



Comhairle na
nDochtúirí Leighis
Medical Council

Artificial Intelligence

Briefing Paper to Inform the Medical
Council on AI in Healthcare

June 2025

Introduction

This paper has been researched and written for the purpose of informing the Medical Council on the use of Artificial Intelligence (AI) in medicine in Ireland.

Artificial Intelligence (AI) is a computer-based technology which has potential to radically alter society, as well as the practice of medicine, and has become a leading worldwide topic of conversation.

AI can be described as a technology capable of making decisions and undertaking tasks which otherwise would require human-like intelligence, such as learning, problem-solving, and decision-making.¹ These advancements hold immense potential for the medical field but also introduce significant ethical, legal, regulatory and professional challenges for doctors integrating AI into their practice. Doctors must ensure that their use of AI augments, rather than replaces their clinical decision making.

When constructed using high-quality data and a robust digital infrastructure, AI has the potential to revolutionise healthcare delivery. It can analyse vast amounts of data in real time, enhance decision-making, support diagnoses through advanced imaging and scans, assist with patient triage, and aid in developing personalised treatment plans. In this evolving landscape, regulatory bodies play a crucial role in guiding Doctors on the responsible use of AI in medical practice, ensuring that doctors remain the ultimate decision-makers in patient care.

This paper explores the uses and risks associated with AI in clinical practice, examines international approaches to regulation, and provides an overview of the evolving legislative landscape surrounding the technology. It highlights the benefits of adopting a principle-based approach to support doctors in integrating AI into their practice.

To achieve this, we propose core principles for the responsible use of AI, emphasising compliance with relevant legislation, professional competence, human-centred care, accountability, clinical governance, and effective communication.

Scope

Given the vast scope of AI, this paper will not cover all aspects of its use, nor is it intended to. For instance, we will not discuss in detail the systems or specific technologies being used in the application of AI in healthcare, given the rapidly evolving nature of AI.

Similarly, transparency requirements for AI developers, especially regarding high-risk AI systems, are outside the scope of this discussion. These requirements aim to ensure that AI systems, particularly those used in critical areas, provide clarity on how decisions are made.

While these considerations are important for the future, they are not the focus of this paper.

¹ The Cambridge handbook of Artificial Intelligence. (Cambridge University Press, 2014).

While the environmental impact of AI is a topic of discussion this shall also be omitted as beyond the scope of this paper.

Uses of AI

AI is being utilised in multiple sectors such as finance, for fraud detection algorithmic training and trend prediction to manufacturing where it has shown potential for automating dangerous processes, quality control and predictive maintenance schedules. However, there is no industry where the sheer transformative powers of AI have been more apparent than in the healthcare field. AI is significantly impacting clinical decision-making and disease diagnosis due to its capacity to process, analyse, and report large volumes of data from different sources, aiding in disease diagnosis and clinical decision-making².

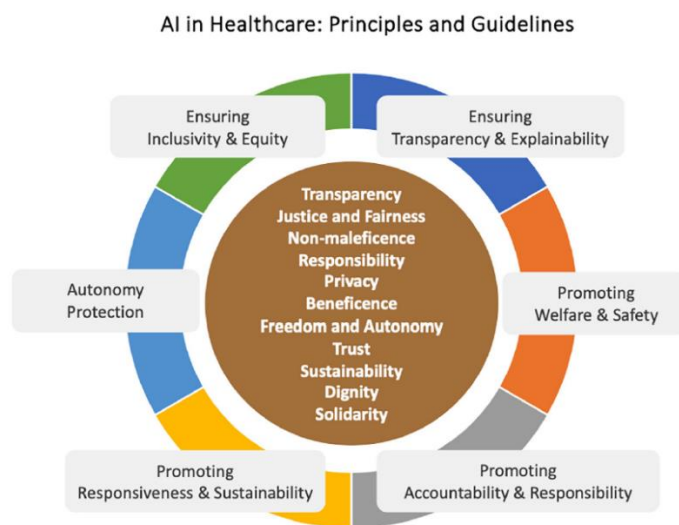


Fig. 4. Ethical principles and guidelines.

Fig. Price, Artificial intelligence in healthcare: Applications and legal implications.

Some AI tools available for health practitioners are designed specifically for healthcare and have been developed for therapeutic purposes, to diagnose and treat patients. Many more are general purpose and are being applied in a healthcare setting.

Some common examples of such applications include³:

- Computer vision systems to analyse medical images,
- Natural language processing to review clinical notes,
- Predictive algorithms and advanced data analytics which forecast clinical trends and provide clinical decision support,
- Voice recognition to support clinical documentation,
- “Chatbots” to provide patient education and triage.

² Mennella, Maniscalco et al., Ethical and regulatory challenges of AI technologies in healthcare: A narrative review in Science Direct Volume 10, Issue 4, 29 February 2024, <https://www.sciencedirect.com/science/article/pii/S2405844024023284>

³ Federal State Medical Board, Navigating the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice (April 2024). <https://www.fsmb.org/siteassets/advocacy/policies/incorporation-of-ai-into-practice.pdf>

Diagnostics	Knowledge Generation	Public Health	System Efficiency	P4 Medicine
• Image Recognition e.g. • Symptoms Checkers and Decision Support • Risk Stratification	• Drug Discovery • Pattern Recognition • Greater knowledge of rare diseases • Greater understanding of causality	• Digital epidemiology • National screening programmes	• Optimisation of care pathways • Prediction of Do Not Attends • Identification of staffing requirements	• Prediction of deterioration • Personalised treatments • Preventative advice

Potential uses for Ai in healthcare – NHSX AI report: Getting it right

The pace of AI development is accelerating at unprecedented rates in modern society, presenting novel opportunities and challenges (Appendix 1). Breakthroughs occur rapidly, with some AI systems surpassing human capabilities in tasks like image recognition, text generation, and problem-solving. These advancements are driven by generative AI, an advanced form of artificial intelligence capable of generating content of its own volition, based on training on vast datasets. Whereas traditional AI focused on analysing and classifying data, generative AI produces outputs that mimic human creativity and problem-solving abilities.

