

Australian Alliance
for Artificial Intelligence in Healthcare

Response to Australian Government Department of Health and Aged Care

Consultation on Safe and Responsible AI in Health Care

October 2024

Table 1: Consultation questions and AAAiH Roadmap responses

Consultation questions	AAAiH Roadmap response
1. How can AI benefit health care in Australia and how can we measure and deliver these benefits?	**INDUSTRY** – Support development of the local healthcare AI industry to become globally competitive and deliver significant clinical and economic benefits to Australia. *Roadmap pages 16-17* **Key Recommendations:** 11. Develop national clinical AI procurement guidelines in partnership with the jurisdictions, health services and industry. 12. Provide **support and incentives for local industry** (and SMEs in particularly). a. Consider **expanding the R&D Tax incentives scheme to cover regulatory compliance** costs. b. Ensure the pathway to reimbursement for AI-based clinical services via Medical Services Advisory Committee (MSAC) is understood. c. Consider additional funding to support new products to come to market. 13. Develop mechanisms to provide industry with ethical and consent-based **access to clinical data** to support AI development and leverage existing national biomedical data repositories. 14. Support the development of a **National AI Capability Centre in Healthcare (NAICCH)** to assist industry (and SMEs in particular) to bring products to market. 15. Assist future policy by **identifying emerging AI markets and opportunities**.
2. Can AI improve access to care, and what regulations could be amended or added to enable this?	**AI SAFETY, QULAITY, ETHICS AND SECURITY** – Ensure patients receive safe, effective, and ethical care from AI healthcare services which have been developed in accordance with ethical principles, a safety framework and are appropriately monitored post-implementation *Roadmap pages 10-11* **Key Recommendations:** 1. To better coordinate and harmonise the responsibilities and activities of those entities responsible for oversight of AI safety, effectiveness, and ethical and security risks, establish a **National AI in Healthcare Council**.

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	2. To ensure AI in healthcare is safe, effective and therefore does not harm patients, it needs to be **developed and deployed within a robust risk-based safety framework**. 3. For accreditation, healthcare organisations using AI should demonstrate that they meet **minimum AI safety and quality practice standards**. 4. Urgently **communicate the need for caution in the clinical use of generative AI** when it is currently untested or unregulated for clinical settings, including the preparation of clinical documentation. 5. Ensure the **national AI ethical framework** from the Department of Industry, Science and Resources supports the deployment of value based clinical and consumer AI in routine practice.
3. 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? 4. 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?	**AI SAFETY, QULAITY, ETHICS AND SECURITY** – *Roadmap pages 10-11* **Key Recommendations:** 2. To ensure AI in healthcare is safe, effective and therefore does not harm patients, it needs to be **developed and deployed within a robust risk-based safety framework**. 3. For accreditation, healthcare organisations using AI should demonstrate that they meet **minimum AI safety and quality practice standards**. 5. Ensure the **national AI ethical framework** from the Department of Industry, Science and Resources supports the deployment of value based clinical and consumer AI in routine practice. **CONSUMERS -** Help all Australians, including vulnerable consumers, safely use AI to navigate the complex healthcare system and be active participants in the management of their own care and wellbeing. *Roadmap pages 14-15* **Key Recommendations:** 8. Co-design and collaboratively implement a **nationally accessible program for digital health literacy** to inform the public of AI's benefits, risks and safe use, and increase public trust and confidence in AI.

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	9. Work together with Aboriginal and Torres Strait Islander communities to develop a **mechanism that collates health-related data for use in AI in a culturally safe and trusted manner** within their control, in line with principles of Indigenous Data Sovereignty. 10. Ensure **professional codes of conduct and training emphasises the role of clinicians in educating patients** about the responsible use of AI, as part of a commitment to shared decision making.
4. Should health care professionals have a choice about whether they use AI as part of their work?	**WORKFORCE** - Understand knowledge gaps in the workforce and then train the current and future healthcare workforce in the use and implementation of AI-enabled healthcare services. *Roadmap pages 12-13* **Key Recommendations:** 5. Support the development of **a shared code of conduct for the safe, responsible and effective use of AI** by health professionals and organisations. 6. Assist professional bodies in accessing expertise and prior models to support the **development of profession-specific codes of practice for the responsible use of AI**.
6. What unique considerations are specific to AI in health care, and why? Should the government address them through regulatory change? 7. How does the use of AI differ in healthcare settings compared to general or other sectors such as finance, education, etc.?	**AI SAFETY, QULAITY, ETHICS AND SECURITY** *Roadmap pages 10-11* Effective healthcare AI governance requires a more unified and comprehensive approach. There are significant gaps and overlaps in remit which can only be identified through inter-agency collaboration, and targeted resourcing is needed to address emerging challenges. While clinical AI is subject to TGA software as a medical device (SaMD) safety regulation, non-medical generative AI like ChatGPT falls into a grey zone, where it is being used for clinical purposes but evades scrutiny because they are general purpose technologies not explicitly intended for healthcare. Uploading sensitive patient data into a non-medical AI like ChatGPT hosted on United States servers is also problematic from a privacy and consent perspective.

