Australian Government
Department of Health and Aged Care

Senate Select Committee on Adopting Artificial Intelligence (AI)

Submission from the Department of Health and Aged Care

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Introduction

The Department of Health and Aged Care (the department) welcomes the opportunity to make a submission to the Senate Select Committee on Adopting Artificial Intelligence (AI).

The Productivity Commission *Leveraging digital technology in healthcare* research report found that the healthcare sector has the most potential to benefit from AI adoption.[1] The safe adoption of AI has the possibility to solve urgent and emerging challenges in our health system and alleviate the pressure on our healthcare workforce. AI technology could address increased expectations for personalised health services, improved access to care, rising costs and the growing complexity of care for people with chronic conditions.

Australia's population is growing and ageing.[2] Estimated to reach 40.5 million in 2062-63, the number of Australians over 65 will more than double. Meanwhile the workforce participation rate is expected to shrink by more than 4%.[2] Applied safely, AI technology can ease the pressure on a healthcare workforce facing challenges to meet the significant demands ahead.

Health care is recognised as a high-risk use case for AI.[3] With the rapid development of AI systems that can now analyse complex algorithms and self-learn, new settings are required to ensure the safe adoption of AI. The right regulatory settings for AI-powered systems are critical. Risk-based frameworks minimise potential risks and maximise benefits.[4]

Foundational to the safe adoption of AI is the modernisation of our digital systems. The Government's $1.1 billion investment in digital health reforms is giving people living in Australia a world-leading health system through a strengthened Medicare. The *Digital Health Blueprint 2023-2033 and Action Plan*, the *National Digital Health Strategy 2023-2028* and the *National Healthcare Interoperability Plan 2023-2028* will deliver the foundations for data-sharing and digital systems that grows uptake and usability of AI.

The Australian healthcare sector is motivated and engaged to support the safe and responsible adoption of AI. The Australian Alliance for Artificial Intelligence in Health (AAAiH) delivered a proposed policy plan for AI in *A National Policy Roadmap for Artificial Intelligence in Healthcare*. AAAiH is a joint initiative of over 100 national and international partners and stakeholders in academia, government, consumer, clinical, industry organisations and peak bodies.

As part of the *Supporting Safe and Responsible AI Budget 2024 – 25 measure*, the department will review health and aged care legislative and regulatory frameworks impacted by AI[5]. Additionally, the department is contributing to the evidence base by funding health-related AI research.

The department's submission outlines key considerations for the safe adoption of AI in health care, which can improve care outcomes and experiences for everyone in Australia.

Opportunities to adopt AI in ways that benefit consumers

The rapid development of commercial AI solutions reveals opportunities for generative AI to solve urgent and emerging challenges in the Australian health system. AI is not new to health care; machine learning techniques (sometimes grouped within 'traditional AI') have been applied to health and care data sets since the early 1970s[6]. Today's and future clinical opportunities for AI to benefit the Australian health system are broad, spanning diagnosis to monitoring to drug discovery and research.

For consumers, AI might assist in navigating an increasingly complex health system, allow for real time language translation into a preferred language and use of health care outside of traditional business hours. Populations with the greatest potential to benefit from AI, include people in regional communities, shift workers and those who speak languages other than English who may have difficulty using services.[7]

AI has the potential to support the Government's commitment to Closing the Gap and improve the health of First Nations people. Some Aboriginal medical services clinics have implemented AI-assisted screening for diabetic retinopathy and Aboriginal Community Controlled Health Organisations (ACCHOs) are using digital technology to connect their patients with remote specialists while they remain at the ACCHO clinic. The lack of appropriate healthcare services disproportionately affects First Nations people, especially those living outside major cities[8].

Through engagement with the software industry, the Therapeutic Goods Administration (TGA) notes that a wide range of products native to AI or adding AI to existing products are already being developed and supplied in health care. These products are a mix of Australian and global origins and address a wide range of clinical specialities, ranging from smartphone applications to large analytical platforms.

