Australian Government
Australian Digital Health Agency

Submission on the Safe and Responsible AI in Australia discussion paper

26 July 2023
Approved for external use

1. Introduction

The Australian Digital Health Agency (the Agency) thanks the Department of Industry, Science and Resources for the opportunity to provide a submission on the *Safe and responsible AI in Australia* discussion paper.

The Agency supports the development and implementation of policies and governance that promote safe and responsible Artificial Intelligence (AI) in Australia.

AI has immense potential to revolutionise healthcare in Australia to improve patient-centred care and workforce productivity and contribute to the sustainability of quality healthcare.[1] Used safely, with sound clinical governance in place, AI-enabled health services can deliver significant benefits through advanced capability to:

- assess patterns in data and medical imaging to assist with diagnoses;
- manage patient flows in hospitals based on type of medical emergency, bed capacity and daily patient loads; and
- support clinical decision-making.[2]

The success of AI in healthcare will depend on national governance and leadership to maintain trust and ensure these systems are safe, reliable and understandable in how they work.[3]

The Agency recommends that any new governance arrangements around AI (general or sector-specific) should strike a balance between the need to ensure consumer safety and the need to maintain the security of sensitive information and community trust, with the health and economic benefits that AI innovation can provide.[4] As healthcare delivery occurs at different levels of government, a national approach to AI governance (particularly for the development and uptake of AI in the health sector) is desirable to ensure alignment in policy and legislative development, clinical safety, and public health delivery prioritisation.

Sector-specific governance of AI in healthcare is essential given the unique risks, challenges and opportunities posed by AI in healthcare. The Agency recommends employing a mix of regulatory and non-

[1] Bajwa J, Munir U, Nori A, Williams B. Artificial intelligence in healthcare: transforming the practice of medicine. Future Healthc J. 2021 Jul;8(2): e188-e194. DOI: 10.7861/fhj.2021-0095

[2] Choudhury A, Asan O. Role of Artificial Intelligence in Patient Safety Outcomes: Systematic Literature Review. JMIR Med Inform. 2020 Jul 24;8(7): e18599. DOI: 10.2196/18599

[3] Bach AT, Khan A, Hallock H, Beltrão G, Sousa S. A Systematic Literature Review of User Trust in AI-Enabled Systems: An HCI Perspective, Int. J. Hum.-Comput. Interact. 2022 DOI: 10.1080/10447318.2022.2138826

[4] Gilbert S, Anderson S, Daumer M, Li P, Melvin T, Williams R. Learning From Experience and Finding the Right Balance in the Governance of Artificial Intelligence and Digital Health Technologies. J Med Internet Res 2023;25: e43682. DOI: 10.2196/43682

regulatory frameworks to enable a holistic approach in managing the risk of adverse consequences of AI in healthcare, as well as to harness any benefits and promote innovation.

Non-regulation

The Agency supports establishing nationally agreed AI principles as well as nationally agreed ethical, clinical and technical standards for AI.[5] These non-regulatory frameworks could help unlock benefits of AI in healthcare delivery (as outlined above), harness opportunities for innovation and promote safer and more secure data sharing practices. It is important to develop these national principles and standards using a transparent, co-designed and consensus-based approach (and leveraging international standards where appropriate) to support community trust and confidence in AI.

In the digital health space, the Agency's Connecting Australian Healthcare – National Healthcare Interoperability Plan 2023-2028 outlines a national vision to share consumer health information in a safe, secure and seamless manner and identifies 44 actions across five priority areas relating to identity, standards, information sharing, innovation and measuring benefits. Priority area 2 references automated clinical decision support, a form of AI in its implementation. Exploration of how AI systems could support and enhance interoperability between clinical systems could be beneficial.