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	The current model for regulating AI was designed over 30 years ago in an environment where technology was single function and predictable. Today, governance needs to move from a 'certify once' model to one which ensures adaptive AI remains fit for purpose as it evolves. Localisation of AI models by health services will be a common strategy to deal with data biases, and governance is needed to ensure local AI services function as expected.
8. 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?	See answer to questions 2 and 7
9. Are there any specific changes to existing healthcare laws that would address AI-related harms or help AI to be used safely?	See answer to question 7 and comments on Generative AI safety and the regulatory classification of digital scribes, in the main submission. **AI SAFETY, QULAITY, ETHICS AND SECURITY** *Roadmap pages 10-11* 5. Ensure the **national AI ethical framework** from the Department of Industry, Science and Resources supports the deployment of value based clinical and consumer AI in routine practice The framework would integrate many pre-existing ethics frameworks across the jurisdictions, regulators and other bodies. Any national AI ethical framework would need to be complemented by proportionate regulation, standards to guide deployment and upskilling of the workforce to practise safely alongside AI. This is potentially a work package for the proposed National AI in Healthcare Council.
10. Which international approaches should we consider, if any, that are specific to health care?	**AI SAFETY, QUALITY, ETHICS AND SECURITY** - The current model for regulating AI was designed over 30 years ago in an environment where technology was single function and predictable. Today, governance needs to move from a 'certify once' model to one which ensures adaptive AI remains fit for purpose as it evolves. Localisation of AI models by health services will be a common strategy to deal with data biases, and governance is needed to ensure local AI services function as expected.

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	Roadmap pages 10-11 **Key Recommendation:** 5. Ensure the national AI ethical framework from the Department of Industry, Science and Resources supports the deployment of value-based clinical and consumer AI in routine practice. The framework would integrate many pre-existing ethics frameworks across the jurisdictions, regulators and other bodies. Any national AI ethical framework would need to be complemented by proportionate regulation, standards to guide deployment and upskilling of the workforce to practise safely alongside AI. This is potentially a work package for the proposed National AI in Healthcare Council. **RESEARCH** – Ensure the development and deployment of AI in healthcare is based on the most up to date evidence, and that Australia retains world-class sovereign capability to use AI and support industry in the national interest. *Roadmap pages 18-19* Since 2018 England has allocated over £144 million to healthcare AI research and development over multiple funding rounds, part of a much larger investment in embedding AI into the NHS. The EU has announced €220 million worth of investment in four sectoral Testing and Experimentation Facilities for AI, with one focused on health16, and in previous years has made substantial research investments in AI and digital health. **Key Recommendation:** 16. Provide **significant targeted support for healthcare AI research** that builds sovereign capability and can translate to improved priority health services and support for industry. Resourcing may come from existing sources such as the NHMRC/MRFF and could include core funding for national centres of research excellence in healthcare AI. Allocation of funding should be made by panels with expertise in healthcare AI, to ensure funding is allocated to the best science and the best teams.

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11. Should humans be able to overrule a finding or decision made by AI?	**WORKFORCE** - Understand knowledge gaps in the workforce and then train the current and future healthcare workforce in the use and implementation of AI-enabled healthcare services. *Roadmap pages 12-13* **Key Recommendations:** 6. Support the development of **a shared code of conduct for the safe, responsible and effective use of AI** by health professionals and organisations. Ahpra's Shared Code of Conduct sets out 12 National Boards' expectations of the practitioners they regulate and is a possible model. Other professional groups and organisations beyond Ahpra will have interactions with AI in clinical settings (e.g. aged care, social workers) and their organisations are subject to other codes of practice (e.g. the NSW Code of Conduct for Health Organisations). Further discussion is required to explore whether the use of AI is best incorporated into existing codes or be subject to a stand-alone code. 7. Assist professional bodies in accessing expertise and prior models to support the **development of profession-specific codes of practice for the responsible use of AI**. If as recommended, a NAICCH was created (see INDUSTRY), this could be a key role for it. Co-ordination would be required with existing organisations such as the AIDH or ADHA, in partnership with professional groups, who already have a mature approach to codes of practice.
12. 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?	No specific Roadmap recommendations. We note that there already are examples of autonomous or "out of loop" devices with AI or algorithmic components including insulin pumps, and ventilators in ICU.
13. Should errors made by AI be reported? If yes, how should they be reported?	**AI SAFETY, QULAITY, ETHICS AND SECURITY** – Effective healthcare AI governance will require a more unified and comprehensive approach. There

