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Research Australia response to the consultation by the Department of Industry, Science and Resources on Safe and Responsible AI in Australia

July 2023

Background

In June 2023 the Department of Industry, Science and Resources announced a consultation on steps Australia can take to mitigate the potential risks of AI, accompanied by a Discussion paper.

Research Australia's submission in response to the Discussion paper addresses some of the questions posed in the Discussion paper.

Definitions

1. Do you agree with the definitions in this discussion paper? If not, what definitions do you prefer and why?

Yes. Research Australia is the peak body for the Australian health and medical research and innovation sector. Our submission is focussed on AI in medical products (therapeutic goods), and the potential use of AI in health more broadly, for example to interrogate medical records.

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?

The TGA has an existing regulatory framework for medical devices which incorporates AI.[1] Research Australia is also aware the Department of Health and Aged Care is developing a Regulatory Impact Statement focused on GP Data and electronic Clinical Decision Support (eCDS).[2]

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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
2 https://consultations.health.gov.au/primary-health-network/gp-data-and-ecds-cris/

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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.

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.

In respect of healthcare, the applications for AI are evolving rapidly, and understanding even the near-term implications of AI for healthcare is difficult. The same is true of other critical areas, including education and transport.

Research Australia submits 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.

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.

Coordination across Government is valuable but so is having sector specific focus, as the risks, implications and opportunities with AI vary with the jurisdiction. **As a first step, Research Australia submits the Department of Health and Aged Care should undertake a risk assessment of the current and potential uses of AI across the entire Australian health and aged care systems.** (As noted above, it has already commenced a review in relation to eCDS general practice.)

We note the paper identifies the current role of the TGA in relation to AI through regulation of Software as a Medical Device (SaMD). **Research Australia submits the TGA is the most appropriate body to govern AI in therapeutic goods.**

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?

In the area of medical devices there is already strong international cooperation between regulators. This is important for clarity for healthcare providers and industry in an international market, by promoting a consistent international health software safety regulation framework. The TGA currently plays a leading role in this international cooperation, which has significant benefits for both industry and consumers.[3]

[3] https://www.tga.gov.au/resources/publication/publications/tga-international-engagement-strategy-2021-2025

Target areas

6. Should different approaches apply to public and private sector use of AI technologies? If so, how should the approaches differ?

7. How can the Australian Government further support responsible AI practices in its own agencies?

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.

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.

The Australian Government has developed the *8 Artificial Intelligence (AI) Ethics Principles* as a voluntary framework, and Research Australia submits that these should form the basis for the development and operation of any national regulatory framework for AI.[4]

> 'As an enabling technology, AI is increasingly combined with other components and emerging technologies to produce innovative new businesses, products and services. This often means that AI is regulated under multiple laws, increasing the likelihood of possible duplication or conflict between regulatory systems, and associated compliance burdens on AI developers and adopters.' (Discussion Paper, Page 13)

This characteristic of AI also means that AI is often best regulated not as a separate function but as part of the product.

For example, in the case of therapeutic goods, application of the AI Ethics Principles to AI in therapeutic goods should remain the responsibility of the TGA, using industry specific regulations, as part of its overall regulation of therapeutic goods.

9. Given the importance of transparency across the AI 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.

Healthcare is clearly an area where trust in the use of AI is critical and transparency is central to this trust.

A risk-based assessment should guide the determination of where and when transparency in the use of AI will be most important. 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. (See the case study in our response to

[4] https://www.industry.gov.au/publications/australias-artificial-intelligence-ethics-framework/australias-ai-ethics-principles

question 14 below on how AI is currently being used.) 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.

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 AI applications or technologies that should be banned, and in which contexts?

11. What initiatives or government action can increase public trust in AI deployment to encourage more people to use AI?

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?

13. What changes (if any) to Australian conformity infrastructure might be required to support assurance processes to mitigate against potential AI risks?

Risk-based approaches

14. Do you support a risk-based approach for addressing potential AI risks? If not, is there a better approach?

Research Australia supports a risk-based approach to addressing potential AI risks. This approach is already evident in health.

In relation to medical devices, the TGA's overall approach to regulation is risk based, and this is the appropriate approach for the TGA to apply to AI in therapeutic goods. The Department of Health and Aged Care has also adopted a risk-based approach to its review of eCDS by GPs.

Case Study: ConsultNote.ai
ConsultNote.ai uses AI to automatically generate referral and consultation letters, consultation notes, treatment advice and care plans.[5]

In an interview, one of the product's developers, Dr Umair Masood, noted that 'his technology complied with all relevant laws, did not store any personal information about patients and was exempt from TGA regulation because it was "intended only for the purpose of providing or supporting a recommendation to a health professional about prevention, diagnosis, curing or alleviating a disease, ailment....[and] not intended to replace the clinical judgement of a health care professional."'[6]

At least one aspect of this product, the treatment advice, would appear to fall within the scope of the Department of Health and Aged Care's consultation on eCDS. Other components, such as the generation of case notes and letters, may not.

The risk associated with AI generating a referral letter or case notes, which have to be reviewed and actioned by the GP, is potentially less than the risk associated with the AI generating treatment advice, where the GP is still required to make the decision but may have less clarity about the basis on which the software has generated the treatment advice.

15. What do you see as the main benefits or limitations of a risk-based approach? How can any limitations be overcome?

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 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.

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?

17. What elements should be in a risk-based approach for addressing potential AI risks? Do you support the elements presented in Attachment C?

[5] https://www.consultnote.ai/product/
[6] https://www.theage.com.au/national/victoria/eric-was-diagnosed-with-low-bone-density-ai-made-his-gp-wonder-if-there-was-more-to-it-20230720-p5dpsu.html

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?

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.

19. How might a risk-based approach apply to general purpose AI systems, such as large language models (LLMs) or multimodal foundation models (MFMs)?

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:

a. public or private organisations or both?

b. developers or deployers or both?

Regulation of AI in therapeutic goods should continue to be mandatory as a component of the overall regulation of medical devices in Australia.

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

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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