Australian
Private Hospitals
Association

Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review

SURVEY RESPONSE

October 2024

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Introduction

Purpose

This document is intended to provide responses to the ongoing consultation by the Department of Health and Aged Care on "Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review".

AI Consultation Survey Questions

Q1. How can AI benefit health care in Australia and how can we measure and deliver these benefits?

- AI has the potential to revolutionise healthcare in Australia by enhancing efficiency, accuracy, and patient outcomes.
- It can improve diagnostics by analysing medical images and data with high precision, aiding in early disease detection and timely interventions.
- AI also enables personalised treatment plans by processing vast amounts of patient data, ensuring effective therapies tailored to individual needs.
- Operational efficiency is boosted as AI streamlines administrative tasks, allowing healthcare providers to focus more on patient care.
- Predictive analytics help manage resources by forecasting patient admissions and disease outbreaks.

To measure these benefits, hospitals can track clinical outcomes like admission rates and faster recovery times, gauge patient satisfaction through surveys, monitor operational metrics such as reduced waiting times and cost savings, and implement continuous evaluation frameworks to ensure AI systems remain effective and safe. By leveraging AI, private hospitals can deliver more efficient, accurate, and personalized healthcare, ultimately improving patient outcomes and operational efficiency.

Q2. Can AI improve access to care, and what regulations could be amended or added to enable this?

AI can certainly support greater access to care such as through enhanced diagnostic capabilities, predictive analytics and efficient scheduling, among others. Regulations relating to the funding of private healthcare products should ensure that hospitals have adequate resourcing to implement regulations specific to AI. In addition, new privacy regulations should take the financial impacts of implementation by private healthcare providers into consideration.

Q3. What risk does AI pose to patients/consumers or health care professionals? Are the risks high or low? What criteria could be used to characterise risk? Should consumers be informed when AI is used in these low-risk ways?

AI poses certain risks to patients and healthcare professionals, but these can be managed with proper oversight. Risks include potential errors in diagnosis or treatment recommendations, data privacy concerns, and biases in AI algorithms. The severity of these risks can vary; they are generally low when AI is used for administrative tasks but higher when involved in direct patient care.

Criteria to characterise risk should include the complexity of the task, the potential impact on patient outcomes, and the level of human oversight involved. It is essential to inform consumers when AI is used, even in low-risk scenarios, to maintain transparency and trust. Clear communication ensures that patients are aware of how their care is being managed and can make informed decisions about their treatment.

Q4. What factors are important for rural and regional Australia when assessing the benefits, risks, and safety of AI? Are there other communities that face specific risks when implementing AI-driven health care? What considerations should be made to ensure all Australians have access to the benefits of AI?

It will be important to consider the current level of infrastructure, education and awareness on AI and AI in healthcare, patient attitudes towards AI use, health professional familiarity with AI use and the nature of procedures being performed, among others. Recognising that AI is a relatively new technology, the impacts on different communities, including marginalised groups, is difficult to predict. However, algorithms for AI must be cognisant of biases that may adversely impact patient health.

Q5. Should health care professionals have a choice about whether they use AI as part of their work?

Clinician choice is paramount and should be carefully considered with regards to the clinical application of AI. Therefore, clinicians should have autonomy in determining whether to place any reliance on AI in their work.

Q6. What unique considerations are specific to AI in health care, and why? Should the government address them through regulatory change?

AI in healthcare requires unique considerations due to the sensitivity of patient data, the need for high accuracy in diagnostics and treatment, and the potential for bias in AI algorithms. These factors can significantly impact patient outcomes and trust in the healthcare system. Therefore, it is crucial for the government to address these issues through both regulatory and non-regulatory changes. Implementing stringent data privacy laws, ensuring transparency in AI decision-making, and establishing standards for AI accuracy and fairness can help mitigate risks and enhance the safe use of AI in healthcare.

Q7. How does the use of AI differ in healthcare settings compared to general or other sectors such as finance, education, etc.?

