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# Automated Decision Making and AI Regulation

## AMA submission to the Prime Minister and Cabinet consultation on positioning Australia as the leader in digital economy regulation

**Submitted to:** https://www.pmc.gov.au/domestic-policy/digital-technology-taskforce/positioning-australia-leader-digital-economy-regulation-automated-decision-making-ai-regulation

### Introduction

The AMA welcomes the proactive approach taken by the Government on Artificial Intelligence (AI) and Automated Decision Making (ADM) in Australia. While it is important that Australia keeps pace with international developments, the AMA argues that application of AI and ADM in the healthcare/medical field is unique as it can have direct influence over human health and ultimately life. Application of AI and ADM therefore requires more meticulous consideration, perhaps outside of scope of this consultation.

E-health has been making enormous progress over the last couple of decades, resulting in increased application of AI and ADM in healthcare, from health screening and diagnosing to managing health conditions and remote monitoring of patients. While the AMA does not see a future where human interaction and human care will be replaced by AI and ADM in healthcare, AI has the potential to change how the simple tasks are conducted. Work processes will likely need to be adapted to fully utilise the opportunities created by AI, while at the same time establishing effective frameworks for managing risks.

The AMA believes that appropriate regulation of this growing area of medicine will be the key to striking the balance between their functionality and effectiveness. Any future regulation of this field will need to ensure that AI and ADM are utilised only where this will genuinely contribute to improving health outcomes of patients, and ensuring equity by applying adequate ethical principles and protections.

While the AMA understands that regulations considered by this consultation are broader than just health and medicine, the AMA is concerned that a one-size-fits-all approach to the legislation could have unintended consequences if applied to healthcare. It will be important to ensure that regulation does not impose additional burdens of compliance on the medical profession while at the same time promoting innovation and progress in this important field.

**AI and ADM in healthcare**

While AI and ADM have incredible potential in healthcare, as medical practitioners we must first do no harm.[1] For AI and ADM to be successfully regulated in healthcare, there will have to be a common set of agreed principles embedded in legislation that will establish a compliance baseline for all those involved. Those principles will have to be formulated around appropriate governance of AI and ADM that should ensure the following:

- safety and quality of care provided to patients,
- patient data privacy and protection,
- appropriate application of medical ethics,
- ensuring equity of access and equity of outcomes through elimination of bias,
- transparency in how algorithms used by AI and ADMs are developed and applied, and
- that final decision on treatment should always rest with the patient and the medical professional, while at the same time recognising the instances where responsibility will have to be shared between the AI (manufacturers), the medical professionals and service providers (hospitals or medical practices).

The AMA sees a **need for new regulation or guidance to minimise existing and emerging risks of adopting AI and ADM** in healthcare, in accordance with the above principles.

Therapeutics Goods Administration (TGA) currently regulates medical software including software as a medical device[2], but it does not regulate AI or ADM in healthcare.[3] While the TGA approach to regulation is supported, the AMA believes that further regulation or guidance on AI and ADM will be required. Notably, within the consultation on the Scope of regulated software-based products[4] TGA acknowledged the plan for development of Australian guidance as a separate initiative to considerations of carve-out of Software as Medical Advice.

This is important because healthcare can constitute a high-risk application for AI, potentially resulting in patient injury from system errors, increased risk to patient privacy, or through systemic bias embedded in algorithms.[5] Any future regulation or guidance must ensure that the rights of patients are protected, and improved health outcomes are achieved. One way of achieving this is ensuring that AI and ADM are a tool, a means to achieving a goal, but not a goal in itself. In Canada for example, there is a legislative requirement that "AI cannot be deployed without specific safeguards, such as 'human intervention points during the decision-making process', with the final decision made by a human.[6] While this is not to say that healthcare is an

[1] https://www.ama.com.au/articles/ama-digital-health-vision-statement-preamble
[2] https://www.tga.gov.au/regulation-software-based-medical-devices
[3] https://www.tga.gov.au/sites/default/files/consultation_submissions_analysis-scope_of_regulated_software_based_products.pdf
[4] https://www.tga.gov.au/sites/default/files/consultation_submissions_analysis-scope_of_regulated_software_based_products.pdf
[5] https://www.brookings.edu/research/risks-and-remedies-for-artificial-intelligence-in-health-care/
[6] https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=32592

**environment in which AI or ADM are not appropriate**, the AMA argues that in healthcare there must be safeguards put in place.