Regulation

The Agency supports having patient safety and data security regulation from the outset and measuring risk before deployment. This is important to manage risks of poor clinical outcomes for patients due to misapplication of AI or bias in training AI which can lead to patient harm and/or misdiagnosis. Regulation is required for certain high-risk AI technology applications in healthcare delivery. Consideration could be given to the European Union's proposed AI Act, which lists high-risk AI systems including those relating to healthcare i.e., the management and operation of critical infrastructure, software for managing public healthcare services and electronic health records. In addition, AI applications such as large language models (LLMs) which have a medical purpose may be subject to medical device regulations for software and require approval by the Therapeutic Goods Administration (TGA). The TGA's *Software as a Medical Device* outlines how the TGA regulates software based medical devices.

Public trust and transparency are the bedrock of AI technology adoption, and this can be achieved by having the consumer at the centre of decisions made about their healthcare and placing the control of data in their hands. Promoting transparency and consumer control over the collection, use and disclosure of their data would enable and empower consumers to be the decision makers in the AI ecosystem. The Agency has seen major growth in the connection and use of digital health systems like My Health Record which is in part attributed to the consumer-controlled nature of these systems.

2. About the Agency

The Agency's vision is a healthier future for Australians through connected healthcare. Funded by the Commonwealth and the States and Territories in recognition that digital health must be a national enterprise, the Agency plays a key role in connecting Australians to a modern healthcare system that ensures they can access the care they need, when and where they need it.

The Agency was established by the Public Governance, *Performance and Accountability (Establishing Digital Health Agency) Rule 2016* (the PGPA Rule) and performs the role of System Operator for the purposes of the *My Health Records Act 2012* (Cth). The Agency also has data and digital specific responsibilities under various other legislation, including the *Privacy Act 1988* (Cth) and the *Healthcare Identifiers Act 2010* (Cth).

[5] Joerin A, Rauws M, Fulmer R, et al. Ethical Artificial Intelligence for Digital Health Organizations. 2020. Cureus 12(3): e7202. DOI:10.7759/cureus.7202

The Agency is responsible for national digital health infrastructure including the My Health Record system. The Agency is also responsible for driving interoperability standards and delivery of digital health products and services including electronic prescribing and related medicine safety initiatives.

The Agency has responsibilities for the coordination and ongoing development of the National Digital Health Strategy (the strategy) under the PGPA Rule. The strategy guides the coordination of digital health at a national level, providing direction to inform and enable digital health technological innovation. It identifies opportunities for digital health to support planned national health system reforms and address emerging contemporary health system challenges.

The draft National Digital Health Strategy (2023-2028)[6] proposes Governments, researchers, healthcare providers and industry to actively prepare for modernising Australia's digital health infrastructure. Modernisation is required to support a contemporary, data-rich digital health ecosystem that sets the groundwork for personalised treatment and tailored care using medical science and technologies such as AI and sensor technologies. This data-rich environment will also enable improved analytics to inform self-care, clinical decision-making, public health policy and health research. National coordination and collaboration is essential to ensuring the digital health ecosystem can adapt to and embrace these developments as they occur.

The Agency's key interests in AI across the health sector align with the Agency's role and functions as follows:

2.1. Clinical governance

Clinical governance underpins the work of the Agency and is one of our key statutory functions. Clinical governance promotes clinical safety, quality, assurance, and continuous improvement in the delivery of healthcare, including through health technologies. Clinical governance puts the person at the centre of their care including everything that wraps around the delivery of their care.

As highlighted in the Agency's Clinical Governance Framework for Digital Health, health technology advancements and the associated increase in data is enabling the use of AI and its applications (machine learning) in delivering healthcare and care services. AI technology, with its ability to analyse very large amounts of data and generate insights, has the potential to revolutionise healthcare. Clinical governance can promote safe and responsible use of AI in healthcare by ensuring clinical safety and ethical practices, monitoring performance, and enabling collaboration.

