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SUBMISSION

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Safe and responsible AI in Australia

AMA submission to the Department of Industry, Science and Resources Discussion Paper

Online submission via https://consult.industry.gov.au/supporting-responsible-ai/submission

The AMA welcomes the discussion paper on safe and responsible Artificial Intelligence (AI) in Australia. As the peak professional body for doctors in Australia, this submission will focus on the regulation of AI in health and medicine only.

Regulating the application of AI in healthcare will require a tailored approach that allows for the adoption and integration of safe technologies while protecting patient and practitioner privacy and patient safety. The AMA is concerned that Australia is behind other comparable countries in AI policy.

In healthcare, the development and implementation of AI technologies must be undertaken with appropriate consultation, transparency, accountability and regular, ongoing review to determine its clinical and social impact and ensure it continues to benefit, and not harm, patients, health care professionals and the wider community.

Therefore, while we welcome this consultation, the AMA would like to see a separate discussion process focusing specifically on AI in healthcare that would bring together all relevant stakeholders.

Opportunities and challenges

The AMA sees significant opportunities in appropriate application of AI in healthcare. As the discussion paper rightly points out, examples of AI deployment in medicine already exist. However, a key challenge is that deployment and application remains largely unregulated and there is lack of transparency on the ethical principles of the developers and no real governance arrangements in place. There should also be an acknowledgement that it is a rapidly evolving field with varying degrees of understanding among clinicians, other health care professionals, administrators, consumers and the wider community.

The discussion paper recognises the problems that can be created by inaccuracies in AI models, including biases and erroneous outputs. Biases in AI applied in healthcare can result in worse patient outcomes. A good example is provided by a recent study of pulse oximeters that became household items during COVID-19 pandemic and an indispensable tool for emergency departments worldwide. Pulse oximeters help determine whether COVID-19 patients have developed hypoxemia or hypoxia and can help hospitals triage patients and provide oxygen as needed. However, recent studies found that these devices tend to overestimate oxygen levels in people with darker skin and that hypoxemia is three times more likely to go undetected in black patients, putting their lives at risk.[1] This is a direct result of exclusion of diverse groups of patients in the original clinical trials.

Therefore, the AMA argues that to avoid similar challenges with AI application in healthcare, adequate regulation and regulatory protections must be inclusive and representative. We contend that the application of AI in healthcare must be relevant to the target population. Having this requirement in place would also help Australia establish its sovereign capability in AI development and implementation.

AI requires regulation as does any other technology involved in the diagnosis and treatment of patients. Governments have a crucial role to play in regulating the use and application of AI in healthcare to ensure it is used appropriately. We call for the government regulation of AI in healthcare to place adequate protections around patients and consumers, as well as healthcare professionals, engendering trust in the system. Those protections must:

- support improved patient outcomes
- ensure that the final clinical decision is made by the clinician
- allow for informed consent by the patient for any treatment or diagnostic procedure undertaken
- ensure patient and practitioner data are protected.

Furthermore, the application of AI in healthcare must only occur with appropriate ethical oversight and must never lead to greater health inequalities for any population. This can be achieved by ensuring the development and application is accountable and transparent to patients, medical and healthcare professionals and the wider community.

The regulatory environment in Australia must ensure that AI tools developed by private profit-oriented companies do not undermine healthcare delivery nor trust in the system. If patients and clinicians do not trust AI, their successful integration into clinical practice will ultimately fail.

Responses suitable for Australia

The discussion paper states that its focus is to identify potential gaps in the existing domestic governance landscape and whether additional AI governance mechanisms are required to support the safe and responsible development and adoption of AI. The AMA argues that

[1] https://lifesciences.dlapiper.com/post/102icu6/esg-issues-clinical-trials-and-diversity-racial-bias-in-medical-technology#page=1

regulation of AI in healthcare is a gap that needs to be addressed and we welcome the acknowledgement in the discussion paper that AI regulatory landscape may necessitate context-specific responses. The AMA has been calling for a context-specific regulatory response for AI in healthcare in Australia.[2]

Australia's governance responses to date in the healthcare space have been inadequate, primarily because, as the discussion paper acknowledges, they have been largely voluntary. For example, the AI Ethics Framework 2019 is aimed at 'guiding businesses and government', with its 8 voluntary AI Ethics Principles. While the AMA supports those principles, we argue that self-regulation and voluntary application of these principles in healthcare is not the appropriate way forward. Furthermore, those principles do not include the important issue of patient/consumer consent. In the AI in healthcare space, the key principle of consent must be introduced to ensure that patients and practitioners consent to the episode of care and/or their personal data being used for machine learning purposes.