While some parts of health care are undoubtedly high-risk settings for the use of AI, there are opportunities with medium to low risk[9]. Predicting pre-admission rates or hospital bed allocations would increase facility preparedness and efficiency. Appointment scheduling and patient registration, drafting referral letters and care plans, billing and human resource management could free up as much as 30% of clinicians' time to care for patients.[1] Further consideration as to how to define risks within the healthcare setting, and the appropriate mitigations, is critical to safe adoption and maximisation of benefits in health care.

Safe adoption of AI

The Australian Government has committed to taking immediate action to support the safe adoption of AI in the broader economy. Ethical, safety, trust, data, social, liability, and regulation clarity concerns must be addressed to integrate AI technologies within health care.[10]

Ethical

The development of AI, research using AI and the application of AI in health care raises ethical issues that should be core to meaningful discussion about the uptake of AI. Addressing these concerns requires efforts by industry, health providers and policymakers. The application of Australia's *8 AI Ethics Principles*[11] to regulatory and non-regulatory frameworks and guidelines must be targeted and rigorous to ensure safe, secure and reliable AI solutions to the challenges of the Australian healthcare environment. Any framework must be tested against Government commitments to the *Closing the Gap* agreement to ensure success of the shared *Health Plan Vision*[12].

Safety and trust

Patient safety and trust is of greatest importance in health care. Despite AI's benefits in health care, between 27% and 43 % of Australians approve of its use in health care, compared to the 60% who support AI development more broadly.[13] International studies have shown that consumers do not trust AI[14] in a healthcare setting because of the risks. The submission from the Australian Medical Association into the Safe and Responsible Use of AI consultation states "*If patients and clinicians do not trust AIs, their successful integration into clinical practice will ultimately fail*".[15]

The Australian Government's *interim response to the Safe and responsible AI in Australia consultation* commits to creating a regulatory environment that builds community trust. The Australian Government announced in Budget 2024-25 an investment of $1.5 million to clarify and strengthen AI regulation in the healthcare sector.

Additionally, future policy needs to address healthcare providers' concerns about AI.[10] Healthcare providers have limited to no training in evaluating AI software. There is a lack of randomised controlled trials (RCTs) and peer-reviewed cases on AI for clinicians to appraise, and in some cases RCTs are not appropriate for developing clinical evidence for AI technologies. Furthermore, the lack of transparency, explainability and understanding of an AI algorithm can complicate a clinical consultation and reduce trust in the system's outputs.[16] Research shows that healthcare providers won't use AI technology if they believe it is not sophisticated enough to handle complex conditions and if decisions cannot be reviewed.[10]

Data

Access to and use of high-quality, complete data is essential for AI performance, accuracy, and reliability.[17] In Australia, data regulations, including formal legislation and policies, are often seen as barriers to data sharing. The Australian Bureau of Statistics led Person-Level Integrated Data Asset (PLIDA) and the Australian Institute of Health and Welfare led National Health Data Hub (NHDH) are examples of available health data assets. These data assets enable insights into the Australian health landscape and social determinants of health and show collaborative efforts across jurisdictions to improve data accessibility and sharing. Academics and industry are the dominant users of health data for AI, however there may be opportunities for academics to boost utilisation of health data through the *Data Availability and Transparency Act 2022*.

The Australian Government's investment into digital health will improve data sharing. Under the *Digital Health Blueprint 2023-2033* the department is working with state and territories to implement the standards and information sharing actions in Australia's *National Healthcare Interoperability Plan*. This will enable an open national data exchange and data sharing capabilities for Australia's health system. The department is also investigating national health information sharing and consent legislation framework to support the sharing of health information across care settings and across jurisdictional borders.

Regulation clarity

Submissions to the *Australian Government's interim response to the Safe and responsible AI in Australia consultation* and policy statements by the Royal Australian College of General Practitioners (RACGP)[18], Medical Software Industry Association (MSIA)[19], Australian Medical Association (AMA)[15] among others call[3] for regulation clarity and to be part of the consultation on regulatory safeguards in Australia for the use of AI in health care.