As AI systems become increasingly sophisticated, the challenges associated with ensuring their safe usage become more profound. Indeed, even the creators – or developers – of AI cannot say for sure how the internal workings of their AI systems function and how it reaches its conclusions, raising questions about the autonomy of these systems.⁴

Risks

While the opportunities to enhance healthcare with AI are numerous and its integration into clinical practice also presents significant risks that must be carefully managed. As per the EU AI Act, 'risk' means the combination of the probability of an occurrence of harm and the severity of that harm⁵;

Some of these risks include but are not limited to:

- Blind trust in AI recommendations can lead to misdiagnoses or inappropriate treatments if Doctors do not critically evaluate the system's outputs,
- AI models are also prone to 'hallucinations'—a term used in artificial intelligence to describe the generation of incorrect or misleading information that appears plausible. In a healthcare context, such outputs could potentially endanger patients.⁶

⁴ WHO, regulatory concerns on artificial intelligence for health, 2023

<https://iris.who.int/bitstream/handle/10665/373421/9789240078871-eng.pdf>

⁵ EU AI Act <https://artificialintelligenceact.eu/article/3/>

⁶ Bertalan Meskó and Marton Görög , A short guide for medical professionals in the era of artificial Intelligence NPJ Digit Med. 2020 Sep 24;3:126. <https://pubmed.ncbi.nlm.nih.gov/33043150/>

- Biases in training data can result in AI systems disproportionately misdiagnosing or undertreating certain demographic groups, exacerbating existing healthcare disparities and finally,
- Concerns arise as AI systems process vast amounts of sensitive patient data, increasing the risk of data breaches or misuse.
- The benefit of using AI assistance should be weighed against the risks associated with any model.

Challenge for Regulators

With varying international legal and regulatory frameworks, it is crucial for regulatory bodies to take a proactive role in addressing the legal, ethical, and professional concerns relevant to doctors in their jurisdiction. Just as other technologies such as telemedicine and virtual wards have altered the nature of regulation, so too will the advent of AI and professional regulators must keep pace with these developments.⁷

Regulating AI in healthcare presents a complex challenge for professional regulators, who must balance innovation with patient safety. While regulators can leverage AI to enhance their internal functions - such as mapping regulatory complaints to improve upstream regulation and predict areas of heightened risk - they must also provide guidance to the doctors they regulate on its ethical use. This support is vital in ensuring the responsible use of AI in medical practice, serving the dual purpose of assisting doctors in the interest of public protection. Regulators can promote the principles of safe use by providing principle-based guidance, that set out the broad parameters for using technological advancements.⁸

A recent study by the BMJ revealed that 20% of General Practitioners (GPs) surveyed are using generative artificial intelligence in their clinical practice.⁹ Among those using AI, 29% reported using these tools to generate documentation after patient appointments, and 28% to suggest a differential diagnosis. These findings suggest that GPs find value in these tools and are incorporating them into their practice. However, doctors also reported having inadequate knowledge about the limitations of these tools, highlighting the need for further education and support for healthcare professionals.¹⁰

Effective regulation of AI in clinical practice must evolve alongside the technology itself, ensuring patient safety remains uncompromised while supporting technological and medical innovation. While we are not a competent authority with direct responsibilities under the EU AI Act¹¹, the legislation governing the regulation of artificial intelligence, recognises the importance of supporting doctors in confidently adapting to emerging technologies.¹² Doctors are required

⁷ WHO, regulatory concerns on artificial intelligence for health, 2023
<https://iris.who.int/bitstream/handle/10665/373421/9789240078871-eng.pdf>

⁸ World Health Organization. Ethics and Governance of Artificial Intelligence for Health: WHO Guidance, (2021)
<https://www.who.int/publications/i/item/9789240029200>

⁹ Blease CR, Locher C, Gaab J, Hägglund M, Mandl KD. Generative artificial intelligence in primary care: an online survey of UK general practitioners. *BMJ Health Care Inform.* 2024 Sep 17;31(1) pp 43-78. Hyoe link

¹⁰ Ibid p. 45

¹¹ European Parliament & Council of the European Union. (2024). Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending various regulations and directives (Official Journal of the European Union). <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32024R1689>

¹² Named competent authorities are Central Bank of Ireland, the Commission for Communications Regulation, Commission for Railway Regulation, Competition and Consumer Protection Commission, Data Protection

to maintain familiarity and compliance with relevant legislation as per the ‘Guide to Professional Conduct and Ethics for Registered Medical Practitioners’ prepared by the Medical Council.¹³

European regulators in particular are now within the remit of the EU AI Act, under which article 4 states that providers and deployers of AI, or developers and users, “*must ensure to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.*”

There is a growing narrative that regulation can stifle technological advancement; to counter this, regulatory frameworks must strike a balance by which protects that public without impeding innovation.¹⁴ This can be achieved by consideration of levels of risk of various applications, and by ensuring that more resources and scrutiny are applied to higher risk applications, and low risk applications are not unnecessarily burdened. The graph below illustrates the spectrum of potential risks associated with various types of AI applications, and their relationship to patient safety.

