Artificial intelligence in healthcare and medico-legal risk

The use of artificial intelligence (AI) has great potential to enhance the provision of healthcare in Australia. As part of a broader rapidly growing digital ecosystem, it will significantly affect the way medicine is practised, bringing new opportunities and distinct challenges that require responsive regulatory frameworks.

To maximise AI's potential and manage its risks, Avant's approach focuses on advocating for clear, enforceable regulations and guidelines that address the complexity of AI applications while reducing medico-legal risks. Ensuring clarity around responsibility, liability and patient safety is essential for the successful and sustainable integration of AI in healthcare.

Background

As a member-owned doctors' organisation, Avant provides professional indemnity insurance and legal advice and assistance to more than half of Australia's doctors. We assist members in civil litigation, professional conduct matters, coronial matters and a range of other matters. Our Medico-legal Advisory and Risk Advisory Services provides support and advice to members and insured medical practices when they encounter medico-legal issues.

Overall, feedback from our members highlights strong interest among doctors in using AI to support patient care and improve efficiency. However, they face challenges due to the rapid pace of AI developments, the need to balance clinical safety and efficacy, and limited knowledge about how AI works and its risks.

Members are increasingly seeking advice about meeting their professional obligations and safe use of AI, including general purpose AI tools such as ChatGPT and AI scribes for clinical notetaking. A recent survey of 600 members indicated three in four respondents had fair to poor knowledge of AI overall. While only 10% were using AI, around 40% of respondents indicated they were likely to use an AI scribe in the future.

The Australian Government has proposed a risk-based approach to regulating AI that involves mandatory guardrails for AI systems in high-risk settings including healthcare. The mandatory guardrails require developers and deployers of AI to take steps to ensure their products are safe. At the same time, health laws are being reviewed to strengthen legislation and regulation for AI in healthcare settings.

Avant aims to create an important and timely policy discussion, bringing its unique lens on medico-legal risks and patient safety informed by a deep understanding of the daily practice of more than 90,000 doctor members across all specialties and career stages. We recommend specific policy actions to strengthen transparency, assign accountability and establish robust regulatory oversight and governance for AI in healthcare. These recommendations emphasise the need for proactive measures that complement existing professional obligations and safeguard both doctors and patients against potential harm as AI continues to advance.

Obligations and potential challenges of AI in healthcare

The use of AI in healthcare comes with additional sensitivities compared with other sectors, given the potential for patient harm.

Doctors have professional obligations for delivering safe and quality care that continue to apply when using AI in their practice – this is highlighted in recent guidance from the Australian Health Practitioner Regulation Agency (Ahpra) and National Boards[1].

However, using AI in healthcare introduces new and complex medico-legal, privacy and legal risks that existing regulatory frameworks are ill-equipped to address. These factors, summarised below, must be carefully considered to ensure AI is safely adopted in ways that support doctors and build both public and professional trust.

Medico-legal and other risks explained

Risk type	Risk explained and examples
Inaccuracies and errors in AI and AI outputs	Hidden biases within the AI system leading to unforeseen errors • AI prioritising tool selects one patient group over another, creating a risk for both patient and doctor. • AI tool is trained on inappropriate population data, leading to incorrect conclusions.
	Misunderstanding and misinterpreting terms and substituting incorrect terms • AI scribe may misinterpret a term during a consultation and substitute a term the doctor has used previously. There is a risk of misdiagnosis if the error is not identified.
	Failing to capture all relevant information • AI scribe will not capture non-verbal cues, psychosocial dimensions or examination findings that are not heard or understood (for example, describing breast augmentation with reference to location and measurements in centimetres).
	Automation bias – complacency around accuracy of outputs • Doctors may become complacent and fail to check AI output for accuracy because it appears to be logical and comprehensive. If doctors delegate responsibility to the AI scribe, they may overlook an aspect of patient care. There is a risk of misdiagnosis if doctors do not apply their own clinical reasoning to all of the evidence available.
Loss of clinical skills	Over-reliance on AI leading to reduction in clinical skills • Doctors may become dependent on AI diagnostic and management tools and this may impact clinical care if the doctor cannot rely on their own skills to check the accuracy of the AI output, or if the AI system is inaccessible.
Lack of transparency	Inability to evaluate an AI's outputs because of its "black box" nature • If doctors do not know how the AI works and cannot identify the methods used to make predictions due to the "black box" nature of the tool, errors can be undetectable.
	Evolution through machine learning • AI systems can evolve over time in a manner that is not foreseeable or intended by the developer or deployer.
	Lack of knowledge of AI use (patients and practitioners) • If patients are not aware of the use of AI there is potential for loss of trust. • If doctors are not aware of the use of AI they cannot explain it to patients.
Privacy and data security	An AI tool may breach privacy if it does not comply with privacy law • Doctors may be subject to regulatory action if they fail to comply with privacy obligations when using an AI tool.
	Data may be lost if security is not robust • If there are insufficient security safeguards, sensitive data may be at risk of cyber attack.
	Secondary use of data may breach privacy laws or ethical principles • Use of data by the AI tool for purposes other than clinical care may breach privacy laws or ethical principles if done without patient knowledge or consent.
Legal liability risks	Legal uncertainty regarding accountability, responsibility and liability across the AI lifecycle • It is difficult to determine at what point in the AI lifecycle a risk eventuates and therefore who or which entity is accountable for any resulting harm. • If the data and operational information the AI system relies upon are not properly recorded, stored and maintained, it becomes extremely difficult at a later date to trace the source of the error that has caused patient harm and allocate responsibility.
	Broad indemnity clauses which seek to absolve developers of liability • Contracts can contain clauses that redirect liability from the developer of the tool to the doctor. • As professional indemnity policies typically do not cover product liability or liability assumed under a contract, this situation can leave doctors exposed to legal liability and patients potentially unable to obtain redress in the case of harm.
	Breach of surveillance devices legislation • The operation of AI scribes may be captured by the surveillance devices legislation because the tool "listens to" patient consultations. If a doctor fails to obtain patient consent to use the AI scribe, depending on the nature of the AI scribe and the location of the consultation, this may breach surveillance devices legislation.

