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Research Australia response to the "Introducing mandatory guardrails for AI in high-risk settings: proposals paper"

October 2023

Background

The Australian Government's interim response to the Safe and Responsible AI in Australia discussion paper has been released and are seeking views on:

- the proposed guardrails
- how they are proposing to define high-risk AI
- regulatory options for mandating the guardrails.

Research Australia

Research Australia is the peak body for the Australian health and medical research and innovation sector. Our membership is drawn from the whole pipeline of health and medical research and innovation, from universities and medical research institutes to charities and patient groups, and health care providers and companies commercialising new health technologies.

This submission has been informed by the previous work of Research Australia, including its response to the consultation by the Department of Industry, Science and Resources on Safe and Responsible AI in Australia in 2023.

Do the proposed principles adequately capture high-risk

Research Australia supports the proposed principles, and acknowledges the importance of health and safety having a stand-alone principle. We also believe they provide clarity and certainty on high-risk AI settings and high-risk AI models. The principles, however, could be strengthened through demonstrating how they interact with each other. For example, all principles are interlinked with health and safety. We also believe the proposed principles are flexible enough to capture new and emerging forms of high-risk AI, such as general-purpose AI (GPAI).

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In our previous submission, we recommended that the Government should support research into AI in key areas such as health, aged care, transport and education to better understand the evolving risks and opportunities of the current and potential uses of AI across these domains. We maintain this position. Monitoring and evaluating the principles across the key areas would enable the ongoing certainty that the principles adequately capture high-risk.

Do the proposed mandatory guardrails appropriately mitigate the risks of AI used in high-risk settings?

Research Australia supports the following proposed mandatory guardrails for high-risk AI. Organisations developing or deploying high-risk AI systems are required to:
1. Establish, implement and publish an accountability process including governance, internal capability and a strategy for regulatory compliance
2. Establish and implement a risk management process to identify and mitigate risks
3. Protect AI systems, and implement data governance measures to manage data quality and provenance
4. Test AI models and systems to evaluate model performance and monitor the system once deployed
5. Enable human control or intervention in an AI system to achieve meaningful human oversight
6. Inform end-users regarding AI-enabled decisions, interactions with AI and AI-generated content
7. Establish processes for people impacted by AI systems to challenge use or outcomes
8. Be transparent with other organisations across the AI supply chain about data, models and systems to help them effectively address risks
9. Keep and maintain records to allow third parties to assess compliance with guardrails
10. Undertake conformity assessments to demonstrate and certify compliance with the guardrails

We believe the approach takes a risk-based approach to addressing potential AI risks.

As noted in the consultation paper, the following have been identified as high risk use cases in other countries: biomentrics, access to essential public services and products (including healthcare), and products and services affecting individual and public health and safety. A risk-based assessment should guide the determination of where and when transparency in the use of AI will be most important across these specific cases. For example, there are greater risks to the use of AI to support a clinician in making a diagnosis than, for example in helping to compose a referral letter or complete a pathology request. A general disclosure that AI 'may be used by your clinician in the course of the consultation' is probably so vague as to be meaningless. However detailing all the possible ways in which AI may be used in the course of a consultation and treatment may risk overwhelming a consumer with information in a way that does not assist them to comprehend the use of AI and its attendant risks. Any description of the use of AI should make it clear where the AI is being used to support the clinician in making a decision and/or undertaking tasks, and where AI is entirely substituting for a clinician's intervention/action. (The latter goes beyond current expectations of the role of AI in healthcare.)

The application of transparency and disclosure also needs to be as consistent as possible, across healthcare services delivered by Commonwealth State and Territory governments, the private

sector and not for profit service providers. To the greatest extent possible we need a comprehensive and nationally consistent approach that provides a uniform level of transparency and disclosure across all healthcare settings.

In relation to medical devices, the TGA's overall approach to regulation is already risk based, and this is the appropriate approach for the TGA to apply to AI in therapeutic goods. AI has the potential to be integrated into an enormous range of activities in the future. In health care for example, AI could be used to:

- Substitute for decision making by a clinician (not currently envisaged)
- Support decision making by a clinician
- Assist with administrative tasks such as composing notes, referral letters, stock control etc.
- Support rostering of healthcare staff, scheduling of appointments,
- Monitor equipment performance and maintenance scheduling

A risk based approach supported by the suggested guardrails enables resources (regulation, disclosure) to be focused on the applications of AI which have the greatest potential consequences for the health outcomes for individuals and populations. The TGA provides a model for how this can be done, as it has already incorporated a risk-based approach into its assessment frameworks, including for AI.

Which legislative options do you feel will best address the use of AI in high-risk settings and which regulatory option(s) will best ensure that guardrails for high-risk AI can adapt and respond to step-changes in technology?

Research Australia supports a domain specific approach – adapting existing regulatory frameworks to include the proposed mandatory guardrails. Further to this, Research Australia proposes a two-tier approach to governance, with general principles applied across the whole of government to guide regulation, with detailed implementation provided by the regulator closest to the industry.

For health, the TGA would be best positioned to undertake this role. For example, the TGA has an existing regulatory framework for medical devices which incorporates AI.[1] There are potentially other areas of healthcare where AI could be applied (for example medical records held by hospitals) where consideration of the risks associated with healthcare have yet to be considered. Coordination across Government is valuable but so is having sector specific focus, as the risks, implications and opportunities with AI vary with the jurisdiction.

The use of AI elsewhere in Australia's healthcare system should be subject to a risk-based assessment to determine whether a voluntary or mandatory approach is most appropriate. While a single approach across private and public sector providers is desirable, Research Australia recognises that healthcare in Australia is delivered by a mix of Commonwealth, state and territory

1 https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-devices-reforms/medical-devices-reforms-medical-device-software-regulation

governments, for profit companies and not for profit entities. A single regulatory approach, while ideal, may not be possible, or the most effective approach.

Thank you for the opportunity to provide a submission.

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ABOUT RESEARCH AUSTRALIA

Established with the assistance of the Federal Government in 2002, Research Australia is the national alliance representing the entire health and medical research (HMR) pipeline, from the laboratory to the patient and the marketplace. Research Australia works to position Australian HMR as a significant driver of a healthy population and a healthy economy.

Our vision: Research Australia envisions a world where Australia unlocks the full potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation.

Our mission: To use our unique convening power to position health and medical research as a significant driver of a healthy population and contributor to a healthy economy.

Our role:

Engage

Australia in a conversation about the health benefits and economic value of its investment in health and medical research.

Connect

researchers, funders and consumers to increase investment in health and medical research from all sources.

Influence

government policies that support effective health and medical research and its routine translation into evidence-based practices and better health outcomes