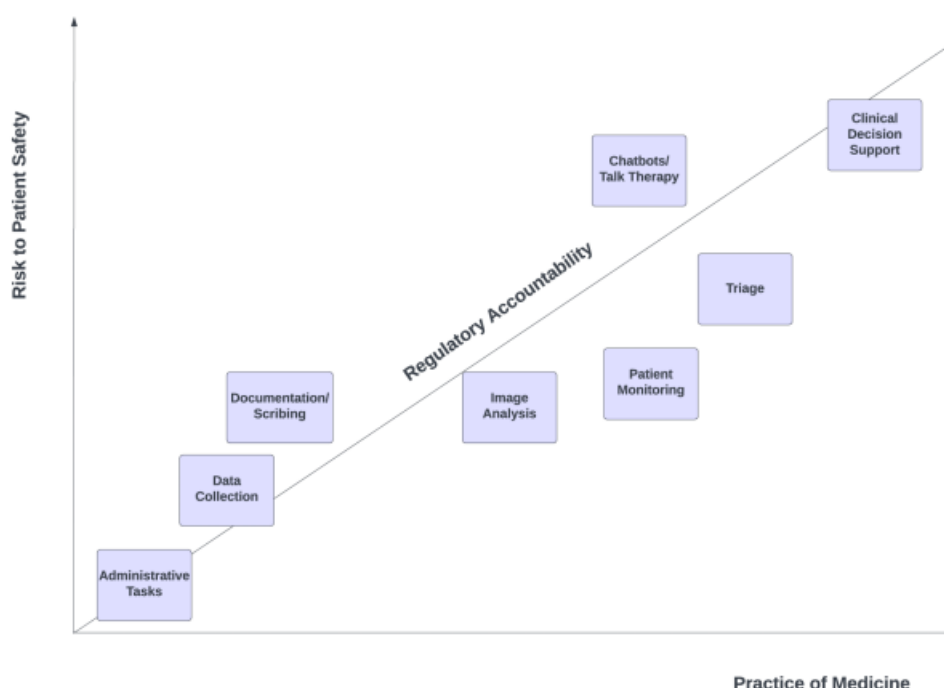


Fig. 1 - Modeling Risk v. Function

Federal State Medical Board, Navigating the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice, pg. 6.

Commission, Health and Safety Authority and Marine Survey Office/Department of Transport – These are in addition to the Data Protection Commission (DPC), Coimisiún na Meán, and the Irish Human Rights and Equality Commission (IHREC) whom have specific powers under the Act.

¹³ Guide to Professional Conduct and Ethics for Registered Medical Practitioners 9th edition

<https://www.medicalcouncil.ie/news-and-publications/publications/guide-to-professional-conduct-and-ethics-for-registered-medical-practitioners-2024.pdf>

¹⁴ Federation of State Medical Boards, Navigating the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice (April 2024) <https://www.fsmb.org/siteassets/advocacy/policies/incorporation-of-ai-into-practice.pdf>

International Approaches

Internationally, medical regulators are working to support their registrants in using AI effectively and safely in clinical practice. The Australian Health Practitioner Regulation Agency (AHPRA) has developed a principles-based framework to guide doctors in the safe and effective use of AI, providing overarching principles to help doctors consider their obligations and the associated risks. AHPRA's principle-based framework highlights key concepts that health practitioners should embed in their practise to ensure ethical use of AI.

The key concepts identified by their research are transparency, accountability, understanding, informed consent and ethical and legal alignment.¹⁵ They highlight the Health Practitioner's responsibility to keep informed of updates to legal frameworks and regulatory positions around AI use, ensure compliance with indemnity requirements and ensure care remains patient centred.¹⁶

As well as this values-based guidance, they have created enabling documentation to support registrants, such as case studies and FAQs surrounding AI use in practice.

In the United Kingdom, the General Medical Council (GMC) aligns AI use with their existing standards on technology and accountability. While AI is an emerging area requiring attention to its unique risk profiles, existing medical device frameworks can be adapted to identify basic principles for medical technology and apply them to AI.¹⁷ They emphasise that doctors must adhere to the same principles for medical device failure, as outlined by the Medicines and Healthcare Products Regulatory Agency (MHRA), which approves and regulates new healthcare technologies. The GMC stresses that doctors are responsible for decisions made using new technologies, including AI, and that their Professional Standards remain applicable.¹⁸

In the event of adverse outcomes related to AI use, the GMC reaffirms that the principles in their Good Medical Practice guidelines continue to apply. This reflects the approach underway in Ireland, where the Health Information Quality Authority (HIQA) has been tasked with developing a framework for the responsible and safe use of AI in health and social care.

Legislation and EU AI Act

The EU is taking a relatively prescriptive approach that seeks to be balanced and ethical, prioritising innovations, patient safety and data protection.

The EU AI Act is the world's first comprehensive legal framework for artificial intelligence, designed to ensure AI systems are safe, transparent, and aligned with fundamental rights.¹⁹ It classifies AI systems based on risk levels, imposing different regulatory requirements accordingly. It will have a phased implementation, coming into full effect by 2026.

