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Positioning Australia as a leader in digital economy regulation- Artificial Intelligence and Automated Decision making

Response to the Issues Paper

Introduction

Research Australia is pleased to have the opportunity to make this submission in response to the Issues Paper.

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 interest in AI and ADM lies in health and medical research and innovation with AI and ADM, and the application of AI and ADM in healthcare.

The scope for the use of AI and ADM is only limited by our imagination. Research Australia is of the view that AI and ADM in healthcare need to be subject to regulation which can cover potential future applications and adapt and develop as AI and ADM changes without requiring constant revisitation of the framework.

Healthcare and health products are necessarily subject to more regulation than most industries. Health practitioners in all disciplines are required to be registered and are subject to a range of different role-specific requirements, including ongoing training and educational requirements. Medical products (medical devices and medicines) are subject to stricter regulation and approval than most consumer or industrial products. Healthcare settings are also subject to regulation, with mandatory standards in place for safety, quality and clinical care.

Research Australia believes the existing regulators and responsible agencies are best placed to regulate the use of AI and ADM in healthcare and in health and medical research and innovation. **While a robust national safety framework with common principles is required to guide regulators and promote consistency, existing regulatory bodies should be appropriately resourced to ensure they have the capacity to effectively regulate and support the implementation of AI and ADM now and into the future within their own areas of responsibility.**

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The current reality and the opportunity

There is enormous scope for AI and ADM in healthcare across the full spectrum of care delivery; from products used by consumers to maintain or improve their health through to tools used by health professionals to intervene and save lives. In many cases, AI and ADM is integrated into medical devices, services and systems, as a component or feature of the product/service. This relatively new trend will continue to expand in the future.

The Opportunity

AI and ADM are increasingly embedded in medical devices and/or used in their development. AI and/or ADM applications currently in use or development in devices include:

- heart monitors embedded in smart watches,
- fall monitors for elderly people living alone,
- ECG devices used in conjunction with smart phones,
- Closed loop glucose monitoring pumps which automatically dispense insulin,
- AI enhanced imaging for diagnosis,
- Decision support tools for clinicians to support prescribing,

AI and ADM also have a role in other areas, for example in online mental health support, addressing mental illness and evaluating suicide risk.[1][2]

Emerging Issues

While there are opportunities there are also emerging issues with AI in healthcare settings.

AI systems built using machine learning do not necessarily generalise well beyond the data upon which they are trained, meaning they need to be adapted for different populations. For example, a tool developed by a major US software vendor for predicting the onset of sepsis was shown to perform much worse (accuracy = 63%) than reported by the vendor (76-83%) when tested in a new population group[3]. Therefore, AI might need to be tuned to local populations and then performance monitored as population changes over time. In another study undertaken across 24 US hospitals, the proportion of patients generating

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[1] https://www.barwonhealth.org.au/news/item/chime-new-barwon-health-deakin-university-centre-of-excellence-to-improve-mental-health

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7460360/

[3] Wong A, Otles E, Donnelly JP, Krumm A, McCullough J, DeTroyer-Cooley O, Pestrue J, Phillips M, Konye J, Penoza C, Ghous M, Singh K. External Validation of a Widely Implemented Proprietary Sepsis Prediction Model in Hospitalized Patients. JAMA Intern Med. 2021 Aug 1;181(8):1065-1070. doi: 10.1001/jamainternmed.2021.2626.

sepsis alerts per day more than doubled, even though the hospital census of sepsis cases declined by more than a third in the 3 weeks before and after the first COVID-19 case.[4]

While software embedded in medical devices is subject to regulation, standalone clinical software has not been subject to the same level of rigour. There are currently no standards for accrediting clinicians in the safe use of clinical software systems.

Automation also makes humans complacent. A major challenge here is automation bias, which is when humans over-rely on, or delegate full responsibility to, automation rather than continuing to be vigilant. Automation bias is common when using clinical decision aids.[5]

These are all issues that need to be considered and addressed in any approach to the regulation of AI and ADM.

Research

The use of AI and ADM in the Australian healthcare system is itself the subject of research. For example, the NHMRC has funded research which will *'examine how AI is changing healthcare, and the values of data scientists, health professionals and the public. Drawing on ethics, social sciences and the law, we will develop a new approach to guide future use of machine learning for diagnosis and screening.'*[6]

The NHMRC Centre of Research Excellence in Digital Health is actively investigating the role of AI in improving healthcare. '*Working with healthcare data, artificial intelligence (AI) tools and techniques and together with our partners, collaborators and front-line healthcare providers, the CRE in Digital Health addresses key issues to drive the development of a fully integrated and digitally enabled Australian healthcare system. With the support of the Australian Digital Health Agency and the Australasian Institute of Digital Health, we are tackling the challenges that impede the creation of safe, efficient and effective digital health services for clinicians and consumers.'*[7]

At the national level, the Australian Alliance for Artificial Intelligence in Healthcare (AAAiH) brings together almost 100 national and international member organisations and 270 individuals in academia, government, consumer, clinical and industry organisations to translate frontier artificial intelligence (AI) technologies into real-world health services. In 2021, the Alliance undertook an extensive community consultation and a national survey to develop the AI in Healthcare Roadmap for Australia.[8] The highest community priority identified was for healthcare AI to be safe for patients and developed and used ethically.