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	are significant gaps and overlaps in remit which can only be identified through inter-agency collaboration, and targeted resourcing is needed to address emerging challenges. While clinical AI is subject to TGA software as a medical device (SaMD) safety regulation, non-medical generative AI like ChatGPT falls into a grey zone, where it is being used for clinical purposes but evades scrutiny because they are general purpose technologies not explicitly intended for healthcare. *Roadmap pages 10-11* **Key Recommendations:** 2. To ensure AI in healthcare is safe, effective and therefore does not harm patients, it needs to be **developed and deployed within a robust risk-based safety framework**. a. Pre-market, vendors must **provide regulators with rigorous evidence that their algorithms perform well in real-world settings**. Given that AI algorithms do not always work well in settings different to the ones they are developed in, a model portability assessment would test for biases in algorithm performance and suitability for intended populations and health services, including culturally or geographically diverse populations. This would require transparency regarding the populations used for algorithm training and testing. b. Post-market, **improve the effectiveness of national post-market safety monitoring** so that cases of AI-related patient risk and harm are rapidly detected, reported and communicated. Linkage of state-based, primary care and consumer safety reporting systems to those of the TGA is needed, as is increased resourcing for the expected increase in report volumes and complexity.
14. Should there be transparency about when AI is involved in health care, and should consent be requested from the consumer or health care professional?	**AI SAFETY, QUALITY, ETHICS AND SECURITY** - Today, governance needs to move from a 'certify once' model to one which ensures adaptive AI remains fit for purpose as it evolves. Localisation of AI models by health services will be a common strategy to deal with data biases, and governance is needed to ensure local AI services function as expected.

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	Roadmap pages 10-11 **Key Recommendations:** 5. Ensure the **national AI ethical framework** from the Department of Industry, Science and Resources supports the deployment of value-based clinical and consumer AI in routine practice. The framework would integrate many pre-existing ethics frameworks across the jurisdictions, regulators and other bodies. Any national AI ethical framework would need to be complemented by proportionate regulation, standards to guide deployment and upskilling of the workforce to practise safely alongside AI. This is potentially a work package for the proposed National AI in Healthcare Council.
15. Generative AI may be developed for general use, yet used in health care. Should generative AI developed have any special treatment, regulatory or otherwise?	**AI SAFETY, QULAITY, ETHICS AND SECURITY** – *Roadmap pages 10-11* **Key Recommendations:** 4. Urgently **communicate the need for caution in the clinical use of generative AI** when it is currently untested or unregulated for clinical settings, including the preparation of clinical documentation.
16. What protections are needed for patient data used or generated by AI that are different for health care?	**INDUSTRY** - *Roadmap pages 16-17* **Key Recommendations:** 13. Develop mechanisms to provide industry with ethical and consent-based access to clinical data to support AI development and leverage existing national biomedical data repositories. To maximise national benefit these mechanisms should be based on consistent use of identifiers across the healthcare system and national interoperability standards (e.g. FHIR, SNOMED CT) and be aligned with minimum national datasets and software vendor conformance profiles. Data use for research purposes would likely have a governance framework, similar to the 'secondary use framework for My Health Record' stewarded by the Australian Institute of Health and Welfare.

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	CONSUMERS – *Roadmap pages 14-15* 9. Work together with Aboriginal and Torres Strait Islander communities to develop a mechanism that collates health-related data for use in AI in a culturally safe and trusted manner within their control, in line with principles of Indigenous Data Sovereignty.7,8 Developed and guided in consultation with Aboriginal and Torres Strait Islander peak bodies and representative organisations such as the National Aboriginal Community Controlled Health Organisation (NACCHO), the purposes for such a data collection include the provision of training data for AI systems in a manner that reflects Aboriginal and Torres Strait Islander communities' unique strengths and priorities.
17. 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?	See answer to 16.
18. 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?	See answers to 10 and 16.
19. Are there any specific safety considerations that have not been raised elsewhere?	See comments on Generative AI safety and the regulatory classification of digital scribes, in the main submission.