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AMA submission to the Select Committee on Adopting Artificial Intelligence (AI)

Select Committee on Adopting Artificial Intelligence (AI) PO Box 6100 Parliament House Canberra ACT 2600

The AMA is the peak body representing medical professionals in Australia. Doctors are on the forefront of Artificial Intelligence (AI) use in Australia. This submission will focus on the essential steps Australia must take to safely and effectively adopt AI in the healthcare landscape.

While sometimes overstated, AI has real potential to greatly improve the efficiency and quality of healthcare delivery. Simultaneously, it also creates new risks for patients and the medical profession if it is not adopted with care, oversight and deliberate guidance towards the needs of the public. This submission will address the terms of reference considered by the committee with the following key principles underpinning the AMA's position:

- The Government has a crucial role to play in regulating the use and application of AI in healthcare to ensure it is adopted in an appropriate manner.
- Al must never compromise medical practitioners' clinical independence and professional autonomy. The ultimate decision on patient care should always be made by a clinician to protect against algorithmic error and safeguard patient interests.
- The use of AI in healthcare must ensure that the privacy of patient health data is protected at all times.
- Al technologies must not be applied in a way that exacerbates disparities in healthcare, including but not limited to those related to race, gender or socioeconomic status.

The <u>AMA's Position Statement on Artificial Intelligence in Healthcare</u> provides further detail on these principles.

Risks and harms arising from the adoption of AI technologies, including bias, discrimination and error

Potential risks that may arise from a rushed or unregulated adoption of AI in healthcare are considerable. Risks include, but are not limited to, a potential over automation of decision making, poorly defined measures of accountability, transparency and liability, adverse outcomes for groups with diverse needs, and misuse of patient information.

Al tools function to analyse a vast collection of medical information and as such the quality of any algorithmic output must be assessed by a doctor for its relevance to the individual patient. It is the AMA's position that AI must never compromise medical practitioners' clinical independence decisions and professional autonomy. To avoid machine error or over-reliance on AI technology, decisions relating to patient care must always be made by a human, and this decision must be a clinically sound, meaningful decision, not merely a tick-box exercise. This assertion is core to the AMA's perspective on safe adoption of AI in healthcare to ensure that patient interests are always protected by a human doctor.

Despite the existence of strong consumer protection mechanisms in Australia, the novelty of AI poses a unique challenge to questions of liability in cases where harm to patients may arise as a result of treatment which incorporates AI technology. Regulation must clearly define responsibility and accountability for errors in diagnosis and treatment related to the use of AI products. In the absence of suitable regulatory measures, compensation for patients who have been misdiagnosed or mistreated will be impossible to achieve. While regulation should make clear that the ultimate decision on patient care should always be made by a medical practitioner, it should also require AI systems to substantiate the information which supports decision making at any point in time.

There is an opportunity for this committee to address Australia's poorly defined civil and criminal liability rules in relation to cases of damages caused by artificial intelligence systems. This a matter that the Attorney General's department should consider as part of the outcome of this committee hearing. Encouraging respect for human life and recognition of vicarious liability from AI developers would likely support engagement with the medical community in the development of healthcare AI tools.

Biases in healthcare applications of AI can result in worse patient outcomes. A good example of bias caused by insufficient data training of algorithmic technology is provided by the case of pulse oximeters during the COVID-19 pandemic¹. Pulse oximeters help determine whether COVID-19 patients have developed hypoxemia or hypoxia and can help hospitals triage patients and provide oxygen as needed. Study findings are 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^{2 3}. This is a direct result of exclusion of diverse groups of patients in the original clinical trials, highlighting the potential for AI to further marginalise specific communities, ethnicities or cultural groups if appropriate measures are not taken to guarantee a diversity of data utilised in the training of machine learning algorithms.

To avoid similar distortions of AI application in healthcare, adequate regulation and regulatory protections must be inclusive and representative. It is imperative that AI technologies are applied in a way that does not exacerbate disparities in healthcare, including but not limited to those related to race, gender or socioeconomic status.

¹ Tyacke et. al. (2023) ESG Issues; Clinical Trials and Diversity (Racial Bias in Medical Technology) <u>https://lifesciences.dlapiper.com/post/102icu6/esg-issues-clinical-trials-and-diversity-racial-bias-in-medical-technology#page=1</u>

² Fawzy A, Wu TD, Wang K, et al (2022) Racial and Ethnic Discrepancy in Pulse Oximetry and Delayed Identification of Treatment Eligibility Among Patients With COVID-19. JAMA Intern Med. 2022;182(7):730–738. doi:10.1001/jamainternmed.2022.1906

³ Sudat et. al. (2023) Racial Disparities in Pulse Oximeter Device Inaccuracy and Estimated Clinical Impact on COVID-19 Treatment Course. Am J Epidemiol. 2023 May 5;192(5):703-713. doi: 10.1093/aje/kwac164.

The use of AI in healthcare must protect the privacy of patient health information. It must continue to uphold the rights of patients to know what information is held about them, their right to access their medical records and their right to have control over its use and disclosure, with limited exceptions.

Training AI algorithms to identify patterns relies upon large repositories of patient data being available, therefore patient data is critical to the development of AI that can provide meaningful insights to improve human health. Governments must recognise the novel relationship between data, AI and machine learning, and the importance of protecting sensitive data in the AI landscape. It is essential that we implement stringent governance and security measures to protect sensitive patient data that is collected by AI systems. Clear and enforceable regulation underpinning a transparent and accessible legislative landscape is essential to engender the trust of clinicians and consumers who may allow their data to be utilised within AI systems. For more detail on the AMA's advice around data governance, see the AMA Position Statement on Data Governance and Patient Privacy in Healthcare (2022).