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[4] Wong A, Cao J, Lyons PG, Dutta S, Major VJ, Ötles E, Singh K. Quantification of Sepsis Model Alerts in 24 US Hospitals Before and During the COVID-19 Pandemic. JAMA Netw Open. 2021 Nov 1;4(11):e2135286. doi: 10.1001/jamanetworkopen.2021.35286.

[5] Lyell D, Magrabi F, Raban MZ, Pont LG, Baysari MT, Day RO, Coiera E. Automation bias in electronic prescribing. BMC Med Inform Decis Mak. 2017 Mar 16;17(1):28. doi: 10.1186/s12911-017-0425-5.

[6] https://www.uow.edu.au/the-arts-social-sciences-humanities/research/acheev/data-technology-health-futures/#tab-172103

[7] https://digitalhealth.edu.au/

[8] https://aihealthalliance.org/2021/12/01/a-roadmap-for-ai-in-healthcare-for-australia/

Existing regulators and responsible agencies

Research Australia contends that the existing regulators in the healthcare sector are best placed to monitor and regulate the use of AI and ADM in the delivery of healthcare and should be appropriately resourced and authorised to do so.

As just one example, the use of AI and ADM in health care and research raise new considerations with patient privacy and consent, interactions with different cultural and first nations groups, data security and use, and use across national borders. These need to be considered and addressed within the broader framework of consent that operates in health care and in research, and the existing bodies responsible for consent issues are best placed to do this.

Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) is responsible for regulating therapeutic goods, which include medicines, diagnostics, and medical devices. The TGA adopts a risk-based approach to the regulation of therapeutic goods. In the case of medicines, there are three categories with varying levels of regulatory oversight, broadly determined by the risk each category poses to the public:

- Prescription medicines
- Over the Counter medicines
- Complementary medicines.

A similar risk-based approach is taken to the regulation of medical devices, with some consumer health apps unregulated, while other products are subject to TGA approval.

The TGA has been working on approaches to regulating software as a medical device, including providing guidance for Clinical Decision Support Software in October 2021.[9] Thus, use of at least some AI and ADM for diagnosis, monitoring, prediction, prognosis, treatment etc, is already a matter for TGA approval. The Software as a Medical Device approach is being actively studied as the primary approach to healthcare AI regulation in US, UK and Europe.[10]

For example, AliveCor Kardia Mobile 6L ECG is a TGA approved AI enabled product used by both clinicians and consumers to detect atrial fibrillation. It works in conjunction with a smart phone.[11]

While the vast majority of contemporary clinical software and decision support tools are not considered as medical devices or excluded in law, emerging clinical decision support incorporating machine learning algorithms are clearly identified as medical devices subject to regulation. The TGA implemented reforms to the regulation of software-based medical

[9] https://www.tga.gov.au/sites/default/files/clinical-decision-support-software.pdf
[10] https://doi.org/10.1016/S2589-7500(20)30292-2
[11] https://www.alivetec.com/pages/kardiamobile-6l

devices in 2021[12] Any regulatory framework for AI and ADM must be able to evolve and adapt to new developments in technology and its application.

The Australian Commission on Safety and Quality in Health Care

The Australian Commission on Safety and Quality in Health Care (ACSQHC) is responsible for the safety and quality of health care and sets mandatory standards for health care delivery. This includes standards in areas where AI and/or ADM are used in the delivery of health care employed.

For example, the National Safety and Quality Digital Mental Health Standards were published in November 2020 and are applicable to Digital Mental Health Services.[13] Although AI is not explicitly addressed, these standards are foundational because they take a unique approach internationally; technology is not considered in isolation but in context of the health services supported. This facilitates a risk-based approach to governance, thus integrating clinical governance with technical governance.

The National Safety and Quality Digital Mental Health Standards would be the appropriate standards in which to incorporate any specific regulatory requirement relating to the use of AI and ADM in digital mental health services.