Furthermore, the AMA supports collaboration and co-ordination when undertaking or exploring multiple deployment options for AI tools. For example, currently majority of AI deployments in radiology are driven by vendors offering piecemeal type innovations. While we recognise and understand that this is driven by competition in AI industry which can be productive and conducive to innovation, we also contend that such fragmentation of technological advances is suboptimal in the overall scheme of AI development and adoption. We believe a coordinated approach to AI development and deployment is required that should be led by a national body or a national governance structure.

Risk based approaches

The AMA considers the application of AI in healthcare a high-risk application, potentially resulting in patient injury from system errors, increased risk to patient privacy, or through systemic bias embedded in algorithms.

Therefore, we argue that regulation in this field is needed to manage those risks. Such regulation must be built on strong evidence base, take advice from leading experts and be adequately supported by Government to deliver a quality regulatory framework. Government level regulation must be accompanied by specific governance arrangements tailored to individual services and programs.

The discussion paper outlines international examples of AI regulation and self-regulation. The AMA supports the approach the EU and Canada have taken in relation to AI. Firstly, the AMA has been calling for a broader national discussion around the privacy protections and ownership of data in the digital health systems, based on the General Data Protection Regulation (GDPR) models of EU and UK, with transparent limits on how, when and by whom patient data can be accessed, noting that it is the AMA position that patients are the owners

[2] https://www.ama.com.au/articles/automated-decision-making-and-ai-regulation-ama-submission-prime-minister-and-cabinet

of their health data.[3] We were pleased to see that the latest iteration of the Privacy Act Review was considering taking this direction.

Furthermore, the recently proposed EU regulatory approach that defines four levels of risk (for example, AI application in robot surgery is deemed high risk) would be a worthy consideration in the Australian context. The EU Artificial Intelligence Act also proposes establishing an AI Governance structure, a European Artificial Intelligence Board, that would oversee the implementation and regulation. It would also reflect various interest of the AI eco-system.[4]

The AMA would support something similar in the Australian context, establishing a National Governance structure advising on development of policy around AI in healthcare. This governance structure would have to include medical practitioners, patients, AI developers, health informaticians, lawyers, health care administrators, medical defence organisations and any other relevant stakeholders.

The AMA also supports Canada's approach[5] where 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 for Level IV impacts such as on health and wellbeing, where the impacts are irreversible and perpetual."[6]

Future regulation should ensure that clinical decisions that are influenced by AI are made with specified human intervention points during the decision-making process. The final decision must always be made by a human, and this decision must be a meaningful decision, not merely a tick box exercise. The regulation should make clear that the ultimate decision on patient care should always be made by a human, usually a medical practitioner.

Regulating the healthcare field in this way would establish responsibility and accountability for any errors in medical diagnosis and treatment. In the absence of regulation, compensation for patients who have been misdiagnosed or mistreated by application of AI technologies will be impossible to achieve.

As we argued in our previous submission to the AI and automated decision making (ADM) regulation consultation initiated by Prime Minister and Cabinet in 2022,[7] for AI 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 that should ensure the following:

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[3] https://www.ama.com.au/sites/default/files/2023-01/Data%20Governance%20Position%20Statement%20-%20FINAL.pdf

[4] https://eur-lex.europa.eu/resource.html?uri=cellar:e0649735-a372-11eb-9585-01aa75ed71a1.0001.02/DOC_1&format=PDF

[5] https://www.ama.com.au/sites/default/files/2022-06/AMA%20Submission%20to%20Automated%20Decision%20Making%20and%20AI%20Regulation_Final.pdf

[6] https://www.tbs-sct.canada.ca/pol/doc-eng.aspx?id=32592

[7] https://www.ama.com.au/sites/default/files/2022-06/AMA%20Submission%20to%20Automated%20Decision%20Making%20and%20AI%20Regulation_Final.pdf

- 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 ADM tools are developed and applied
- 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).

Conclusion

The AMA commends the Department of Industry, Science and Resources for initiating the important discussion on AI regulation in Australia. The AMA would like to see broad adoption of AI throughout the healthcare system and support for Australian initiatives and tools. This will require regulation that ensures appropriate implementation of ethical principles pertaining to AI in healthcare, including elimination of biases, maintaining privacy of patient and practitioner data and the establishment of national governance structure. There are international models available that we can base our structures on. Individual health services should also begin establishing their own governance arrangements. The AMA remains open to working with the department further on this important topic.

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