First, clinical governance ensures AI systems are developed and implemented with a strong focus on clinical safety and quality of care. This includes validating the accuracy and reliability of AI algorithms, ensuring they adhere to established clinical guidelines and standards, and minimising the potential for errors or biases in the decision-making process. Clinical governance helps maintain the highest standards of person-centred health and care while leveraging the benefits of AI.

Second, clinical governance promotes ethical considerations in AI implementation. This involves ensuring patient privacy and data security, maintaining transparency in AI algorithms, and addressing issues related to algorithmic bias and fairness. Ethical guidelines and frameworks help guide the responsible development and deployment of AI technologies, ensuring they align with peoples' rights and societal values.

Third, clinical governance promotes ongoing monitoring and evaluation of AI systems. Continuous evaluation and improvement are crucial to identifying potential issues or limitations of AI algorithms, allowing for adjustments. By monitoring the performance and outcomes of AI systems, healthcare providers can make informed decisions and provide evidence-based care.

Finally, clinical governance promotes partnership between healthcare recipients (the person, consumer, citizen, or their carer), healthcare professionals, AI developers, and regulatory bodies. This multi-

[6] As of 26 July 2023, the 2023-28 National Digital Health Strategy is still in draft and not yet publicly available.

disciplinary approach ensures AI technologies are effectively integrated into clinical workflows, with clear communication and understanding among all stakeholders. Partnership facilitates the sharing of best practices, knowledge, and experiences, leading to the responsible and successful implementation of AI in healthcare. By aligning AI use to robust clinical governance principles, healthcare and technology organisations can work in concert to harness the potential of AI to improve healthcare outcomes and experiences while ensuring patient safety.

Establishing clinical governance principles and mechanisms upfront would allow health and technology service providers to deliver the right outcomes for patients at the outset, while keeping pace with AI development.

2.2. Digital technology innovation

The Agency is a strong contributor to digital health innovation – partnering with governments and industry to incubate and test new ideas that enable health information sharing and digital transformation across the health sector. Consistent with extending the reach of technology into new geographies and health settings, the Agency also engages across the globe to learn about other world-leading health innovations and to tell Australia's story in an international context. Harnessing the opportunities of AI in the sector can position our healthcare system to meet current and emerging challenges, including increasing levels of chronic disease, rising healthcare costs, global health threats and longstanding health inequity.

2.3. My Health Record

The Agency is the System Operator of My Health Record - Australia's national digital health record system that provides a summary of key patient health information. One of the Agency's priorities is the modernisation of the My Health Record system to support greater connectivity and drive near real-time information sharing across care settings. Developed responsibly, the application of AI in My Health Record could improve patient safety, user experience including identifying and better targeting treatment options and support the use of data for secondary research or public health purposes. This includes the use of AI technology to detect conflicting diagnosis, identify inconsistencies and trends in the provision of healthcare and repetition on tests or treatments, enhance security processes and minimise privacy breaches.

3. Specific responses to the consultation questions

The Agency has considered the consultation questions and the application of AI in healthcare from a digital health perspective. The Agency's responses to the questions can be found at Attachment A.

Should you have any queries or require any further information, please do not hesitate to contact Jess Carew, Branch Manager, Strategy and Policy, on jessica.carew@digitalhealth.gov.au or +61 2 6183 3663.

