

A blue-tinted photograph of a modern building's facade, showing a grid of windows and structural elements.

# **Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review**

Productivity Commission submission

**The Productivity Commission acknowledges the Traditional Owners of Country throughout Australia and their continuing connection to land, waters and community. We pay our respects to their Cultures, Country and Elders past and present.**

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Publication enquiries:  
Phone 03 9653 2244 | email [publications@pc.gov.au](mailto:publications@pc.gov.au)

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## Introduction

The Productivity Commission (PC) welcomes the opportunity to make a submission to the Department of Health and Aged Care consultation, *Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review*.

This submission provides information on the opportunities for AI in healthcare, drawing from the PC's recent research.<sup>1</sup>

- **AI has significant productive potential:** The PC is of the view that AI will have a substantial impact on productivity and could help to overcome some of Australia's longstanding productivity challenges, including in healthcare.
- **Regulation already covers most risks, and any new regulation should be technology-agnostic:** The PC has outlined a framework for regulating AI, which focusses on using existing regulation and regulators to manage risks from AI applications wherever possible.
- **There are real challenges to getting data access right:** There is a clear role for government in lifting data sharing to socially optimal levels. The PC has made recommendations to improve data sharing, including developing a national strategy for data to facilitate sharing within the public sector, and challenging data excludability in the private sector. As we enter this new phase of policy and regulation, there is an opportunity to embed the principles of Indigenous data sovereignty from the outset.

## AI has significant productive potential

The contribution AI could make to the Australian economy is likely to be sizeable. Healthcare has been identified as the sector with the most potential to benefit from AI in Australia (PWC 2017). There are two main areas where the development or application of AI can generate improvements in productivity for the healthcare sector:

- **Freeing up the workforce:** Automating administrative tasks and processing information for clinicians can bolster workforce capacity and enhance the precision and quality of diagnosis and treatment.
  - Automation of administrative tasks saves workforce time.
    - » One international study estimated that around 35% of time spent in the health sector could be automated, but that the percentage varied by occupation (Spatharou et al. 2020, figure 5.2). The OECD has estimated that the time saving for Australian health professionals could be 29% (OECD 2021). If the effect of both automation and augmentation of tasks is estimated, this impact rises to over 65% for workers in administrative roles (Faethm 2022).
    - » There are specific examples of AI currently being used to generate productivity benefits through routine record keeping and clinical coding, ambient listening (listening to consultations and preparing draft clinical notes), medication alerts and treatment adherence, and management of hospital bed capacity.
  - Supporting clinical decision making allows clinicians for focus on higher value tasks, speeds decision-making and improves performance.

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<sup>1</sup> The PC released a series of three papers relating to AI in January 2024 (2024c, 2024b, 2024d). The PC has also examined AI specifically in the healthcare sector in a May 2024 research paper (2024a, chap. 5). The PC made a submission to the Senate Select Committee on Adopting Artificial Intelligence in May 2024 (2024e).