¹⁵ AHPRA, Meeting your professional obligations when using Artificial Intelligence in healthcare, <https://www.ahpra.gov.au/Resources/Artificial-Intelligence-in-healthcare.aspx>

¹⁶ AHPRA, Applying your code of conduct to evolving technologies - AI in healthcare (August 2024). <https://www.ahpra.gov.au/News/2024-08-22-AI-in-healthcare-code-of-conduct.aspx>

¹⁷ GMC, Good Medical Practice (2024) <https://www.gmc-uk.org/-/media/documents/good-medical-practice-2024---english-102607294.pdf>

¹⁸ EU AI Act, 2025

¹⁹ Ibid

Under the Act, systems that pose an unacceptable risk, such as those used for social scoring or manipulative techniques, are banned. High-risk AI systems, including those used in healthcare, law enforcement, and employment, must meet strict requirements related to data quality, transparency, and human oversight. Limited-risk AI, such as chatbots and deepfakes, must disclose their AI nature to users, while minimal-risk AI, like spam filters and AI in video games, remains largely unregulated. The Act distinguishes between responsibilities for providers (developers) or AI and deployers (users of the product).

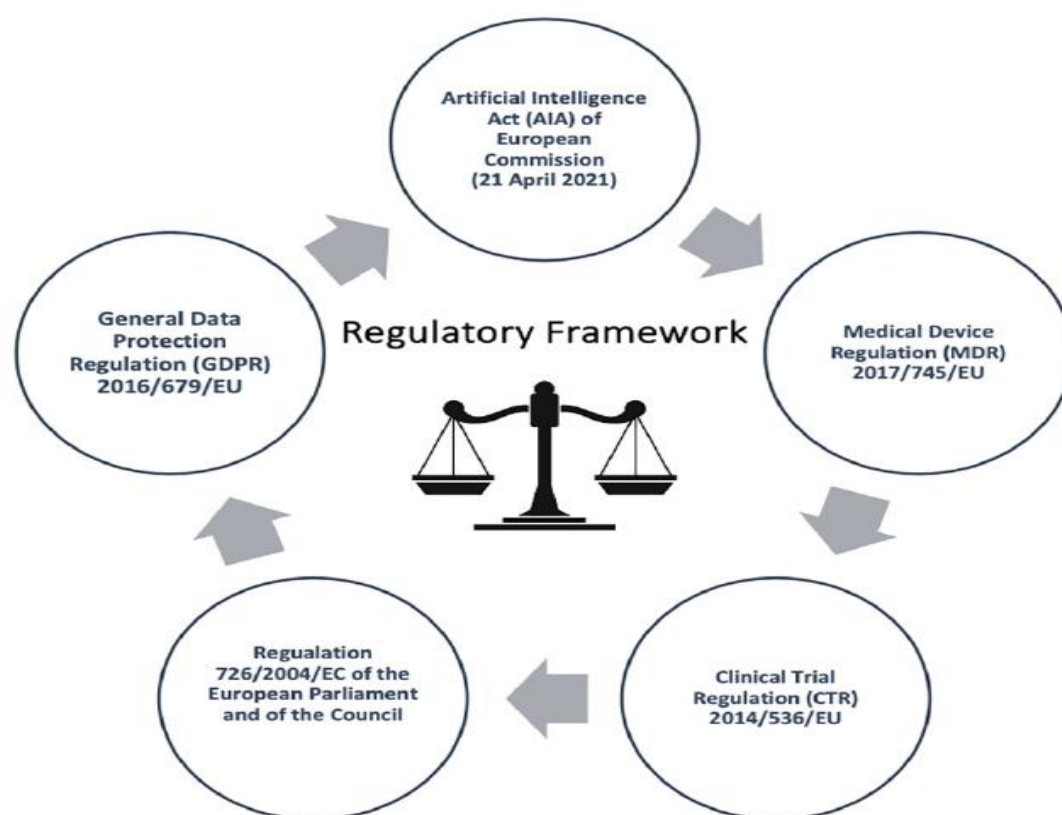
The below chart summarises relevant provisions and their potential implications.

Article	Provision Summary	Potential Implications for Deployers (Doctors)
Article 13 Transparency and Instructions	High-risk AI systems must come with: • Ensure operation is sufficiently transparent to enable deployers to interpret the systems output – explainable AI • Clear usage instructions with explanation of system capabilities, limitations, and risks	• Ensure that users (clinicians, staff) are trained and understand how to use the system • Keep and follow documentation on AI usage in clinical decision making • Provide transparency to patients when appropriate
Article 14 Human Oversight	AI use must include effective human oversight to: • Detect, prevent or correct issues • Avoid over-reliance	• Oversight procedures • Assign responsibility for monitoring and intervention • Prevent automation bias by ensuring human judgment in decisions
Article 15 Accuracy, Robustness, Cybersecurity	High-risk AI must be: • Accurate • Robust against failure • Secure from cyber threats	• Ensure the system is clinically validated and maintained • Perform technical audits and updates • Maintain IT security standards • Report significant system failures or breaches

The Act is applied horizontally with a majority for its regulations implicated for the developers. It also introduces the concept of regulatory sandboxes for the safe testing of new forms of technology in protected environments. This act applies additional legislative responsibilities when using AI and should be read in conjunction with other relevant legislation at EU level, such as GDPR and Medical Device Regulation, both of which have significant bearing on the uses of AI in healthcare – for example, any generative AI used as diagnostic tools. These concepts must be read in conjunction to provide a full picture of the legislative responsibilities required of a doctor within their scope of practise.²⁰

²⁰ Mennella, Maniscalco et al., Ethical and regulatory challenges of AI technologies in healthcare: A narrative review in Science Direct Volume 10, Issue 4, 29 February 2024, <https://www.sciencedirect.com/science/article/pii/S2405844024023284>

When using any AI-enabled medical device, doctors must comply with relevant regulations, including the EU Medical Device Regulation (MDR) 2017/745, which requires all devices and software's to be CE marked.