Attachment A: Specific responses to the consultation questions

Discussion questions		
Definitions	1. Do you agree with the definitions in this discussion paper? If not, what definitions do you prefer and why?	Yes. An alternative workable definition is "an engineered system with one or more of the capabilities normally attributed to human intelligence, such as capacities for learning, problem solving, pattern recognition, or creativity". The Agency recommends clearly distinguishing rules-based AI systems from their stochastic (i.e., machine learning-based) counterparts, because these different architectures have different strengths, weaknesses and risks in real world applications. It is recommended to also include a definition for Automated Decision Making (ADM) to avoid misinterpreting ADM as fully autonomous. From a legislation perspective, it is recommended to keep the definition as technologically neutral as possible and consider future use-cases for AI to help maintain relevance.
Potential gaps in approaches	2. What potential risks from AI are not covered by Australia's existing regulatory approaches? Do you have suggestions for possible regulatory action to mitigate these risks?	AI presents a risk to the maintenance of quality healthcare information, which is currently not covered by Australia's existing regulatory approaches. The maintenance of healthcare information is currently governed by professional standards and regulatory frameworks that promote accuracy, quality and handling of personal health information, such as the *My Health Records Act 2012*, *Healthcare Identifiers Act 2010* and *Privacy Act 1988*. None of this legislation currently contemplates risks from AI nor the benefits, and although the *My Health Records Act 2012* does allow for decision making using a computer program, there is no specific instruction on automated decision-making. The Government is considering reforms to each of these Acts so there are opportunities to include AI-specific regulation as necessary. Current mitigations would be limited to relying on healthcare professionals undergoing mandatory training and have them meet a set of professional standards. As AI usage becomes more prominent in healthcare delivery, it will be important to maintain the quality of healthcare information, for example by validating AI systems for accuracy and ensuring that healthcare professionals are adequately trained to interpret and utilise AI-generated insights. The use of AI to assist in the drafting and development of health information must be accompanied by critical quality checkpoints by health

		professionals before information is used or uploaded to a wider system. This could be achieved through professional standards or legislative amendments, and/or technical requirements could leverage those standards to the extent necessary to mitigate clinical safety risk. If legislative amendment is contemplated, consideration could be given to recommended reforms to the *Privacy Act 1988* (in the Review report published by the Attorney-General's Department) that relate to automated decision-making. Another potential risk from AI that is not covered by Australia's existing regulatory approaches relates to the use of AI in policy development and administration in the Australian Public Service. Clarity and disclosure around the use of AI data and algorithms, and the limitations of these methods, is crucial when AI outcomes are used to develop policy. The Agency welcomes the recently published Interim guidance for agencies on government use of generative AI platforms and recommends the development of more detailed guidance in the future, particularly in relation to policy development and administration. It may also be helpful to consider the recommendations from the Royal Commission into the Robodebt Scheme regarding automated decision-making when shaping legislation about AI.
	3. Are there any further non-regulatory initiatives the Australian Government could implement to support responsible AI practices in Australia? Please describe these and their benefits or impacts.	Consideration could be given to the following non-regulatory initiatives to support responsible AI practices in healthcare: • Establishing nationally agreed AI principles as well as nationally agreed ethical, clinical and technical standards for AI. • Developing national guidance to ensure transparent and consistent health outcomes for all patients where AI based technologies are deployed in clinical settings (see also response to Q4). • Regulatory sandboxes (as referenced on page 29 of the consultation paper and explored in a 2020 OECD paper *Trustworthy AI in Health*) can be useful to test the utility and scalability of AI while ring-fencing wider health systems from risks. The United Kingdom's Care Quality Commission and the Singaporean government are using regulatory sandboxes to test new (digital) health models. • Continuous research, monitoring and evaluation could help ensure benefits and risks of AI in healthcare are identified early, allowing prompt action to be taken if required.