Emerging international approaches to mitigating AI risks

The AMA supports the approach the EU and Canada have taken in relation to data privacy. 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 Regulations (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 of their health data. We were pleased to see that the latest iteration of the Privacy Act Review was considering taking this direction.

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. The AMA would support something similar in the Australian context, establishing a National Governance structure advising on the 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 where there is a legislative requirement that "AI cannot be deployed without specific safeguards, such as 'decisions cannot be made without having specific 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'"⁴.

Given the prevalence and impact that Europe's AI-specific laws are likely to have on the global AI market, Australia may be positioned globally as a 'regulation taker' rather than a top-down regulation maker in many areas. While this means that Australia need not relitigate the extensive regulatory process taking place in the European Union, it is essential that Australia's legislative framework keeps pace with guidelines that are set by regulation-makers such as the EU, and existing legislation is updated to ensure that Australians are protected from potential risks of harm that may arise as we increasingly adopt AI technologies as part of our healthcare system.

⁴ Government of Canada, Directive on Automated Decision-Making (Accessed 5 May 2024) Available at; <u>https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=32592#appB</u> Appendix B, C

Opportunities to adopt AI in ways that benefit citizens, the environment and/or economic growth, for example in health and climate management

Al has the potential to greatly benefit patients and the medical community if harnessed in a safe and appropriate manner. Large language models and dictation tools have the potential to greatly reduce the administrative burden placed on medical professionals. Imaging and vision technologies have the potential to assist doctors in the diagnosis of illnesses. Predictive analytics have the potential to assist in diagnosis and treatment plans. Al technologies may even be able to reduce current inequities of healthcare outcomes experienced by diverse and disadvantaged patients.

Recently, the ambient listening and transcription software *Lyrebird* was integrated with the medical software *Best Practice*. The software is designed to automatically generate relevant medical documentation during a consultation, streamlining workflows and increasing administrative efficiencies. With doctors currently spending a large proportion of time on burdensome administrative tasks⁵, Al assistance in this area may result in highly impactful increases to efficiency.

Many tools similar to Lyrebird currently exist on the market, something which highlights both the potential for widespread efficiency increases to medical consultations, and simultaneously the challenge of ensuring that patient data is not misused or shared without consent in this period that many individual companies are competing for market space.

A 2024 CSRIO report highlights the success of Aaron Nicholson, a post-doctorate student from AEHRC, who developed a medical imaging analysis tool that won the 'ImageCLEFmedical' international competition⁶. The research, designed to contribute to the scientific community's understanding of medical imaging tools, adds to the current landscape of AI imaging technologies, an area with a growing prevalence in the fields of radiology and neuroscience. The success from this CSRIO project is a positive example of government's contribution towards our understanding of AI in healthcare, and should also present an opportunity for government to ensure it inserts the Australian public's interest in the ethics, safety and regulation of such technologies from the ground-up.

The application of AI in healthcare must occur in collaboration with clinicians, with appropriate guidance and guidelines in place. A positive example of this is the inclusion of a chapter on AI Standards in the Royal Australian and New Zealand College of Radiologists' (RANZCR) Standards of Practice for Clinical Radiology⁷.

Potential opportunities to foster a responsible AI industry in Australia

Technological progress in the AI space will be largely driven by free market, profit driven entities. While we should expect and incentivise all private corporations involved in development of AI to act in a responsible manner, reliance on self-regulation in this space poses an unacceptable risk to consumers and medical professionals. The AMA supports the eight voluntary AI principles established through the AI ethics framework 2019, however we argue that self-regulation and voluntary application of these principles in healthcare is not the appropriate way forward.

⁵ Royal Australian College of General Practitioners (2021) *How do Australian general practitioners spend their time?* <u>https://www1.racgp.org.au/getattachment/4f596068-36e8-438d-b4b4-fe0b90cd549b/MABEL-data-examining-workload.aspx</u>

⁶ CSRIO (2024) *AI Trends for Healthcare* (p11) <u>https://aehrc.csiro.au/wp-content/uploads/2024/03/AI-Trends-for-Healthcare.pdf</u>

⁷ Royal Australian and New Zealand College of Radiologists' (2020) Standards of Practice for Clinical Radiology, Chapter 9. <u>https://www.ranzcr.com/index.php?option=com_edocman&task=document.download&id=77</u>

The AMA believes that the Government has a crucial role to play in regulating the use and application of AI in healthcare to ensure it is used appropriately. A stringent regulatory environment must ensure that AI tools developed by private companies do not undermine healthcare delivery nor trust in the system in the pursuit of profit.

We anticipate that this committee will receive a number of submissions from private organisations outlining internal plans to develop technologies and products in a responsible manner, an approach that we would encourage – corporate commitment to ethical adoption of AI is essential to fostering a responsible industry. However, government must proactively define clear and enforceable guidelines in the AI space and not allow the AI industry to become one which is self-regulated.

The Therapeutic Goods Administration may have a role to play as a regulator as they currently regulate medical software. However, regulation must fit the dynamic nature of AI so that compliance does not prevent AI from entering the market. The current regulation of medical software by the TGA is not suitable for AI.

In order to safely foster a responsible AI industry in Australia, we call on 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
- Clearly establish responsibility and accountability for any errors in diagnosis and treatment.

10 May 2024

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