- » Using AI to analyse and interpret images, electronic and paper records, and academic literature across multiple languages – scanning millions of pages in seconds – can save time for clinicians, speeding up decision-making and reducing errors (Reddy et al. 2019).
  - » One Australian study found that a psychiatric registrar spends more than double the amount of time handling patient records and administration than they do in consultation, and so using AI to prepare for consultations and update patient records could free up clinicians to have ‘3 extra contacts per clinician per day’ (CareMappr pers. comm., 22 April 2024; Patrickson et al. 2022).
  - » Applying AI to complete the clinical audit process reduced the mean time to deliver a report from 10.2 days for humans to 5.8 seconds for AI (Brzezicki et al. 2020).
  - » AI has been used in medical imaging for decades. In one Australian-based study, use of a comprehensive deep learning model reduced radiologists’ average interpretation time by around 11%, while improving their detection performance (Buchlak et al. 2024).
- **Predicting care needs:** Using data to anticipate care outcomes can guide cost-effective choices for individual patients, service providers and the healthcare system more broadly.
    - AI applications can be used to ensure patients do not spend more time in hospital than is needed, thereby reducing costs and benefitting consumers. One international study found that using AI to streamline discharge planning can reduce the average length of stay by around 17% (Khalifa 2017). This application could be a significant cost saver given 286,050 public hospital patient days in 2020-21 were for patients waiting for aged care support (AMA 2023, pp. 3–4). AI tools are also being applied in Australia’s virtual hospitals to identify patients suitable for discharge with virtual care and to create alerts to assist in remotely monitoring changes in a patients’ condition.
    - AI can support a patient outside of a hospital setting (such as the home or primary health care) to avoid hospitalisation, which provides benefits for the patient and cost savings for the healthcare system. AI can be used to identify patients at risk of re-admission and proactively manage those risks. The South Australian government developed software to detect patients who are not adhering to medication or disengaging from treatment (CareMappr, pers. comm., 22 April 2024; PC 2024a).
    - AI can also be applied to enable older Australians to live at home longer and reduce the need for care in more costly settings (such as aged care or hospital). AI is being applied through the use of sensors to monitor for declining functional independence and to prevent falls, which are a leading cause of hospitalised injuries and injury deaths among older Australians (AIHW 2023d; O’Connor et al. 2022).

## Regulation should draw on existing frameworks

The PC has cautioned against alarmist approaches to regulating AI, which threaten to stifle uptake and squander potential benefits. While there are clearly risks from AI adoption in healthcare, government should take a considered approach to regulation that also keeps the benefits of AI in view.

The PC has proposed a stepped approach to regulating heightened or emerging risks from AI (2024d, p. 7).

- In the first instance, effective regulation of AI should be a matter of **assessing existing regulation** to see whether it is fit to manage heightened and emerging risks, and whether regulators are equipped with the resources and skills necessary to apply relevant regulation.
- If it is not sufficient to manage the risk arising from AI use, **existing regulation should be clarified or amended** to bridge these gaps. This can be done through amendments to existing legislation, but also through guidance provided by the regulator or through test cases.

- Where existing regulation is not sufficient and cannot be made sufficient, **new regulation should be risk-based, technology neutral and balance the risks arising from AI use with the benefits of AI and real-world counterfactuals.**

The health sector is one of the most highly regulated industries, with a range of regulatory levers that already apply to the specific risks around AI (table 1). The health sector operates in the context of economy-wide regulation which is technology-neutral and of general application – such as consumer law, civil liability for harm, privacy law and corporate governance requirements. The Australian, state and territory governments also impose health-specific regulation aimed at ensuring that health professionals are adequately qualified, medicines and devices are safe to use, and that providers meet certain standards (Solomon and Davis 2023).

In considering how these regulatory frameworks apply to AI, the PC notes:

- A technology-neutral approach is preferred. The types of AI and the way it is being applied are rapidly changing and difficult to predict. The speed at which technology is advancing is creating challenges for the regulatory framework and the various regulators, as new risks arise. But rapid technological change also implies that any technology-specific regulations are likely to be rapidly obsolete.
- The international context within which software is developed is also evolving rapidly. The medical software industry is dominated by companies that operate across borders and differences in regulatory regimes can create disincentives for developers to supply to Australia. These considerations imply that the optimal strategy may be to wait for regulation to be passed in other jurisdictions, and to harmonize Australian regulation with international standards.