		• Educating the public about AI and increasing digital literacy could help inform the public of AI benefits, risks and usage, and increase public trust and confidence in AI. Within the Australian Public Service (APS), the Government could consider performing an audit of current automated processes that use AI in order to promote transparency and ensure AI is being used safely and responsibly within the APS.
	4. Do you have suggestions on coordination of AI governance across government? Please outline the goals that any coordination mechanisms could achieve and how they could influence the development and uptake of AI in Australia.	The Agency recommends that any new governance arrangements around AI (general or sector-specific) should strike a balance between the need to ensure consumer safety and the need to maintain the security of sensitive information and community trust, with the health and economic benefits that AI innovation can provide. As healthcare delivery occurs at different levels of government, a national approach to AI governance (particularly for the development and uptake of AI in the health sector) is desirable to ensure alignment in policy and legislative development, clinical safety, and public health delivery prioritisation. There is an opportunity for the Commonwealth to co-design with jurisdictions a national AI ethical and governance framework, in consultation with industry experts and the public. The new national framework would refresh the existing Commonwealth AI Ethics Framework and could be expanded to cover more specific guidance for key sectors in the economy where AI is already having, and will have, a significant impact, including healthcare. Such framework could form the basis to support for future self-regulation or government legislation. Sector-specific governance of AI in healthcare is essential given the unique risks, challenges and opportunities posed by AI in healthcare. The Australian Alliance for Artificial Intelligence in Healthcare's Roadmap for Artificial Intelligence in Healthcare for Australia could help inform Australia's approach to managing the opportunities and risks that AI brings.
Responses suitable for Australia	5. Are there any governance measures being taken or considered by other countries (including any not discussed in this paper) that are relevant, adaptable and desirable for Australia?	A governance measure that is not discussed in the consultation paper that might help inform Australia's approach to AI is the United States' proposed Algorithmic Accountability Act 2022. This legislation aims to establish a regulatory framework for assessing and mitigating bias and discrimination in AI systems used by large entities. It contains principles that might help Australia address algorithmic bias and promote fairness in AI applications.

Target areas	6. Should different approaches apply to public and private sector use of AI technologies? If so, how should the approaches differ?	As healthcare delivery occurs at different levels of government and within the private sector, it is highly desirable to have a consistent approach to public and private sector use of AI technologies to ensure consistent health outcomes for all patients.
	7. How can the Australian Government further support responsible AI practices in its own agencies?	In addition to the recently published Interim guidance for agencies on government use of generative AI platforms, consideration could be given to the following activities: • Invest in training and education programs. For instance, further to priority 5 in the Australian Alliance for Artificial Intelligence in Healthcare's Roadmap for Artificial Intelligence in Healthcare for Australia, the training workforce for the use of AI should also include policy makers. • Establish an AI ethics review board or committee to oversee AI projects within government agencies. • Regularly assess and audit AI systems used by government agencies to identify and mitigate any bias, discrimination, or unintended consequences. • Collaborate with international organisations and governments to align responsible AI practices and standards and foster knowledge-sharing. • Establish mechanisms for reporting and addressing concerns or complaints related to AI systems used by government agencies. • Mandatory reporting of AI use and activities (where relevant) through each Commonwealth entity's corporate plan to enable monitoring, oversight, compliance, and insights into evolving AI technologies.
	8. In what circumstances are generic solutions to the risks of AI most valuable? And in what circumstances are technology-specific solutions better? Please provide some examples.	N/A.
	9. Given the importance of transparency across the AI	a. In a healthcare setting, information transparency is critical to delivering high-quality and safe care, and promoting trust among patients, particularly in the following areas:

	lifecycle, please share your thoughts on: a. where and when transparency will be most critical and valuable to mitigate potential AI risks and to improve public trust and confidence in AI? b. mandating transparency requirements across the private and public sectors, including how these requirements could be implemented.	○ Data collection and use: Disclosing how data is collected, stored, and used in AI systems to mitigate privacy risks, data biases, and unauthorised access. ○ System behaviour and limitations: Providing visibility into AI system operations, capabilities, and limitations to manage expectations, prevent overreliance, and avoid errors or unintended health consequences. b. Transparency requirements could be mandated through existing corporate reporting requirements and/or by requiring healthcare providers to obtain informed consent from patients regarding the use of AI technology in their medical diagnosis and treatment.
	10. Do you have suggestions for: a. Whether any high-risk AI applications or technologies should be banned completely? b. Criteria or requirements to identify	a. In a healthcare setting, it is not appropriate for AI to both predict and respond to a health situation without human intervention. Treatments recommended by AI may not consider the holistic needs of patients, such as their values or preferences. For example, an AI algorithm may recommend healthcare based on what will lengthen a patient's life expectancy, not taking into an account their preference for at home care or an ethical objection to certain treatments. Regulation is required for high-risk AI technology applications in healthcare delivery. Consideration could be given to the European Union's proposed AI Act, which lists high-risk AI systems including those relating to healthcare i.e., the management and operation of critical infrastructure, software for managing public healthcare services and electronic health records. b. In a healthcare setting, we recommend considering patient safety and privacy requirements when identifying whether any high-risk AI applications should be banned completely. AI regulation is an area where the precautionary principle should be applied where potential harm to individuals or society is present, and the likelihood of such harm to materialise even where there is a paucity of evidence.
	11. What initiatives or government action can	• Collaborate with interested parties e.g., industry, academia, not-for-profit sector to establish a registry of endorsed training/test data sets relevant to specific domains which is maintained to stay relevant

