effective, prioritising human values and ethical

⁶ World Health Organization. (2024). Ethics and governance of artificial intelligence for health: Guidance on large multi-modal models. <https://www.who.int/publications/i/item/9789240084759>

⁷ EU, UK, Australia, Canada, Japan, Italy, Brazil, Egypt, Rwanda, Saudi Arabia, Singapore, India, China, and Hong Kong

⁸ Chakraborty, A., & Karhade, M. (2024). Global AI governance in healthcare: A cross-jurisdictional regulatory analysis. <https://doi.org/10.48550/arXiv.2406.08695>

⁹ Ministry of Health Malaysia. (2023). Health white paper for Malaysia: Strengthening people's health, future-proofing the nation's health system. [https://www.moh.gov.my/moh/resources/Penerbitan/Penerbitan%20Utama/Kertas%20Putih%20Kesihatan/Kertas_Putih_Kesihatan_\(ENG\)_compressed.pdf](https://www.moh.gov.my/moh/resources/Penerbitan/Penerbitan%20Utama/Kertas%20Putih%20Kesihatan/Kertas_Putih_Kesihatan_(ENG)_compressed.pdf)

¹⁰ Annuar, A. (2024, June 30). AI and EV innovations entering Malaysia's healthcare system. The Malaysian Reserve. <https://themalaysianreserve.com/2024/06/19/ai-and-ev-innovations-entering-malaysias-healthcare-system/>

¹¹ Ministry of Science, Technology, and Innovation. (2024, September). Artificial Intelligence governance and ethics guidelines (AIGE): The national guidelines on AI governance and ethics. <https://mastic.mosti.gov.my/publication/the-national-guidelines-on-ai-governance-ethics/>

considerations. Privacy, confidentiality, informed consent, and data protection laws all, play a crucial role in safeguarding patient autonomy.

1.2.2 Promote human well-being, human safety, and public interest.

AI technologies should assist registered medical practitioners in improving patient care. There should be no harm, physical or mental, caused by the use of AI. Any output generated by AI should be meticulously evaluated and balanced in line with the professional obligations of registered medical practitioners.

1.2.3 Ensure transparency, explainability, and intelligibility.

AI used in healthcare should be intelligible or understandable to registered medical practitioners. Sufficient information about the AI technology should be documented and made available before any AI technology is used. Such information and documentation should be updated periodically throughout the deployment of the AI. Transparency regarding the AI's operations and algorithms would help identify and address algorithm bias. It would also aid medical professionals in explaining to patients how AI models make decisions.

1.2.4 Foster responsibility and accountability.

AI technology should be used responsibly. Registered medical practitioners and AI developers remain accountable for the use of AI. There should be clear lines of accountability in the development and deployment of AI.

1.2.5 Privacy and data protection.

Privacy and data protection must be ensured when developing and deploying AI systems. A good understanding of data protection laws and a robust system against breaches are necessary to prevent harm.

1.3 What is AI?

- (a) AI is a technology that allows computers and machines to imitate human intelligence and problem-solving skills. It involves a combination of computer science, statistics, and engineering, using algorithms or models to carry out tasks and demonstrate behaviours like learning, decision-making, and prediction.
- (b) AI systems combine extensive sets of data with intelligent, iterative processing algorithms to learn from patterns and features in the data that they analyse. Each round of data processing allows AI to learn from its performance and improve its ability. Since AI can work continuously without a break, it can quickly process large amounts of data and become capable of performing the task for which it is trained.

- (c) The growth of data has been exponential. As new data becomes available, the continuous loop of data processing enhances and refines AI models. This ever-changing data landscape and dynamic AI technology require healthcare providers and ethical guidelines to continuously adapt.