Creating clear regulation and guidance for AI in healthcare

Avant's targeted recommendations aim to ensure the use of AI in healthcare can contribute positively to patient care while mitigating risks, enhancing trust and providing clear pathways for accountability and legal recourse.

Transparency and explainability of AI

For AI to be effective and widely accepted in healthcare, doctors and patients must understand when and why it is being used. Doctors must understand the operation of the AI tool sufficiently to use the AI tool safely and meet their professional obligations. Doctors also play a critical role in educating patients about the use of AI in their treatment regimes.

Despite this, there is a lack of comprehensive education around using AI in healthcare and its risks and benefits. The "black box" nature of many AI systems and their continuous evolution through machine learning makes it difficult for doctors to assess their suitability and reliability, both initially and over time.

This creates uncertainty and hesitancy, as patients may not fully trust AI-assisted decisions, and doctors may lack confidence in explaining these technologies to their patients.

Without sufficient information and transparency from developers about how AI systems operate and the data they rely on, doctors are left in a precarious position, unsure if the AI is fit for its intended purpose.

Recommendations

- **Plain language information:** AI developers should be required to provide users with plain language information about their products.
- **Clear labelling:** Both doctors and patients should be informed when AI is being used, with clear labelling of AI-based products to provide transparency.

Responsibility, liability and indemnity

Currently, there is significant legal uncertainty about accountability, responsibility and liability across the AI lifecycle in healthcare.

Regardless of what technology is used in providing healthcare, doctors remain responsible for delivering safe and quality care and for ensuring their own practice meets the professional obligations set out in the Medical Board's code of conduct.[1] This means that doctors must apply human oversight and judgement to the use of AI and any outputs. To exercise this oversight, doctors must understand the operation of the AI tool sufficiently to use it safely and meet their professional obligations. This is complicated by the "black box" and evolving nature of AI technology.

However, determining who is accountable when AI-driven decisions result in errors or adverse outcomes is challenging due to the complexity of AI algorithms and machine learning, which hinders the traceability of decision-making processes, increases medico-legal risks, and compromises effective risk management processes and the assignment of liability.

This lack of clarity creates significant challenges for doctors who must navigate the complexities of AI without clear guidelines on responsibility if something goes wrong. Without effective regulation and guidance, this could result in inadequate outcomes for patients if they are unable to obtain redress in the case of harm.

There is also a risk that responsibility for the design or function of AI could unfairly shift onto doctors. This is exacerbated by the presence of broad indemnity clauses in some AI provider contracts, which attempt to absolve these companies of responsibility and place the burden onto doctors. It is inappropriate for doctors to bear sole liability for any harm caused by AI-related decisions, particularly given they have no control over the risk.

This situation raises concerns about whether professional indemnity insurance will cover practitioner liability under such contracts, as product liability and liability assumed under a contract, is typically outside the scope of such coverage.

Without clear mechanisms to apportion liability and responsibility in the development, deployment and use of AI in clinical care, there is a risk that developers are incentivised not to take steps to mitigate risk. To address this moral hazard, developers should bear the responsibility for the foreseeable risks embedded within the technology and for failing to take steps to mitigate these risks.