**Table 1 – Regulatory levers to manage AI risks**

**Coverage of AI risks by health-specific and economy-wide regulation**

| Risk                         | Health-sector guardrails   | General economy-wide guardrails   |
|------------------------------|--|---|
| <b>Data and data quality</b> | <p><b>Practitioner code of practice</b> obliges clinicians to exercise reasonable care and skill and act in the best interests of the patient, including in relation to reliance or use of AI as part of providing care</p> <p><b>Practitioner accreditation</b> obliges clinicians to comply with best practice standards and undertake ongoing education (including in relation to relevant use of AI)</p> <p><b>Therapeutic goods regulation</b> obliges developers and suppliers of some AI software to meet efficacy and quality standards (including around data quality) prior to sale and through post-approval monitoring</p> | <p><b>Australian Consumer Law</b> prohibits unconscionable conduct (which could include discrimination in service delivery caused by algorithmic bias)</p> <p><b>Discrimination laws</b> contain protections that oblige AI developers and end-users to protect against algorithmic bias in training and implementation on the basis of personal characteristics (protected attributes)</p> |
| <b>Privacy and security</b>  | <p><b>Health information legislation (including state legislation)</b> obliges anyone using health information to obtain consent and to meet minimum standards around information collection, storage and use</p>  | <p><b>The Privacy Act 1988</b> regulates private information collection, storage and use and imposes liability for breaches of privacy</p> <p><b>Australia’s Privacy Principles</b> requires consent to use AI for sensitive information</p>  |
| <b>Accountability</b>        | <p><b>Therapeutic goods regulation</b> obliges developers and suppliers of AI software to comply with</p>  | <p><b>Tort law</b> imposes liability for negligence (noting that AI may make it difficult to identify which character – developer, programmer, provider,</p>  |

| Risk                | Health-sector guardrails  | General economy-wide guardrails  |
|---------------------|---|--|
|                     | <p>requirements around supply, import, export, manufacturing and advertising</p> <p><b>Practitioner registration</b> obliges clinicians to exercise reasonable care and skill and provides a mechanism to manage complaints about the conduct of clinicians through the Australian Health Practitioner Regulation Agency</p> <p><b>Accreditation of service providers</b> imposes minimum standards for quality and clinical care</p> | <p>customer, user – was responsible for causation of harm)</p> <p><b>Manufacturer’s liability</b> imposes liability on manufacturers where an AI system has a safety defect that causes loss or damage to the consumer</p> <p><b>Contract law</b> can be used by consumers or suppliers to define the scope of liability for AI use / application and facilitate monitoring of performance</p> |
| <b>Transparency</b> | <p><b>Practitioner code of practice</b> obliges clinicians to act in the best interests of the patient, including the need for informed patient consent</p> <p><b>Therapeutic goods regulation</b> obliges developers and suppliers of some AI software to seek approval for medical devices, including being able to explain and demonstrate the efficacy prior to sale and during post-approval monitoring</p>                      | <p><b>Australian Consumer Law</b> prohibits users from misleading consumers (including about how their data is used by an AI system)</p> <p><b>Directors’ duties</b> oblige company directors to exercise due care and diligence and act in good faith, including appropriate risk management for the use of AI and making informed decisions around AI use.</p>                               |

## Getting data settings right will facilitate quality AI use

Getting the right settings and enablers around dataset maintenance and use is a necessary early step to realise the potential for substantial productivity gains from data intensive technologies such as AI. High-quality AI applications in health and in other realms are trained on vast amounts of data: AI is fundamentally a prediction technique, and that technique often relies on large datasets.

Given that the vast majority of AI foundation models are developed overseas (Hajkovicz 2024), capturing productivity benefits from AI will not rely solely on Australian data access. One possible policy for Australia is to restrict health organisations to only using technologies that were developed and trained overseas.

However, there are risks if we do not allow AI developers (including private companies) to access context-specific patient data and patient sub-groups to train AI models. Context specific data is critical to the accuracy of AI models, particularly in clinical applications (Norori et al. 2021). If an AI makes predictions in a fundamentally different context, the predictions could be misleading. For example, if AI were used to predict the optimal time of discharge, it would be important to consider that Australia has a very different hospital system to that of the US, where patients are often discharged into rehabilitation facilities and are therefore discharged earlier than in Australia (Figueroa et al. 2021). Improved access to Australian data would improve the quality and relevance of AI models on the market.