1.4 AI in Healthcare

AI technology has the potential to revolutionise healthcare through task automation, improving medical diagnosis, personalised treatments, streamlined clinical trials, development of self-care tools, and enhanced evidence-based insights. The potential of AI appears to be infinite, and all indications are that its use will only continue to grow. Some of the examples are listed below:¹²

1.4.1 Diagnosis.

AI's ability to rapidly process patient medical records makes it a promising diagnostic tool. It can identify rare diagnoses and unusual presentations in complex cases and provide registered medical practitioners with additional opinions to ensure obvious diagnoses are not overlooked. Integrating AI into clinical guidelines could revolutionize the diagnostic process.¹³

1.4.2 Personalised treatment.

AI, especially machine learning (ML), accelerates drug discovery and development. Personalised treatments based on an individual's genetics and medical history would make way for targeted and cost-effective treatments.

1.4.3 Clinical care.

AI can enhance remote patient monitoring and early disease detection through telemedicine, chatbots, and wearable monitoring devices. Chatbots could offer patients and lay people crucial information about their condition before they see a healthcare provider.¹⁴

1.4.4 Better patient management.

AI such as Natural Language Processing (NLP) can extract insights from unstructured data, such as clinical notes, potentially aiding registered medical practitioners in making better and more informed decisions on patient care. AI-powered technologies, like health coaching systems and apps, enhance patient outcomes and support

¹² Indian Council of Medical Research. (2023). Ethical guidelines for application of artificial intelligence in biomedical research and healthcare.

https://main.icmr.nic.in/sites/default/files/upload_documents/Ethical_Guidelines_AI_Healthcare_2023.pdf

¹³ World Health Organization. (2024). Ethics and governance of artificial intelligence for health: Guidance on large multi-modal models. <https://www.who.int/publications/i/item/9789240084759>

¹⁴ World Health Organization. (2024). Ethics and governance of artificial intelligence for health: Guidance on large multi-modal models. <https://www.who.int/publications/i/item/9789240084759>

self-management.

1.4.5 Epidemiology and AI.

AI incorporates various data sources in epidemiology, enabling the analysis of disease trends, risk prediction, early detection, and infection patterns. AI holds promise for significantly contributing to the management of pandemics.

1.4.6 Behavioural and mental health

AI can be used to understand, diagnose, and manage mental health. AI-powered chatbots can yield higher engagement in behavioural and mental healthcare. AI can also help patients cope with symptoms and be engineered to detect signs of distress in patients and trigger a referral to a healthcare professional. This is a potential general benefit of AI.

1.4.7 Health management

Health management systems benefit from AI-driven automation. This enhances efficiency in scheduling, EMR management, billing, and claims processing. AI optimises both patient care and administrative workflows, enhancing productivity and potentially reducing costs in healthcare organisations. The ability of AI to manage clinic and hospital management systems by automating tasks, optimising resource allocation, and facilitating interdepartmental coordination, may lead to better healthcare outcomes.

2 AI in Healthcare – The need for specific guidelines.

Despite AI's immense potential, AI's integration into clinical practice raises several ethical concerns, particularly regarding patient care and data management. Given that AI technology in healthcare directly impacts human lives and could potentially have significant consequences for patients, a careful approach is essential before integrating AI technologies into routine healthcare practices.

Over-reliance on AI recommendations could result in patients' preferences being undervalued or overlooked. AI systems built on data and algorithms may fail to capture the nuances of individual patients. The large amount of data needed for AI to function may be more than what patients are willing or comfortable disclosing resulting in either a sense of loss of control over one's private information or patients completely avoiding AI.

While AI may improve health equity in underserved areas, AI could also lead to unequal healthcare outcomes as AI algorithms may perpetuate or amplify biases inherent in the data they are trained on.

Registered medical practitioners should develop skills and knowledge in applying AI in clinical practice and critically evaluate any recommendations based on professional clinical insight and judgment. Registered medical practitioners must also find effective ways to communicate the benefits, risks, and limitations of AI-driven interventions to facilitate informed consent.