Regulatory Framework of AI use in Europe²¹

Recommendations

The development of guidelines for advising medical professionals on AI use should be underpinned by robust evidence and informed by internationally established frameworks, standards and regulation. In recent years, a number of international and national health advisory bodies have begun work in this area, issuing a range of recommendations that serve as vital foundations for developing professional guidance on AI use in healthcare, many of which centre on principles and values rather than prescriptive guides. Many of these remain evolving frameworks and regulators must engage with these on a continuous basis to ensure the most relevant information is being shared.

²¹ Ibid

The World Health Organisation (WHO) stresses the importance of transparent documentation, robust risk management, high-quality and representative data, privacy protections, meaningful stakeholder engagement, and strengthened regulatory capacity. These measures are designed to ensure AI technologies enhance health outcomes without compromising patient safety or equity.²²

The WHO's 2024 guidance on Ethics and Governance of Artificial Intelligence for Health offers a practical framework to support safe and ethical use of large multi-modal models (LMMs) in healthcare. For medical regulators, it provides a robust foundation to guide clinicians in the responsible adoption of AI. Central to this is the operationalisation of core values such as mechanisms to ensure equity— such as ensuring that AI tools are tested on diverse populations to avoid systemic biases; transparency — which could take the shape of requiring clinicians to understand and explain how AI-driven recommendations are generated; and human oversight— preserving clinician autonomy so that AI supports, rather than overrides, professional judgment.

The guidance recommends that clinicians be actively involved in selecting, evaluating, and monitoring AI tools, with clear documentation to ensure accountability. It also emphasises the importance of ongoing training to build digital literacy, so that healthcare professionals can interpret AI outputs critically and maintain patient-centred care. By anchoring these values in everyday clinical practice, WHO's framework aims to foster trust and ethical resilience as AI becomes more embedded in healthcare delivery.

The values-based principles developed by the Organisation for Economic Co-Operation and Development (OECD)—adopted in 2019 and updated in 2024— also serve as a key global reference point for AI in healthcare, particularly in promoting transparency, accountability, and human-centred design. These principles aim to provide timely guidance for current challenges while being adaptable and enduring in a rapidly evolving technological landscape. The values outlined highlight trustworthy AI grounded in human rights, transparency, accountability, and safety, alongside preparing the workforce for AI as well as fostering international cooperation.²³

The updates between the 2019 and 2024 versions focused on strengthening safeguards for AI system safety, highlighting the importance of transparency, human centred design. They seek to address the challenges of mis- and disinformation, promoting responsible business conduct across the AI lifecycle, clarifying transparency and disclosure requirements, integrating environmental sustainability considerations, and enhancing international cooperation for interoperable AI governance.²⁴

The European Union's AI Continent Action Plan complements this by advancing human-centred, democratically aligned AI through targeted skills programmes, including AI education and training tailored to health professionals.²⁵ These frameworks collectively recommend ethical oversight, patient involvement, investment in professional training, and adaptable

²² WHO, regulatory concerns on artificial intelligence for health, 2023

<https://iris.who.int/bitstream/handle/10665/373421/9789240078871-eng.pdf>

World Health Organization. Ethics and Governance of Artificial Intelligence for Health: WHO Guidance, (2021)

<https://www.who.int/publications/i/item/9789240029200>

²³ OECD Legal Instruments, Recommendation of the Council on Artificial Intelligence, 2019

<https://legalinstruments.oecd.org/en/instruments/oecd-legal-0449>

²⁴ OECD updates AI Principles to stay abreast of rapid technological developments, May 3rd 2024,

<https://www.oecd.org/en/about/news/press-releases/2024/05/oecd-updates-ai-principles-to-stay-abreast-of-rapid-technological-developments.html>

²⁵ European Approach to Artificial Intelligence, <https://digital-strategy.ec.europa.eu/en/policies/european-approach-artificial-intelligence>

governance aligned with global standards. This aligns with the framework adopted by the global regulators forum, the Council on Licensure, Enforcement and Accreditation (CLEAR), which echo principles of professional competence and education as a key tool for regulators in ensuring that AI technologies are only integrated and applied within a practitioner's verified scope of knowledge and expertise. It further emphasises ethical implementation by mandating that AI supports, rather than replaces, human judgment, and lastly stresses transparency, accountability, and security through regular audits for bias, clear operational standards, and strong safeguards against security threats.²⁶

In Ireland, national bodies have echoed similar principles. The Department of Enterprise's AI Advisory Council also calls for harmonised, human-centred approaches, clear national guidance, and strengthened capacity across the health workforce to support safe and responsible AI use.²⁷ IPPOSI, an organisation advocating for the rights of patients, recently conducted a citizens' Jury whose recommendations centred on the patient voice, emphasised the need for human oversight in clinical care, informed consent, clear explanations when AI is used, strong data governance, and professional training that upholds clinical integrity.