**While the AMA cannot identify any specific regulatory changes the Commonwealth could implement to promote increased adoption of AI and ADM**, there are actions and specific tasks currently under way that will likely need to be accelerated. Specifically, the effectiveness if AI and ADM in medicine will largely depend on the usability and the value of the data available, the so-called input data. Therefore, the AMA argues that the implementation of healthcare system interoperability that enables meaningful input and exchange of data will play a crucial role in the effective application of AI and ADM in healthcare. Australia has thus far taken some steps in the right direction, but it still has a long way to go to fully implementing health system interoperability.

Furthermore, the Australian health digital landscape is vast, with numerous providers/vendors of clinical software, including AI and ADM software. Any future regulation in this space will need to ensure standards compliance by software vendors. In addition, transparency by and accountability of the developers of health care AI systems along with those who mandate use of such systems must be ensured, for any adverse events resulting from malfunctions or inaccuracy in output.[7]

It will also be crucial to balance the prospective benefits and risks of private sector vendors and AI initiatives in health. Motives of private profit-oriented companies who develop AI and are increasingly expanding into healthcare may be at odds with the broader public interest. The Government has a crucial role to play in regulating this field and putting adequate protections around the patients and consumers, thus ensuring the trust in the system. If patients and clinicians do not trust AIs, their successful integration into clinical practice will ultimately fail.[8]

The AMA sees **significant risks to increased automation of decision making that can have adverse implications for vulnerable groups, particularly in healthcare.** There have been examples internationally of biases, including racial biases, implemented in AI algorithms that resulted in negative outcomes for patients.[9] Algorithms and AI are created by humans, and will, if not considered and regulated properly, result in imbedded biases and stereotypes.[10] Hence, the needs of minority and underrepresented groups in healthcare will have to be considered. Application of AI and ADM in healthcare will have to ensure inclusiveness and equity for all, irrespective of not just race, but also age, gender, socioeconomic status, physical ability or any other determinant.

Therefore, it is the AMA position that AI and ADM in healthcare should be co-designed, developed and tested in close consultation with patients and medical practitioners. This should be part of a standardised approach to applying AI and ADM in healthcare.

[7] https://www.wma.net/policies-post/wma-statement-on-augmented-intelligence-in-medical-care/
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7332220/
[9] https://www.science.org/doi/10.1126/science.aax2342
[10] https://www.oecd.org/health/trustworthy-artificial-intelligence-in-health.pdf

Furthermore, the AMA believes there should be a National Governance structure established monitoring the implementation of policy around AI and ADM. Any such governance structure should include medical practitioners, patients, health informaticians, lawyers, health care administrators and any other relevant stakeholders. The AMA would welcome participation in any such governance body.

The AMA would like to draw the Department's attention to the World Health Organisation's recently published guidance on Ethics and Governance of Artificial Intelligence for Health.[11] The extensive document provides substantive guidance on how inclusiveness and equity in healthcare can be achieved.

The AMA sees several **regulatory barriers to achieving the potential offered by AI and ADM**, and they are largely aligned with barriers to achieving health system interoperability.

Firstly, there are differing legislative requirements across jurisdictions in Australia. One example is a recent introduction of new legislation in Victoria to enable sharing of healthcare information between public hospitals.[12] Any legislative change will require strong engagement from jurisdictional stakeholders to identify potential issues and manage them accordingly.

The barriers to successful implementation of AI and ADM in healthcare are often the same ones that slow down or disable health system interoperability:

- inconsistent implementation of technical standards – resulting in an inability to integrate information; and
- divergent policies related to privacy and security that govern electronic health records across jurisdictions.

Finally, AI and ADM implementation in healthcare will require significant data collection and data sharing of sensitive healthcare information. Adequate application of relevant privacy regulation will therefore be crucial but must not be a barrier and a careful balance will need to be found. Without this, there is a serious risk of undermining the utility of information used by AI and ADM.

## Conclusion

For AI technologies to be adopted into and improve healthcare, it is important to have regulatory clarity, which can only be achieved by thorough examination of existing legislation with clear directions on how it should be reformed and improved. The AMA therefore welcomes this consultation as the first step in that direction, but sees the need for deeper consideration and consultation focusing specifically on healthcare, resulting in a system co-designed with patients and clinicians.

[11] https://www.who.int/publications/i/item/9789240029200

[12] Gorton, Tomlinson and Braitberg (2021) "Victorian information sharing legislation aids patient quality and safety",
MJA Insight+. 44 https://insightplus.mja.com.au/2021/44/victorian-information-sharing-legislation-aids-patient-quality-and-safety/

The AMA would like to see future regulatory reform in this space that ensures the development and implementation of relevant governance and ethical principles that protect the rights of patients/consumers, support the work of clinicians, and results in improved health outcomes for individual patients and society as a whole.

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