3 Ethical Guidelines for Registered Medical Practitioners

1. When utilizing AI technologies in clinical practice, registered medical practitioners continue to be bound by MMC's Code of Professional Conduct and all existing MMC Ethical Guidelines, in particular: -
 - (a) Good Medical Practice;
 - (b) Guideline on Consent for Treatment of Patients by Registered Medical Practitioners; and
 - (c) Guideline on Confidentiality.
2. Registered medical practitioners should only use AI tools and/or technologies which are reliable and meet the standards of 'reasonable confidence'.
3. An AI tool and/or technology is said to meet the standards of 'reasonable confidence' when it fulfils all of the following criteria:¹⁵
 - (a) Trustworthiness.
The AI tool and/or technology must adhere to standards and best practices, and its implementation must align with clear indications and clinical practice guidelines.
 - (b) Appropriateness.
The AI tool and/or technology should not contradict strong clinical evidence or be used in clinical situations where its use has not been accepted.
 - (c) Transparency.
The AI tool and/or technology must be able to provide clear explanations of its decision-making processes. It must disclose how the data is utilised to produce outcomes and the rationale behind specific outcomes.
 - (d) Conforms to Standards.
The AI tool and/or technology used must have been assessed and validated. It must comply with any applicable regulatory frameworks and standards.
 - (e) Liability
The AI tool and/or technology user must clear on the issue of liability.
4. Registered medical practitioners should seek appropriate training before using AI tools and/or technology in their clinical practice.

¹⁵ Health Education England, & NHS AI Lab. (2022). Understanding healthcare workers' confidence in AI. NHS Transformation Directorate.

5. Due to the unique risks posed by AI tools and/or technologies to patient autonomy, registered medical practitioners must also adhere to the following additional requirements:

With regards to consent, when using and relying on an AI tool and/or technology.

- (a) Registered medical practitioners should provide safeguards to protect patient autonomy and patient safety.
- (b) Registered medical practitioners should inform patients before the consultation of the following, where appropriate:
 - (i) How the AI tools and/or technology are being used in their clinical care.
 - (ii) Basis of the results or recommendation generated by AI.
 - (iii) Any known risks associated with the use of the AI tool and/or technology.
 - (iv) Safeguards in place to prevent errors and/or data breaches.
 - (v) The right to know when an AI tool and/or technology has failed and/or has led to an adverse outcome.
 - (vi) Any conflicts of interest the medical practitioner has or may have in relation to the AI tool and/or technology used.
- (c) Registered medical practitioners remain responsible and accountable for the patient's clinical outcomes.

6. With regards to confidentiality:

- (a) Registered medical practitioners must safeguard patient information.
- (b) Patient data must not be shared on any AI system without the patient's consent.
- (c) Registered medical practitioners must ensure that the AI tool and/or technology being used has a robust encryption system and access control protocols to prevent data breaches and reidentification.

7. When in doubt about an AI tool and/or technology, registered medical practitioners should seek clarification from appropriate regulatory authorities.

8. AI tools and/or technologies must be used conscientiously. Clinical decisions made using and relying on AI tools and/or technologies must align with patients' best interests and the ethical principles of respect for autonomy, beneficence, non-maleficence, and justice.

9. Registered medical practitioners remain responsible for their clinical decisions. When AI tools and/or technologies are used to support clinical

decision-making, recommendations from AI tools and/or technology must be carefully evaluated based on clinical assessment and tailored to patients' individual factors. AI tools and/or technologies should complement, not replace clinical judgement.

10. Registered medical practitioners should be able to confidently overrule or challenge an AI's decision when necessary, and should be capable of completing tasks and procedures in the event of an AI failure.
11. Registered medical practitioners must at all times keep up with their medical knowledge and clinical skills. Registered medical practitioners should be cautious about over-reliance on AI tools and/or technologies and guard against skills degradation.
12. Where the views on diagnosis, treatment and/or patient management of a medical practitioner differ from those generated by an AI tool and/or technology, the patient should be informed whenever possible. In such a case, the patient, in consultation with the registered medical practitioner, and with the best information and/or evidence available, should always have the ultimate authority to decide.
13. AI tools and/or technologies that impact patients should always have human oversight. Registered medical practitioners must validate AI recommendations and intervene as necessary.
14. Registered medical practitioners must promptly report any untoward complications arising from the use of AI tools and/or technologies to both the developers of the AI tool and/or technology and the relevant regulatory bodies.
15. Registered medical practitioners must disclose any conflicts of interest related to the use or recommendation of AI tools and/or technologies. This includes financial, personal, or professional interests that could influence their judgment, thus ensuring transparency and maintaining trust with patients and the public.