The use of AI in healthcare settings can lead to direct impacts on patient health and wellbeing. For instance, an incorrect finding can result in inappropriate treatment leading to direct adverse outcomes. It is easier to remedy shortcomings in AI assistive technology in other sectors than in healthcare where the results can be life-altering.

Q8. Should there be an Australian body specifically dedicated to overseeing AI in health care? If so, how would this body differ from a broader organisation like the National AI Centre?

There are benefits to having an Australian body specifically dedicated to overseeing AI in healthcare. However, government should be careful to ensure that this does not create additional regulatory impediments for the private healthcare sector and effectively restrict patient access to necessary treatment. Unlike a broader organisation like the National AI Centre, which addresses AI across various sectors, a dedicated healthcare AI

- create and enforce regulations tailored to the complexities of healthcare, including patient safety, data privacy, and ethical considerations
- oversee the testing and validation of AI systems to ensure they meet high standards of accuracy and reliability before deployment in clinical settings
- monitor AI systems in use to ensure ongoing compliance with safety and ethical standards and offer specialized knowledge and support to healthcare providers and AI developers, facilitating the safe integration of AI into healthcare practices.

Q9. Are there any specific changes to existing healthcare laws that would address AI-related harms or help AI to be used safely?

Noting ongoing consideration of the *Privacy and Other Legislation Amendment Bill 2024*, there are benefits to be realised from privacy laws that incorporate AI use in high-risk settings. A further change should expressly emphasise the assistive nature of the use of AI technology in healthcare, especially for non-administrative functions.

Q10. Which international approaches should we consider, if any, that are specific to healthcare?

The European Union's landmark AI Act and the European Medical Devices Regulation (EU) 2017/745 (EU MDR) and In-vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (EU IVDR) in combination with the General Data Protection Regulation (EU) 2016/679 (GDPR) which contain requirements for artificial intelligence in healthcare to be safe and effective, should be considered. These requirements, that both define and enforce lawful use of AI, ensure medical devices based on artificial intelligence are safe and effective throughout their entire lifecycle.

Q11. Should humans be able to overrule a finding or decision made by AI?

AI should be used as an assistive technology to support traditional human decision making, not as a determinative tool that supplants professional judgement. AI systems, while powerful, lack the nuanced understanding of human context and the ability to make judgments based on complex, often unquantifiable factors.

Healthcare decisions often involve ethical considerations, patient preferences, and unique circumstances that AI might not fully grasp. Human professionals can integrate these elements into their decision-making process. Further, under the existing legal and legislative frameworks, healthcare providers are accountable for their decisions and actions. If an AI system makes a determinative decision that leads to an adverse outcome, it can be challenging to assign responsibility. Allowing humans to overrule AI ensures that there is a clear line of accountability, which is crucial for maintaining trust in the healthcare system.

Additionally, healthcare is a dynamic field with constantly evolving knowledge and practices. Human professionals can adapt to new information and changing circumstances more flexibly than AI systems. By allowing humans to overrule AI, we can help ensure that the latest medical knowledge and practices are applied appropriately.

Lastly, one of the cornerstones of the private hospital sector is the strong focus on patient centred care. Private hospitals are able to provide patients with access to tailored and high-quality care. Patients often have unique needs and preferences that should be considered in their care plans. Human healthcare providers can engage with patients, understand their concerns, and make decisions that align with their values and wishes, something AI cannot do on its own.

Q12. Should there always be a person or "human in the loop" to make decisions or deliver a health care service? Are there any circumstances in which it would be acceptable to have fully automated health or care decisions made by an AI product?

From the perspective of the private hospital sector, maintaining a "human in the loop" is crucial for ensuring high-quality patient care. Human oversight is essential for interpreting AI recommendations within the broader context of individual patient needs, ethical considerations, and complex medical scenarios. This approach helps build trust and accountability, as healthcare providers are ultimately responsible for patient outcomes.

However, there are specific circumstances where fully automated AI decisions might be acceptable. For instance, in routine, low-risk tasks such as scheduling appointments, managing inventory, or in specific cases, monitoring vital signs, AI can operate independently to improve efficiency and reduce administrative burden. Even in these cases, human oversight should be readily available to intervene

if necessary. The goal is to leverage AI to enhance, not replace, the expertise and compassion that human healthcare providers bring to patient care.