The challenge of ensuring proper accountability is further amplified by the need for accessible and historical data on AI performance. Without maintenance and storage of data and operational information, it becomes extremely difficult to trace the source of errors that may have caused patient harm and determine liability at a later date.

Recommendations

- **Regulatory obligations:** Regulatory obligations for AI in healthcare should be placed on those entities with the ability to manage and mitigate the risk of harm to patients.
- **Developer accountability:** AI developers should be prohibited from transferring responsibility for harms resulting from the design or function of the AI to AI users (eg doctors) when developers have the capability to mitigate these risks directly.
- **Overseas developers:** Developers and/or deployers of AI based outside Australia should be required to have an Australian base or nexus to ensure they fulfil their accountability and reporting obligations.
- **Insurance:** Developers and deployers should be required to have insurance for future liabilities.
- **Data retention:** Developers should be required to keep historical data and operational information for minimum time periods.

Regulatory oversight

Some uses of AI in healthcare, such as AI software used in medical devices, must undergo review under the Therapeutic Goods Administration's regulatory regime for medical devices before being listed on the Australian Register of Therapeutic Goods. However, in contrast, other applications, such as AI scribes for clinical notetaking, are not currently subject to regulatory oversight.

Avant supports a risk-based approach to AI regulation and agrees that overall the use of AI in healthcare is high risk. AI is used in many applications, ranging from information gathering and triage to more complex functions like document summarisation, prediction, clinical decision support, diagnosis, treatment, prognosis and ongoing clinical management.

Avant's position is that the regulatory settings for AI used in healthcare should be proportionate to the level of the risk associated with the product and its intended use. Not all AI applications require the same level of oversight, and regulation needs to be aligned with the potential severity of harm that could arise from their use. This approach will require a rigorous assessment of AI products currently considered low risk.

We are particularly concerned about AI and AI-enabled products used in healthcare that are not regulated but still represent a risk for doctors and

patients. AI scribes are a key example. These tools are not currently subject to any standards, making it difficult for doctors to assess whether they are safe or fit for purpose.

The Ahpra and National Boards' guidance[1] for practitioners on using AI also does not address the assessment of the safety and quality of AI products.

Recommendations

- **Risk-based regulation:** The regulatory settings for AI and AI-enabled products used in healthcare should be proportionate to the risk associated with the product and its intended use.
- **Mandatory minimum standards:** There should be mandatory minimum standards for all AI tools used in healthcare, which means that any AI and AI-enabled products not regulated currently would become subject to regulatory oversight. This includes AI scribes, consumer health products, digital mental health tools and any AI tools that suggest clinical findings or make recommendations that could lead to adverse patient outcomes if inaccurate or not acted upon.

  Mandatory minimum regulatory standards should address:
  - privacy and security
  - transparency and explainability regarding how the tool works and how it has been trained
  - record keeping, access to meta data and access to historical information for relevant time periods
  - service agreements, including the appropriate use of disclaimers and indemnity clauses.
  - safeguards to reduce the risk of patient harm, including monitoring and error and adverse event reporting
  - insurance and indemnity cover.
- **Certification and assurance:** There should be an "approved" mark of assurance or certification issued by an appropriate regulatory body to provide reassurance for doctors and their patients that AI tools comply with Australian regulatory standards.
- **Oversight and education:** Standards development, accreditation, monitoring and education could be within the remit of the Australian Commission on Safety and Quality Health Care, the Australian Digital Health Authority or a newly created independent AI regulatory body.

References

[1]Ahpra and National Boards Meeting your professional obligations when using Artificial Intelligence in healthcare

Avant is a member-owned doctors' organisation and Australia's largest medical indemnity insurer, committed to supporting a sustainable health system that provides quality care to the Australian community.

Our purpose is to provide confidence to doctors so they can keep serving the community. Our products and services in the areas of insurance, finance, and legal and practice management are all designed to support doctors throughout their lives and careers. We reinvest any profits to benefit members and the Australian healthcare community.

Over half of all Australian doctors are Avant members. Members come from all medical specialities and career stages, and every state and territory. Overall, Avant's membership includes over 90,000 doctors and medical students with medical indemnity insurance and over 3,300 doctor-owned practices with practice indemnity protection.

Avant is committed to playing an important role in helping to design and implement health policy that benefits patients and helps doctors in better serving their community.

Contact

advocacy@avant.org.au

Chris Newlan

General Manager,
Public Affairs & Sustainability
christopher.newlan@avant.org.au

avant.org.au | 1800 128 268

Avant
By doctors for doctors