As AI continues to evolve, this guidance will be reviewed annually until 2026 after which it will be reviewed every two years to ensure it remains relevant. MMC has taken all steps to ensure that these guidelines cover a broad spectrum of ethical issues, however, should any issues arise outside that stated in this guideline, clarification can be sought from the MMC.

4 Glossary.

4.1 Artificial Intelligence (AI).¹⁶

AI is a branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviours such as

¹⁶ World Health Organization. (2023). Regulatory considerations on artificial intelligence for health. World Health Organization. <https://iris.who.int/handle/10665/373421>

learning, making decisions, and making predictions. The subset of AI known as Machine Learning (ML) allows computer algorithms to learn through data, without being explicitly programmed to perform a task.

4.2 Artificial Intelligence System.¹⁷

The International Medical Device Regulators Forum (IMDRF) defines an AI system as software that is developed with one or more of the techniques and approaches listed below* and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions that influence the environments they interact with.

**AI techniques and approaches:*

- (a) machine learning approaches, including supervised, unsupervised, and reinforcement learning, using a variety of methods, including deep learning.
- (b) logic and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference, and deductive engines, (symbolic) reasoning and expert systems.
- (c) statistical approaches, Bayesian estimation, search, and optimization methods.

4.3 Artificial Intelligence Technology.¹⁸

In the context of this publication, the term “AI technology” refers to any AI technology (e.g. machine learning, deep learning, natural language processing, computer vision, etc.) used to develop an AI system.

4.4 Data Integrity.¹⁹

Data integrity can be defined as the completeness, consistency, and accuracy of data.

4.5 Data Protection.²⁰

Data protection is a more technical issue under the broader umbrella of privacy which includes more domains beyond the protection of an individual’s data. Data protection in this document additionally includes the requirements and methods used to store and organize data in a physically secure manner. Data protection means securing data against malicious

¹⁷ World Health Organization. (2023). Regulatory considerations on artificial intelligence for health. World Health Organization. <https://iris.who.int/handle/10665/373421>

¹⁸ World Health Organization. (2023). Regulatory considerations on artificial intelligence for health. World Health Organization. <https://iris.who.int/handle/10665/373421>

¹⁹ World Health Organization. (2023). Regulatory considerations on artificial intelligence for health. World Health Organization. <https://iris.who.int/handle/10665/373421>

²⁰ World Health Organization. (2023). Regulatory considerations on artificial intelligence for health. World Health Organization. <https://iris.who.int/handle/10665/373421>

attacks and preventing the potential exploitation of stolen data for profit. Securing data however, may not be in itself sufficient to ensure privacy.

4.6 Explainability.²¹

Explainability (how does the model work?) is achieved when human beings can provide technical explanations about how the algorithm behaves and computes a specific output or probability. An algorithm must be transparent to be explainable.

4.7 Generative AI.²²

A category of AI techniques in which algorithms are trained on data sets that can be used to generate new content, such as text, images or video.

4.8 Health Data.²³

Health data is person's personal data relating to his/her physical or mental health. It includes healthcare services and information regarding a person's health status. Health data is a special category of personal data due to its impact on human life, fundamental rights and freedoms.

4.9 Informed Consent.²⁴

Informed consent involves a clear understanding of the facts, implications, and consequences of an action. The person consenting must have adequate reasoning capacity and have all relevant facts at the time consent is given.

4.10 Intelligibility.²⁵

Intelligibility in AI refers to the requirement that a system needs to be able to explain itself, to represent to its users what it knows, how it knows it, and what it is doing about it. Intelligibility is required for trust in AI systems.