Moreover, algorithmic bias can arise where datasets used to train AI models are not comprehensive. Errors or misleading outcomes can arise where the data AI is trained on draws from a population that is different to the group it is then applied to (DISR 2023, Norori et al. 2021). The quality of the data can be as important as the size of the data sets (Aldoseri et al. 2023; Li et al. 2023; Reddy et al. 2019). Demographic groups that are under-represented or entirely omitted from overseas datasets would be at particular risk of incorrect predictions. To reduce this bias, it is important to ensure that the data used to train AI algorithms is representative of the diversity in the Australian community.



Not having access to Australian data to train AI will also put local firms at a disadvantage. Australian firms that are developing AI for health may need to relocate overseas, if access to health data is more feasible in other markets. In 2023-2024 the PC spoke to several AI health startups who described challenges in accessing data.

The alternative is to draw on Australian data for the development of new AI services and for the localisation of AI developed overseas. Australia is data rich, having invested in data infrastructure such as electronic health records and health information systems to replace paper-based systems.

But access to health data involves delicate trade-offs between the rights of the various parties involved (the individual patient, the clinician providing advice and treatment, the service provider holding the data and the AI owner using the data) and the benefits to the broader public (though improved services and productivity improvements).

Health data is by its nature deeply personal and raises risks around privacy, so the incentives for an individual to share their data are low. But despite the risks, patients have demonstrated some willingness to consent to sharing their health information. One survey found that 74% of Australians are willing to share their personal information to advance medical research (Research Australia 2023). However, that willingness drops if the medical research generates profits for a private company (Gillespie et al. 2023; Isbanner et al. 2022). That poses challenges as many AI innovators are for-profit companies. For example, an AI model may use patient data as an input for model refinement and training. Where that model is owned by a private company, the company can then generate profits by subsequently supplying that model to other healthcare providers (Bell et al. 2023).

The PC has previously discussed the issues around data policy in *Making the most of the AI opportunity* (PC 2024c) and has made recommendations to facilitate the sharing of healthcare data as a priority in the *5-year Productivity inquiry: Australia's data and digital dividend* (PC 2023). There is a clear role for government in lifting data sharing to socially optimal levels. It was recommended that government identify relevant data that can be shared safely and linked to benefit individuals receiving government-funded services (recommendation 4.4), with protections around opting out of the system and deidentification of data.

For instance, there are many applications of AI in healthcare that require access to only a subset of patient information, but where there could be substantial public benefit from creating large datasets that could be safely used by AI. For example, after an appropriate de-identification process, past patient x-ray scans could be productively used to train AI without compromising a full patient record.

Even where patients may be willing to consent to sharing their data, access can be frustrated by lack of coordination and frameworks for data access. Health data is siloed, disconnected, and lacking shared data standards. This emphasises the importance of reforms to improve health information sharing, including enhancing My Health Record as an accessible source of data and progressing interoperability reform, which will be critical to the safe and productive use of AI in health.

Managing data risks is a vital part of ensuring sustainable data sharing. AI raises risks to privacy and the use or misuse of personal information. Failing to manage these risks would erode public confidence in data sharing, among other harms to society and individuals. As discussed above, privacy law, consumer law and anti-discrimination laws (among others) provide a number of tools for government to manage data risks. Indigenous data governance can also play a role as we navigate and regulate emerging data practices.

Upskilling existing regulators to proactively assess the data risks and resulting harms from AI models as they eventuate will safeguard privacy and instil greater confidence in the public about emerging data practices. Risks that cannot be adequately mitigated by existing regulation should be managed in line with the stepped approach to regulation outlined in this submission. Getting the data right and the regulatory settings right around data – both in bolstering access regimes and controlling misuse of data – will enable greater adoption of high-quality and relevant AI models. The PC suggests that further engagement with Aboriginal and Torres Strait Islander representative organisations and communities on these considerations at this early stage of the process is essential.

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