Guidelines for environmental health, health and research ethics, clinical practice and public health

The National Health and Medical Research Council (NHMRC) has the authority to issue guidelines for environmental health, health and research ethics, clinical practice and public health. It also has the authority to approve guidelines developed in these areas by third parties.

The NHMRC provides several resources to support the development of guidelines and is well placed to address the use of AI and ADM in the development of guidelines, as well as guidelines which incorporate AI and ADM in practice.

Individual skills and competencies- AHPRA and accrediting bodies

The Australian Health Practitioners Registration Authority (AHPRA) works with Accreditation Authorities and National Boards which set competencies required for accreditation as a health practitioner in different occupations (doctors, nurses and midwives, allied health).[14] It

[12] Clinical decision support software: scope and examples. Therapeutic Goods Administration, Department of Health, Australian Government. Version 1.1, October 2021. At https://www.tga.gov.au/resource/clinical-decision-support-software

[13] https://www.safetyandquality.gov.au/standards/national-safety-and-quality-digital-mental-health-standards#links-to-the-nsqdmh-standards

[14] https://www.ahpra.gov.au/Accreditation.aspx

also deals with concerns raised from the public about the conduct of individual health practitioners.

As AI and ADM become increasingly integrated in health practice, it is reasonable to expect that training and accreditation in the use of AI and ADM will become more important in specific roles within our health system. AHPRA, together with the Accreditation Authorities and National Bodies, is the appropriate body to implement accreditation in these areas. Such accreditation will ensure our health workforce is able to effectively, safely and ethically use AI and ADM enabled health technologies in the future; ensure AI and ADM enabled technologies are properly integrated into the clinical workflow; and protect the public from the unauthorised or inappropriate use of such technologies by individual practitioners.

Professional Organisations

The professional organisations in health care also play a critical role in regulating the practices of their members and training.

In Australia, the Royal Australian and New Zealand College of Radiologists (RANZCR) has been at the forefront, developing ethical principles for AI in Medicine and standards for practice.[15] [16]. They're currently revising their training requirements and have released a position statement on the regulation of AI in medicine.[17]

In March 2021, the Royal Australian College of General Practitioners issued a position statement on AI in General Practice.[18]

The colleges and the Council of Presidents of Medical Colleges must be included in the development of any regulatory framework, as should other professional bodies within healthcare.

Health and medical research and innovation with AI and ADM

As noted earlier, AI and ADM are an increasing area of focus in health and medical research and innovation. Publicly funded research in this area is subject to the Australian Code for the responsible Conduct of Research and the National Statement on Ethical Conduct in Human Research. Central to the latter is the role of the Human Research Ethics Committee (HREC) in approving research conducted with or about people, or their data or tissue. HRECs have broad responsibilities and scope and are well placed to address issues relating to the use of AI and ADM in research as well as research that is developing AI and ADM applications. Like many others in our community, HREC members may need some training in AI capacities and applications and their implications of data collection and use.

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[15] https://www.ranzcr.com/college/document-library/ethical-principles-for-ai-in-medicine
[16] https://www.ranzcr.com/search/standards-of-practice-for-artificial-intelligence
[17] https://www.ranzcr.com/fellows/clinical-radiology/professional-documents/ranzcr-position-statement-on-the-regulation-of-artificial-intelligence-in-medicine-consultation
[18] https://www.racgp.org.au/FSDEDEV/media/documents/RACGP/Position%20statements/Artificial-intelligence-in-primary-care.pdf

The NHMRC is best placed to ensure the National Statement on Ethical Conduct in Human Research appropriately considers the implications of AI and ADM for the conduct of research.

Conclusion

Safety and public confidence in AI and ADM are nowhere more important than they are in healthcare.

AI and ADM provide significant opportunities to improve the safety, quality and effectiveness of healthcare and to deliver better health outcomes. There is also the opportunity to support the development of AI and ADM enabled technologies by Australian companies, delivering economic growth and new jobs.

To make the most of these opportunities, AI and ADM in healthcare need to be regulated, but not in isolation. **We need a robust national safety framework with common principles that identifies the roles of multiple stakeholders. Research Australia submits that the existing regulatory bodies in healthcare are best placed to provide regulation and support the implementation of AI and ADM within a national framework, and it should figure more explicitly and prominently in their work programs.**

Research Australia further submits that these bodies need to be appropriately resourced and supported in this role to ensure they are able to collectively apply the robust safety framework required, without duplication of effort and regulatory overlap. This includes support in integrating nationally identified priorities/ requirements in their own areas, such as the Australian Government's AI Ethics Framework, and the OECD/G20 AI principles.

We would welcome the opportunity to discuss this submission further. The appropriate contact person is Greg Mullins, Head of Policy, greg.mullins@researchaustralia.org

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