The submissions emphasised the need for widespread adoption of AI in the healthcare system. They advocated for a risk-based approach to regulation[20] that ensures the ethical implementation of AI in healthcare eliminates bias, protects data privacy and supports national governance establishment.[21]

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Wider determinants

People living in Australia have different levels of access to AI-driven health care, because of the wider determinates of health. These include the social, environmental, structural, economic, cultural, biomedical, commercial and digital environments in which we live, work, play and age.[22] More than 25% of Australians miss out on social, educational and economic benefits of digital inclusion or online connectivity.[23]

As AI tools integrated into healthcare, they may increase the digital divide.[24] With wealthy Australians living up to 6.4 years longer than the bottom 20% of income earners,[25] and people in the poorest households at least four times more likely to be digitally excluded[26], considered efforts need to be made so the adoption of AI technology is not only available to those who can most afford it.

AI literacy

In Australia, 60% of people have low health literacy.[27] and most Australians describe having a low understanding of AI, including low awareness of how and when it is used.[28] Development of AI literacy by consumers is critical for health care purposes and everyday life. The non-technical course for consumers offered by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and the Institute of Applied Technology Digital (IATD) is a good example of a program aimed at improving AI literacy.[29]

In Australia, some medical specialist colleges are developing AI competencies and training programs for their members and opportunities to learn more about AI through health professional bodies is increasing. However, many in the healthcare sector historically have had limited access to relevant education or professional development as AI's use grows.[30]

The *National Digital Health Strategy* [31] highlights the importance of creating a digital-ready workforce. The *Australian Digital Health Capability Framework* outlines digital health capabilities for healthcare providers. Efforts to improve AI literacy should build on these existing frameworks and should include how AI can support healthcare providers to reduce human factors that lead to patient harm, including fatigue, burn-out and cognitive biases.[32]

Risks and harms arising from the adoption of AI technologies

The Australian Government's *Interim response to the Safe and Responsible AI consultation* identified main risk areas: technical, unpredictability, opacity, domain-specific, and unforeseen. It also acknowledged widespread public concern about rapid technological advancements in AI.

The application of AI in health care presents heightened ethical, legal, safety, security and regulatory risks. The risks for health care are heightened because of the direct effect on patient safety and the use of sensitive health data for algorithmic development.

Data, Privacy, Security and Sovereignty

Management of patient privacy and consent when collecting, sharing, storing, and using sensitive health data is a critical consideration. AI technologies that use sensitive health data to train and refine models, require explicit consent from a consumer in line with the *Privacy Act 1988*. If this data was to be breached, it creates serious privacy consequences with the potential to erode trust in AI.

The Australian Privacy Principles apply to organisations sharing Australian health information overseas, but more work is needed to protect the data and obtain informed consent. AI also introduces challenges for existing approaches to gain consent and may undermine the role of informed consent, especially about transparency in data usage and sharing.

One example is using general-purpose AI (GPAI) solutions in clinical settings, where clinical data might be entered into the system, stored and then used for future outputs. Commonly known solutions include ChatGPT and Google Gemini. Some Australian jurisdictions have banned the use of GPAI solutions in health care because of data privacy concerns.[33]

To realise the benefits of AI, comprehensive and secure infrastructure is required for ensuring inter-connected sovereign datasets are protected. These datasets are fundamental for developing AI solutions, such as health-specific foundation models, that are appropriate for an Australian population.

Transparency and Explainability

Data standardisation, stewardship and interoperability are important steps in optimising data quality for trusted AI outputs. Many AI algorithms are 'black box technologies'[40], which have internal mechanisms that are non-transparent[34] and difficult to interpret or explain.[41] This results in both low trust and understanding of AI-made recommendations. Additionally, transparency and responsible disclosure are necessary for both consumers and healthcare providers to know when an AI system is engaging with them. Achieving transparency in AI systems through responsible disclosure is essential to ensure that users understand what the system is doing and why. Understanding processes and input data helps consumers and healthcare providers to build confidence in the technology.