	increase public trust in AI deployment to encourage more people to use AI?	• Implement clear regulations and guidelines for responsible AI use • Develop, promote and mandate ethical frameworks and standards • Conduct public awareness campaigns and educational initiatives • Establish independent audits and certifications for AI systems • Encourage user participation and input in decision-making • Promote collaboration, transparency and information-sharing • Establish accountability and resource mechanisms • Foster multi-stakeholder partnerships, and • Highlight societal benefits of AI through use-case demonstrations. Additionally, the Government could increase public awareness through sharing videos, images, stories and use cases that are tailored to audiences. For instance, in healthcare this could involve educating patients and clinicians about the benefits of machine learning and how it is helping address some of the most prevalent diseases or prevent the next pandemic.
Implications and infrastructure	12. How would banning high-risk activities (like social scoring or facial recognition technology in certain circumstances) impact Australia's tech sector and our trade and exports with other countries?	N/A.
	13. What changes (if any) to Australian conformity infrastructure might be required to support assurance processes to mitigate against potential AI risks?	The Agency supports establishing nationally agreed AI principles as well as nationally agreed ethical, clinical and technical standards for AI. These non-regulatory frameworks could help unlock benefits of AI in healthcare delivery, harness opportunities for innovation and promote safer and more secure data sharing practices. It is important to develop these national principles and standards using a transparent, co-designed and consensus-based approach (and leveraging international standards where appropriate) to support community trust and confidence in AI. In the digital health space, the Agency's Connecting Australian Healthcare – National Healthcare Interoperability Plan 2023-2028 outlines a national vision to share consumer health information in a safe, secure and seamless

		manner and identifies 44 actions across five priority areas relating to identity, standards, information sharing, innovation and measuring benefits. Priority area 2 references automated clinical decision support, a form of AI in its implementation. Exploration of how AI systems could support and enhance interoperability between clinical systems could be beneficial.
Risk-based approaches	14. Do you support a risk-based approach for addressing potential AI risks? If not, is there a better approach?	Yes. To promote trust and encourage AI adoption, consideration could also be given to a rights-based approach that places the consumer at the centre and the control of consumer data in the hands of the consumer. Promoting transparency and consumer control over the collection, use and disclosure of their data would enable and empower consumers to be the decision makers in the AI ecosystem. The Agency has seen success in consumer uptake of digital health systems like the My Health Record in part owing to the consumer-controlled nature of the system.
	15. What do you see as the main benefits or limitations of a risk-based approach? How can any limitations be overcome?	A risk-based approach allows for the identification and mitigation of risks early on and prioritisation of resources and effort. An example of this is clinical risks which need to be identified, assessed and mitigated early. Modelling AI regulation on risk also helps to ensure that privacy is maintained to the standards set out in legislation. However, there are limitations to consider, such as subjective judgments and biases in risk assessments, limited data availability and quality which may not capture emerging or unknown risks as technology evolves. These limitations can be overcome through independent evaluation, stakeholder engagement, data sharing, and clear definitions across different use and applications.
	16. Is a risk-based approach better suited to some sectors, AI applications or organisations than others based on organisation size, AI maturity and resources?	A risk-based approach is ideal for high-risk sectors with regulatory requirements, such as healthcare and critical infrastructure. As healthcare delivery occurs at different levels of government and within the private sector, it is highly desirable to have a consistent approach to public and private sector use of AI technologies to ensure consistent health outcomes for all patients.
	17. What elements should be in a risk-based approach for addressing potential AI risks? Do you support the elements presented in Attachment C?	Yes, the Agency supports the elements presented in Attachment C. Other elements that could be considered are: • Transparency and accountability: Promoting transparency in AI systems, such as explaining system behaviour, decision-making processes, and potential limitations. Establishing accountability mechanisms for addressing any harm or concerns arising from AI deployments.