Taken together, these international and national recommendations provide a clear mandate for regulators to support the integration of AI into clinical care in a manner grounded in ethical practise, professional competence and the protection of patient rights.²⁸

Values Based Guidance

Some regulators and responsible bodies have, or are in the process of, adopting a principled values-based approach to AI guidance, ensuring that guidance keeps pace with rapid technological advancements. While professional regulators are not responsible for the regulation or development of medical devices, including AI-based systems, which fall under the purview of European and Regional Medical Device Regulations, the Council's role is to set the professional standards, values, and behaviours expected of clinicians. This includes ensuring Doctors adhere to ethical and professional guidelines when using AI technologies within clinical practice.

Instead of focusing on specific technologies that may quickly become outdated, frameworks should emphasise human behaviour, outlining the qualities and competencies that doctors should apply when using AI to support their decision-making. By prioritising core principles from, and integrating them with, existing guidance on conduct and professionalism for doctors, regulators can support doctors to navigate this evolving field. This approach ensures that AI is used responsibly while maintaining the professional judgment and ethical standards essential to healthcare, in accordance with the behaviours and principles outlined in 'Guide to Professional Conduct and Ethics for Registered Medical Practitioners' prepared by the Medical Council.²⁹ For example, many of the behaviours and principles in the Guide, such as informed consent, confidentiality and record keeping, communication, and the use of sound clinical judgement closely align with the values outlined in the position statement issued.

²⁶ CLEAR Baltimore Principles

²⁷ Dept of Enterprise, AI Advisory Council – Helping to Shape Principles

<https://enterprise.gov.ie/en/publications/publication-files/ai-advisory-council-recommendations-helping-to-shape-irelands-ai-future.pdf>

²⁸ Ipossi, IPPOSI launches Citizens' Jury report on AI in Healthcare, (Feb 2025) <https://ipposi.ie/aicitizensjury/>

²⁹ Guide to Professional Conduct and Ethics for Registered Medical Practitioners 9th edition <https://www.medicalcouncil.ie/news-and-publications/publications/guide-to-professional-conduct-and-ethics-for-registered-medical-practitioners-2024.pdf>

These values include Education, Data Protection, Ethics, Communication, and Professional Accountability.

Both the Guide and the draft statement emphasise the importance of exercising professional judgement. They acknowledge that when a doctor follows relevant guidance, acts in good faith, and respects the will and preferences of their patients, they will be well placed to explain and justify their decisions and actions if any concerns are raised about their practice.³⁰

The goal is human-centred care, supported by AI. AI should be used responsibly and effectively to improve patient outcomes. The emphasis is placed on patient-centred care, professional integrity, ethical decision-making, and ongoing responsibility.

Core principles of AI use in Medical Practice

Compliance

Despite the novelty of AI technologies, their use can be effectively governed within existing legislative frameworks. Healthcare professionals must ensure that AI aligns with established legal and ethical standards, such as GDPR, to uphold patient privacy, data security, and informed consent. The principles that apply to traditional healthcare technologies remain just as crucial when integrating AI, ensuring responsible, transparent, and legally compliant use.³¹

Professional responsibilities and AI

A key professional responsibility of doctors using AI is professional competence. AI, like any medical tool, should be used within the practitioner's expertise and training, in line with the standards set by professional regulators. Doctors are responsible for ensuring they have the necessary knowledge to integrate AI into clinical practice safely. Furthermore, they must guard against overreliance on these technologies to prevent skill degradation, ensuring AI complements rather than replaces critical clinical judgment. This requires ongoing training and supervision to maintain the Doctors expertise.³² Bodies responsible for medical education and training in Ireland are recognising the significant impact of AI and responding by embedding good practices for AI use in clinical practice into both undergraduate training and continuing professional development (CPD) modules, which will be of importance in assisting doctors in meeting their professional responsibilities around AI use.

³⁰ Guide to Professional Conduct and Ethics for Registered Medical Practitioners 9th edition p. 6
<https://www.medicalcouncil.ie/news-and-publications/publications/guide-to-professional-conduct-and-ethics-for-registered-medical-practitioners-2024.pdf>

³¹ Wolff, Josephine, William Lehr, and Christopher S. Yoo. "Lessons from GDPR for AI Policymaking." Virginia Journal of Law & Technology, vol. 27, no. 4, Winter 2024.

https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=1376&context=faculty_articles

³² Bertalan Meskó and Marton Görög, A short guide for medical professionals in the era of artificial Intelligence NPJ Digit Med. 2020 Sep 24;3:126. <https://pubmed.ncbi.nlm.nih.gov/33043150/>

While many doctors (54%) expressed they would disregard the AI recommendations if they were not confident in the information output, a significant number (30%) were unclear about who holds responsibility in the event of an AI-related error. Additionally, only 12% of doctors felt sufficiently trained to understand their professional responsibilities when using AI systems, with the figure even lower (17%) among those already using AI. These findings underscore the need for clearer frameworks and improved training to equip Doctors with the knowledge they need to safely navigate the complexities of AI in healthcare, ensuring both accountability and effective patient care.³³

Human-centred care

While AI in healthcare can make autonomous decisions and assist doctors, it is crucial that it never makes clinical judgments or decisions entirely on its own. Human oversight must be applied to all AI outputs to ensure it complements and enhances human intelligence rather than replacing it. Doctors must ensure they are critically assessing any outputs of AI for hallucinations and other inaccuracies, utilising their own judgement as the ultimate decision maker.³⁴

Accountability and Clinical Governance

Clinical governance is crucial for the safe and effective integration of AI in healthcare, ensuring that AI-driven technologies maintain high standards of quality, safety, and accountability. While AI can assist in clinical decision-making, ultimate responsibility remains with healthcare professionals. Doctors must recognise that they are accountable for patient care, even when AI is involved.