The requirements for transparency in health care are crucial since the decisions directly affect people's lives.[35]

Safety

The accuracy of an AI output is dependent on the quality of data input. In some cases, outputs can be entirely wrong, commonly referred to as hallucinations.[40] This may pose serious patient safety risks when AI software is used to give clinical decision-making support, for example differential diagnosis or disease screening tools. AI algorithm failure could lead to incorrectly categorising a patient resulting in unnecessary, delayed or ineffective treatment.[36] For this reason, incorporating a human in the loop (HITL) during the design and use of AI technologies is critical for health and care applications. It should be acknowledged that AI may also increase patient safety, as human factors that lead to safety risks, including fatigue and burnout, AI systems are not susceptible to.[37]

Bias and Fairness

AI algorithms can inherit biases if they are trained on or developed with limited or biased data sets.[38] Bias can also occur through the intrinsic design or configuration of the AI system itself. Errors or misleading results can arise where the data AI is trained on draws from a population that is different to the group it is then applied to.[1]

In healthcare settings, biased algorithms can lead to exacerbation of inequities[39], existing social inequalities[40], and disparities in patient care, especially in underrepresented populations. For example, a machine learning algorithm was found to be less accurate at the detection of melanoma in darker skinned individuals, as it had mainly trained on fair skinned patients.[10] AI may also predict greater likelihood of disease because of gender or race when those are not causal factors.[41]Therefore, as data diversity is a main enabler for better accuracy and more equitable performance, it is critical that if data limitations are in the AI solution, these gaps should be understood and made available to healthcare providers who are using AI for clinical purposes.[42] Humans are also susceptible to human cognitive biases, an evidence base is building which shows how AI can improve clinical decision making and accuracy in patient care.[32]

Reliance

While it has been shown that more experienced healthcare providers tend to trust their own knowledge and experience more than an AI system[43], there is a well-documented tendency for humans to over-rely on, and delegate responsibility to, decision support systems, rather than continuing to be vigilant, known as automation bias.[1] A healthcare provider receiving information from an automated clinical decision support system may attribute greater weight to the first result, biasing their clinical decision due to anchoring bias.

It is possible that time-poor healthcare providers may be more susceptible to these cognitive biases and accept guidance from automated systems without confirmatory evidence.[44] This creates risks for patient results where the AI makes an error, complicating accountability. This potential risk could be mitigated by fostering AI literacy development amongst healthcare providers.

Role of the Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) regulates software as medical devices (SaMD), including the use of AI and generative AI like large language models (LLMs-such as ChatGPT) when they are used for medical purposes. Guidance about the regulatory requirements for SaMD covers data management (privacy, collection, use), cybersecurity, algorithm and model description and validation, bias, integration with other data, devices or systems.

Regulatory requirements are technology-agnostic for software-based medical devices and apply regardless of whether the product incorporates components like AI, chatbots, cloud, smartphone applications or other technologies.

Classification rules address the potential risk of harm from information and ensure that products are subject to levels of scrutiny and manufacturing standards that are commensurate with the level of risk. These rules specifically consider potential harm caused by providing incorrect information to users of medical devices.

The rules consider medical devices intended for:

- diagnosing or screening for a disease or condition
- monitoring the state or progression of a disease or condition
- specifying or recommending a treatment or intervention
- providing therapy (through provision of information).

The TGA participates in AI international working groups for the International Medical Device Regulators Forum (IMDRF) and the US FDA Digital Health Thinktank, mainly concerned with AI, allowing the TGA to remain abreast of international activities.

Research

The Commonwealth's Medical Research Future Fund (MRFF) and National Health and Medical Research Council (NHMRC) grant programs offer funding opportunities for AI-related health projects. Continued financial investment underpins evidence-based development of AI in health care and supports the safe adoption of AI by healthcare providers and consumers in Australia.