4.11 Large Multi-Modal Models (LMMs).

LMMs are a type of generative AI 'which can accept one or more type of data input and generate diverse outputs that are not limited to the type of data fed into the algorithm.'²⁶ 'LMMs are trained on immense amounts of data making them capable of understanding and generating natural language and other types of content to perform a wide range of tasks'.²⁷

²¹ Tomova, G. D., Gilthorpe, M. S., Bruneau, G. C. A., & Tennant, P. W. (2022). P66 Defining the transparency, explainability, and interpretability of algorithms: A key step towards fair and just decision-making. *Journal of Epidemiology and Community Health*, 76(Suppl 1), A75–A76. <https://doi.org/10.1136/jech-2022-SSMabstracts.158>

²² World Health Organization. (2024). Ethics and governance of artificial intelligence for health: Guidance on large multi-modal models. <https://www.who.int/publications/i/item/9789240084759>

²³ World Health Organization. (2023). Regulatory considerations on artificial intelligence for health. World Health Organization. <https://iris.who.int/handle/10665/373421>

²⁴ Malaysian Medical Council. (2013). Consent for treatment of patients by registered medical practitioners. https://mmc.gov.my/wp-content/uploads/2019/11/Consent_Guideline_21062016.pdf

²⁵ Brdiczka, O. (2019, April 9). Contextual AI: The next frontier of artificial intelligence. Adobe. <https://business.adobe.com/blog/perspectives/contextual-ai-the-next-frontier-of-artificial-intelligence>

²⁶ World Health Organization. (2024). Ethics and governance of artificial intelligence for health: Guidance on large multi-modal models. <https://www.who.int/publications/i/item/9789240084759>

²⁷ IBM. (n.d.). What are large language models (LLMs)? IBM. <https://www.ibm.com/topics/large-language-models>

4.12 Privacy and Data Privacy.²⁸

Privacy is a broad and multidimensional concept. The concept includes control over personal information, often referred to as data or information privacy. Data privacy concerns the proper use and management of personal data, ensuring that consumers' information is collected, shared, and utilized appropriately. Privacy risks include reidentification and the release of unwanted inferences about a data subject.

4.13 Sources of Health Data.²⁹

Data sources from digital health and medical technologies, are numerous. Examples include data from wearable devices, digital health (or electronic health) applications, medical devices, and sensors; electronic health records, administrative hospital data; data from aggregated clinical trials; bioimaging and genomic data from the sequencing of human biological materials; health-related geospatial and contact-tracing data; insurance claims; and data from social media, smartphones and other electronic devices. Health data, derived from these sources, including heart rate, blood glucose, genetic predispositions, fitness levels, age, weight and so on, may be subject to data protection and privacy laws. Although these laws may vary from country to country, they will inform how such data is processed and its purpose.

4.14 Transparency.³⁰

The term “transparency”, in the context of this document, refers to issues such as sharing and making available to the appropriate entities the relevant plans, decisions and associated reasoning and the data/datasets utilized in the conception, development and ongoing deployment and monitoring of AI systems. Transparency is multifaceted and may include public dissemination by publications in peer-reviewed journals, and publishing and documenting pre-specifications for development processes, including clinical trials etc. Consideration should be given to factors such as data privacy and intellectual property, among others.

²⁸ World Health Organization. (2023). Regulatory considerations on artificial intelligence for health. World Health Organization. <https://iris.who.int/handle/10665/373421>

²⁹ World Health Organization. (2023). Regulatory considerations on artificial intelligence for health. World Health Organization. <https://iris.who.int/handle/10665/373421>

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<https://www.ibm.com/topics/large-language-models>

6 NOTE

6.1. The following are the members of the drafting committee for this guideline:

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- Assoc. Prof. Dr. Mark Tan Kiak Min
- Assoc. Prof. Dr. Sharon Kaur a/p Gurmukh Singh
- Dr. Ng Shu Hui
- Ms. Munita Kaur

6.2. This guideline was endorsed by the Ethics Committee on 29th December 2024, and adopted by the Malaysian Medical Council on 18th February 2025.

6.3. This document will be due for review in 5 years, or earlier as necessary.