In cases where AI contributes to errors or adverse outcomes, the same professional and legal standards apply as they would for any other clinical tool or technology. Strong governance frameworks help mitigate risks, ensuring AI is used ethically, transparently, and in alignment with best practices.³⁵

Communication

Patients have the right to be informed about their care and make decisions regarding it. When AI is used in patient care, ethical practice requires that patients are fully informed, understand its role, and provide their consent. The incorporation of AI prompts a reassessment of the conventional doctor-patient relationship.³⁶

³³ Hasham et al., One in four UK doctors are using Artificial Intelligence: Exploring doctors' perspectives on AI after the emergence of large language models, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4997033

³⁴ AI and professional liability assessment in healthcare. A revolution in legal medicine? Claudio Terranova*, Clara Cestonaro, Ludovico Fava and Alessandro Cinquetti, <https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2023.1337335/full>

³⁵ Ibid

³⁶ Mennella, Maniscalco et al., Ethical and regulatory challenges of AI technologies in healthcare: A narrative review in *Science Direct* Volume 10, Issue 4, 29 February 2024, <https://www.sciencedirect.com/science/article/pii/S2405844024023284>

Conclusion

In conclusion, AI has the potential to revolutionise healthcare by improving outcomes, treatment, efficiency, of health care. However, it is essential that doctors use this technology with caution and oversight, ensuring it serves as a tool to enhance, not replace, their expertise and judgement. By upholding ethical principles, accountability, professional responsibility, patient-centred care, and maintaining human oversight, doctors can ensure that AI contributes to safer, fairer, and more effective care. Professional regulators have a crucial role in guiding the integration of AI into healthcare and supporting doctors, by providing values-based guidance with public protection at its core.

Appendices

Appendix 1: Swot Analysis - Use of AI by Doctors in Clinical Decision-Making

Strengths	Weaknesses
- Enhances diagnostic and clinical accuracy, improving patient outcomes.	- Some AI tools lack transparency (“black box” models), making it difficult to assess how decisions are made.
- Promotes consistency and alignment with evidence-based guidelines.	- Potential for over-reliance, Risk of deskilling or reduced clinical judgement if Doctors defer excessively to AI recommendations.
- Improves efficiency, freeing Doctors to focus on patient interaction.	- Risk of biased outputs due to flawed or non-representative data. AI models may reflect existing healthcare disparities, leading to biased or inequitable care
- Supports continuous professional development through performance feedback.	- Ambiguity around responsibility and accountability for AI-influenced decisions.
Opportunities	Threats
- Chance to lead in shaping innovative regulatory frameworks for AI in healthcare.	- Rapid AI development may outpace regulatory oversight, creating gaps in governance, leading to gaps in oversight and potential risks to patient safety
- Collaborate with stakeholders to co-design safe, ethical, and effective AI systems.	- Legal uncertainty and ethical complexity in determining liability in AI-assisted care.
- Enhance public trust, transparent regulation of AI can reinforce trust in both technology and the professional regulation of AI can reinforce trust in both technology and the profession	- Potential for inequitable access to AI tools across sectors and populations, which may exacerbate existing health inequalities
- Use AI-derived insights to inform professional standards and policy development.	- Public trust could be undermined by perceived or actual AI failures in clinical contexts.

Appendix 2: Australian (AHPRA) Position Statement

Meeting your professional obligations when using Artificial Intelligence in healthcare

Artificial Intelligence (AI) technology is rapidly becoming integrated into many areas of healthcare. This guidance explains how existing responsibilities in National Boards' codes of conduct apply when practitioners use AI in their practice.

This guidance will be updated regularly to reflect new developments in AI and share updates from other regulators.

Artificial intelligence in healthcare

AI can be defined as 'computer systems able to perform tasks that normally require human intelligence, such as visual perception, speech recognition, decision making, and translation between languages'¹. Some AI tools available for health practitioners are designed specifically for healthcare and have been developed for a therapeutic purpose, for example, to diagnose and treat patients or clients. Many more are general purpose and are being applied in a healthcare setting. Some professions are increasingly using new AI such as medical scribing tools to support workload management and efficiency in practice to develop or edit documents.

There are different types of AI including machine learning which encompasses generative AI, natural language processing and computer vision. Further information about each type can be found on the [frequently asked questions page](#).

How are AI tools regulated in healthcare?

Some AI tools used in healthcare are regulated by the Therapeutics Goods Administration (TGA). The TGA regulates therapeutic goods that meet the definition of a medical device, which includes software (including AI-enabled software) if it has a therapeutic use and meets the [definition](#).

Generative AI tools used in clinical practice such as AI scribing are usually intended for a general purpose and do not have a therapeutic use or meet the definition of a medical device, and therefore are not regulated by the TGA.

Health practitioners can contact the vendor or search the [Australian Register of Therapeutic Goods \(ARTG\)](#) to check if the tools they are using are registered. To find out more about the TGA and its regulation of AI software, see our [Further information about AI page](#).

on AI

<https://www.ahpra.gov.au/Resources/Artificial-Intelligence-in-healthcare.aspx#>

15/04/2025, 16:15 Australian Health Practitioner Regulation Agency - Meeting your professional obligations when using Artificial Intelligence in h...

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What are the potential benefits of AI?

The potential of AI to transform and support innovation in healthcare has been the subject of much media and professional commentary. Ahpra and National Boards support the safe use of AI in healthcare recognising the significant potential to improve health outcomes and create a more person-centred health system. While the potential of AI to improve health outcomes through improved diagnostics and disease detection has been reported for some time, recent commentary has focussed on the benefits for health practitioners with improved care and patient satisfaction by reducing administrative burdens and health practitioner burnout.