NHMRC's funding opportunities give support for high quality research in any area, including AI-related research. NHMRC is building research capability and supporting the translation of research using AI. Between 2021 and 2023, NHMRC awarded at least 62 grants totalling over $72.7 million for health and medical research where the researcher has indicated that the research will either involve AI or be relevant to AI in their grant titles, keywords, disciplines or plain descriptions. In 2023, NHMRC released guidance to researchers on the use of AI in grant applications and peer review. NHMRC is also working with experts to consider future activities to support the responsible and effective use of AI by the research sector and maximise the benefits of AI for human health.

From its inception in 2015 to 16 May 2023, the Medical Research Future Fund (MRFF) has invested $111.2 million in 50 grants with a focus on research related to artificial intelligence and associated health research.

The MRFF provides funding for research related to artificial intelligence in health through two initiatives:

- The National Critical Research Infrastructure Initiative will provide $650 million over 10 years from 2022-23 for research infrastructure that will be used to conduct world-class health and medical research. Stream 2 of this Initiative is focused on digitisation of health care – developing and translating into practice digital therapeutics, artificial intelligence enabled health interventions and technologies (e.g. wearables), applications or other software for use in clinical practice. The Research Data Infrastructure initiative will provide $100 million over 10 years from 2022–23. It will fund the creation or extension of national research data infrastructure with a focus on data registries, biobanks and data linkage platforms, including the use of artificial intelligence, to support Australian medical research.

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Conclusion

The rapid development of AI has highlighted the significant opportunity to address challenges within the Australian healthcare system. However, preparing for AI's unintended consequences in the health sector is critical[45] and requires consideration of healthcare's unique ethical, legal, safety, and regulatory risks, and how these might be mitigated.

Leveraging existing risk-based approaches, integrating AI-specific risks for health care and aligning to the whole of economy approach led by the Department of Industry, Science and Resources (DISR) are necessary for the maximisation of the benefits of AI in healthcare within Australia.

For healthcare providers, AI may support the provision of quality healthcare by reducing the human factors that can impact patient safety, such as fatigue, burn-out and cognitive biases. AI should not replace healthcare providers in making clinical decisions but assist in information processing and supporting the delivery of health care.

The department will collaborate with stakeholders on how the healthcare legislation and regulatory framework need to be adjusted to support the safe adoption of AI in healthcare. This important next step will ensure that the development and deployment of AI systems in the Australia health system are safe and reliable for future generations. Making our health system more efficient, personalised, and accessible.

Glossary

Artificial Intelligence (AI) system - a machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. Different AI systems vary in their levels of autonomy and adaptiveness after deployment.[46]

Automation Bias - the tendency over-rely on computer output 'as a heuristic replacement of vigilant information seeking and processing.' [47]

Anchoring Bias – a cognitive heuristic whereby people are influenced by specific, often initial, piece of information before a judgement. For example, a clinician receiving information from an automated clinical decision support system and "anchoring" to the first result, biasing their clinical decision. [48]

Explainability - AI models using large amounts of data are often too complex for human understanding of all the patterns and nonlinear relationships it contains. Human users should be able to understand what these AI models 'know' or 'learn' and how they will behave in all contexts to trust the results and output. [46]

General purpose AI (GPAI) - (or general AI) a type of AI system that addresses a broad range of tasks and uses, both intended and unintended by developers.[46]

Generative AI - a branch of AI that develops generative models with the capability of learning to generate content such as images, text, and other media with similar properties as their training data. [46]

Human in the loop – There may be circumstances when having humans in the loop or involved in reviewing or monitoring an AI systems' operations are important for minimising potential risks and supporting public trust and confidence. [49]

Interoperability – The ability of a system or product to transfer meaning of information within and between systems or products without special effort on the part of the user. Interoperability is made possible by the implementation of standards.[50]

Opacity – Decisions made by AI systems are not always traceable and humans cannot always obtain insights into the inner workings of algorithms (i.e. the 'black box'). [46]

Sovereignty – The capability of jurisdictions to build, operate and manage AI technology drawing upon data, skills, knowledge, models and computational resources within the jurisdiction.[51]

Transparency – Users should understand when they are being significantly impacted by AI and when an AI system is engaging with them.[52]

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