		• Stakeholder engagement: Involving relevant stakeholders including users, impacted communities, experts, and regulatory bodies, to gather diverse perspectives, ensure inclusivity, and enhance the effectiveness of risk management strategies. • Intended use of the systems to inform the risk assessment, the dataset and population characteristics, any shortfalls or biases identified in the dataset, learning techniques (supervised/unsupervised). For certain AI applications, consider the clinical markers used to train the AI. • Mandating the requirement for health service organisations to openly report AI and technical risks and impact assessments to Boards and other governing bodies. This could be performed through a mechanism like accreditation to national safety and quality healthcare standards.
	18. How can an AI risk-based approach be incorporated into existing assessment frameworks (like privacy) or risk management processes to streamline and reduce potential duplication?	This could be achieved by integrating AI-specific risks, controls, and references into risk management frameworks and privacy impact assessments, and fostering collaboration and training between relevant teams, such as privacy, risk, AI development, and cyber security.
	19. How might a risk-based approach apply to general purpose AI systems, such as large language models (LLMs) or multimodal foundation models (MFMs)?	A well-structured model may consider specific use-cases and assign them a higher-level of risk accordingly. For example, Privacy Impact Assessments typically identify higher risks in situations where there is a greater amount of personal information being utilised, thus providing a starting point for analysing such risks. The risk-based model could also consider how the LLM is being used. For instance, if the LLM is employed to generate clinical notes from a recorded medical encounter, then regulations should be based on the inherent risks involved in this particular use-case. To mitigate these risks, controls could be put in place such as a review of any information generated.
	20. Should a risk-based approach for responsible AI be a voluntary or self-regulation tool or be mandated through regulation? And should it apply to:	The Agency recommends employing a mix of regulatory and non-regulatory frameworks to enable a holistic approach in managing the risk of adverse consequences of AI in healthcare, as well as to harness any benefits and promote innovation. *Non-regulation*

	a. public or private organisations or both? b. developers or deployers or both?	The Agency supports establishing nationally agreed AI principles as well as nationally agreed ethical, clinical and technical standards for AI.[7] These non-regulatory frameworks could help unlock benefits of AI in healthcare delivery, harness opportunities for innovation and promote safer and more secure data sharing practices. It is important to develop these national principles and standards using a transparent, co-designed and consensus-based approach (and leveraging international standards where appropriate) to support community trust and confidence in AI. *Regulation* The Agency supports having patient safety and data security regulation from the outset and measuring risk before deployment. This is important to manage risks of poor clinical outcomes for patients due to misapplication of AI or bias in training AI which can lead to patient harm and/or misdiagnosis. Regulation is required for certain high-risk AI technology applications in healthcare delivery. Consideration could be given to the European Union's proposed AI Act, which lists high-risk AI systems including those relating to healthcare i.e., the management and operation of critical infrastructure, software for managing public healthcare services and electronic health records. AI applications such as large language models (LLMs) which have a medical purpose may be subject to medical device regulations for software and require approval by the Therapeutic Goods Association (TGA). The TGA's *Software as a Medical Device* outlines how the TGA regulates software based medical devices.

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