Q13. Should errors made by AI be reported? If yes, how should they be reported?

Errors made by AI should be reported to the relevant regulatory authority and to developers and proprietors of such technology. While there are benefits to automated error reporting, there is concern that this may lead to the transfer of sensitive information and commercial data to third parties. Instead, there is merit in considering pathways for hospitals to unilaterally and autonomously report errors to the necessary body and product developer.

Q14. Should there be transparency about when AI is involved in health care, and should consent be requested from the consumer or health care professional?

Yes, there should be transparency about when AI is involved in healthcare and in the spirit of the legislative framework for informed consent, consent should subsequently be requested from the consumer.

Q15. Generative AI may be developed for general use yet used in health care. Should generative AI developed have any special treatment, regulatory or otherwise?

From the perspective of the private hospital sector, generative AI used in healthcare should indeed receive special regulatory treatment. Given the sensitive nature of healthcare data and the potential impact on patient outcomes, it is crucial to ensure that these AI systems are safe, reliable, and ethical. Regulatory frameworks should mandate rigorous testing and validation of generative AI models to ensure they meet high standards of accuracy and safety.

Additionally, transparency in AI decision-making processes is essential. Hospitals and healthcare providers must understand how AI systems generate their outputs to trust and effectively use these tools. Privacy and data security regulations should also be strengthened to protect patient information from misuse.

Q16. What protections are needed for patient data used or generated by AI that are different for health care?

Patient data used or generated by AI requires robust protections tailored to the unique sensitivities of healthcare. First and foremost, strict data encryption is essential to safeguard patient information from unauthorised access and breaches. Additionally, comprehensive consent protocols must be in place, ensuring patients are fully informed about how their data will be used and have the option to opt out.

Regular audits and compliance checks are crucial to ensure AI systems adhere to privacy regulations and ethical standards. Implementing de-identification techniques can help protect patient identities while allowing data to be used for research and development. Furthermore, transparent data usage policies should be established, clearly outlining how patient data is handled, stored, and shared.

Finally, real-time monitoring and incident response plans are necessary to quickly address any data security issues, maintaining trust and integrity in the healthcare system.

Q17. Is it acceptable for developers of AI products to use patient data to develop their products or to sell patient data collected from use of AI?

The use of patient data by AI developers must be handled with the utmost care and ethical consideration. Using patient data to develop AI products can be acceptable if it is done transparently, with explicit patient consent, and in compliance with stringent privacy regulations. This ensures that patient confidentiality is maintained, and that data is used responsibly to improve healthcare outcomes.

However, commercialising patient data collected from AI use is unacceptable. Patient data is highly sensitive, and its commercialisation would lead to breaches of trust and potential misuse. The primary focus should be on safeguarding patient privacy and ensuring that data is used solely for enhancing patient care and advancing medical research. Strict regulatory frameworks should be in place to prevent the exploitation of patient data and to maintain the integrity of the healthcare system.

Q18. Should your healthcare information be kept in Australia? If yes, would your view change if this reduced ability to access advances in AI made overseas?

Sensitive private healthcare information should be kept in Australia, specifically if it is not de-identified. We believe that overseas developers and manufacturers of new AI and AI-enabled technology will be able to develop technologies that can be deployed in Australia without the need for Australian healthcare information being sent overseas.

Q19. Are there any specific safety considerations that have not been raised elsewhere?

Yes, there is the risk that AI systems can generate a large number of alerts which can overwhelm healthcare providers and lead to fatigue which can lead to important alerts being misses or ignored, undermining patient safety. Further, there needs to be clarity on the quality of data and biases that AI systems may harbour. The government needs to place an emphasis on funding models that can support and encourage the uptake of AI systems in the private hospital sector. Shortfalls in doing so can adversely impact patient safety by limiting the ability of the sector to integrate these technologies into healthcare offerings or adequately monitor and maintain them.

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