Meeting your professional obligations - what are the potential challenges of using AI?

As advancements in AI are rapidly evolving and new tools continue to emerge, its safe use in healthcare involves unique practical and ethical issues. Ahpra and National Boards have identified the following key principles to highlight existing professional obligations that apply when health practitioners use AI in their practice.

This guidance will be regularly reviewed and updated to reflect developments in technology. We have also developed some case studies about the use of newer generative AI tools in practice, and will add [case studies](#) focussing on other areas as these are developed.

Key principles for health practitioners to consider to ensure they are meeting professional obligations when using AI in practice include:

Accountability

Regardless of what technology is used in providing healthcare the practitioner remains responsible for delivering safe and quality care and for ensuring their own practice meets the professional obligations set out in their Code of Conduct. Practitioners must apply human judgment to any output of AI. TGA approval of a tool does not change a practitioner's responsibility to apply human oversight and judgment to their use of AI, and all tools/software should be tested by the user/organisation to ensure they are fit-for-purpose prior to its use in clinical practice. If using an AI scribing tool, the practitioner is responsible for checking the accuracy and relevance of records created using generative AI.

Understanding

Health practitioners using AI in their practice need to understand enough about the AI tool to use it safely and in a way that meets their professional obligations. At a minimum, the practitioner should review the product information about an AI tool including how it's trained and tested on populations, intended use, and limitations and clinical contexts where it should not be used. Understanding the 'intended use' of an AI tool is particularly important, as this will inform a practitioner's consideration of when it is appropriate to use the content /imaging generated by the AI and the associated risks and limitations including diagnostic accuracy, data privacy, and ethical considerations. It is also important to understand how the data is being used to retrain the AI, where data is located and how it is stored.

Transparency

Health practitioners should inform patients and clients about their use of AI and consider any concerns raised. The level of information a health practitioner needs to provide will depend on how and when AI is being used. For example, if AI is being used as part of software to improve the accuracy of interpreting diagnostic images, the practitioner would not be expected to provide technical detail about how the software works. However, if a practitioner is using an AI tool to record consultations, they would need to provide more information about how the AI works and may impact the patient in terms of its collection and use of their personal information (for example, if public generative AI software is used personal information becomes public domain).

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Informed consent

Health practitioners need to involve patients in the decision to use AI tools that require input of their personal patient data and if a patient's data is required for care (i.e via a recommended diagnostic device). Make sure you obtain informed consent from your patient, and ideally note the patient's response in the health record. If using an AI scribing tool that uses generative AI, this will generally require input of personal data and therefore require informed consent from your patient/client. Informed consent is particularly important in AI models that record private conversations (consultations) as there may be criminal implications if consent is not obtained before recording, and the AI transcription software should include an explicit consent requirement as an initial step before proceeding.

Ethical and legal issues

Other professional obligations in each Board's Code of Conduct or equivalent that are relevant to the use of AI in practice include:

- ensuring confidentiality and privacy of your patient/client as required by privacy and health record legislation (see below), by checking that data is collected, stored used and disclosed in accordance with legal requirements, and your patient's privacy is not inadvertently breached. Practitioners need to be aware of whether the patient data being used/recorded is also used to train the AI model for future patients, and whether identifiable patient data then finds its way into that learning database.
- supporting the health and safety of Aboriginal and Torres Strait Islander people and all patients/clients from diverse backgrounds by ensuring you understand the inherent bias that can exist within data and algorithms used in AI applications and only using them when appropriate
- complying with any relevant legislation and/or regulatory requirements that relate to using AI in practice, including the requirements of the TGA and your state and/or territory governments
- awareness of the governance arrangements established by your employer, hospital or practice to oversee the implementation, use and monitoring of AI to ensure ongoing safety and performance, including your role and responsibilities, and
- holding appropriate professional indemnity insurance arrangements for all aspects of your practice and consulting your provider if you're unsure if AI tools used in your practice are covered.

<https://www.ahpra.gov.au/Resources/Artificial-Intelligence-in-healthcare.aspx#>

Appendix 3 - Glossary of Terms

Artificial Intelligence	This can be described as a technology capable of making decisions and undertaking tasks which otherwise would require human-like intelligence, such as learning, problem-solving, and decision-making
Black-box Models	AI systems, especially complex neural networks, whose internal workings are not easily interpretable, making it difficult to understand how they arrive at a decision or output.
Hallucinations	Instances where AI systems generate incorrect or fabricated information that appears plausible but is not based on real data or facts.
Generative AI	A type of AI that can produce new content (e.g., text, images, or data) rather than just analysing existing data. In medicine, it might be used to draft documentation, simulate patient interactions, or predict health outcomes
Natural Language Processing (NLP)	A branch of AI that enables computers to understand, interpret, and generate human language, often used in reviewing clinical notes or interpreting patient input
Predictive Analytics / Predictive Algorithms	Techniques that use historical data and statistical methods to predict future outcomes, such as patient deterioration or treatment success
Regulatory Sandbox	A controlled environment where new technologies, like AI tools, can be tested under regulatory supervision before full implementation, to ensure safety and compliance.



Comhairle na
nDochtúirí Leighis
Medical Council

Medical Council

Kingram House

Kingram Place

Dublin 2

D02 XY88

info@mcirl.ie

www.medicalcouncil.ie