Australian Government
Department of Health, Disability and Ageing

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

Final Report

March 2025

Contents

Overview

This document forms the final report for the **Safe and Responsible Artificial Intelligence (AI) in Health Care Legislation and Regulation Review** (the review).

The Australian Government is taking a whole of economy approach to capturing the benefits of AI while building trust in the Australian community. To build trust and boost AI adoption, government is taking an integrated approach with five pillars of action: delivering regulatory clarity; supporting and promoting best-practice governance; supporting AI capability; positioning government as an exemplar; and engaging internationally. The government's consultations on Safe and Responsible AI have shown that our current regulatory system is not fit for purpose. As part of this, the government has consulted on proposed mandatory guardrails for AI in high-risk settings. The government is considering the feedback received and next steps.

The 2024-25 Budget included funding for priority reviews of consumer, copyright and healthcare laws as they apply to AI. As part of this, the Department of Health, Disability and Ageing(the department) has conducted a public consultation to clarify and strengthen legislation and regulation for AI in Australia's healthcare settings.

This priority review, including the public consultation, was designed to complement the work on mandatory guardrails and has a more specific focus on the use of AI in health and care settings. These issues will be separately addressed in the government response to the consultation on introducing mandatory guardrails for AI in high-risk settings. This review considers the potential impact of AI on the regulation of health care in Australia, and the potential role for non-regulatory initiatives.

It is also important to note that the landscape for this review, particularly regarding technology and regulation, is rapidly changing. This review represents point-in-time perspectives from a public consultation about the use of AI in health care.

For example, the department will need to consider the subsequent addition of portfolio responsibilities including the National Disability Insurance Scheme (NDIS), the National Disability Insurance Agency (NDIA), the NDIS Quality and Safeguards Commission, and Hearing Australia in any future work regarding AI.

All references to AI within the report relate to its use within a healthcare setting unless otherwise indicated.

Findings

While the scope of this review focused on regulation administered by the department, this report should be understood within the following context:

- AI in health care will be impacted by local state/territory and national legislation that sits outside the health portfolio.
- There are a range of risks and limitations raised within the consultation that could be addressed or supported by non-regulatory initiatives.
- Where gaps do exist, economy-wide safeguards such as the proposed mandatory AI guardrails, may support the safe and responsible adoption of AI in health care.

There are seven findings that draw on all aspects of the review:

Finding 1: Regulation

The regulation of health care in Australia is achieved through a complex network of both state/territory and national legislation. Examples of existing national frameworks which impact AI in health care are privacy law, consumer law, therapeutic goods and the regulation of health

practitioners. The departmental legislation reviewed for this report is largely administrative in nature and underpins cornerstone health systems such as aged care, the Medicare Benefits Schedule, Pharmaceutical Benefits Scheme, My Health Record and healthcare identifiers. Within its scope, this legislation is likely to require minor and technical amendments for clarity.

Where gaps do exist (notably health products which fall outside the scope of TGA regulations) economy-wide AI guardrails, incorporating pre-market and post-market requirements may provide clarity, which contributes to building trust and enabling innovation.

Finding 2: National AI health policy leadership

The consultation identified a need for national and centralised policy leadership to steward equitable benefit realisation of AI in health and care across Australia. Due to the unique complexities of AI in health and care, there was widespread support for AI guidance tailored to the complexities of health and care to expand on existing advice provided by the National AI Centre. This could include initiatives for:

- the ethical, safe and responsible use of sensitive health data in AI technologies
- the unique governance risks for adopting and implementing AI in healthcare delivery
- the development of an evidence base to understand the impact of AI on specific populations
- timely guidance on emerging products with widespread impact that responds to the rapid pace of AI innovation
- the effects of AI on different medical specialties.

Policy leadership to address the rapid pace and extent of transformation occurring within the healthcare sector aligns with a holistic approach across government including whole-of-economy AI policy led by Department of Industry, Science and Resources (DISR).

Finding 3: Resources and support for safe implementation

Knowledge gaps exist around the ethical, safe and responsible implementation of AI. There is a lack of high-quality, contemporary guidance to support the evidence-based implementation of AI across health care, as well as specific considerations for human-AI interactions in health care. To support decision making, guidance on how to evaluate and validate new AI technologies through the product lifecycle could include:

- suitability assessments for the setting in which AI is used
- assessment of the quality and relevance of datasets used for training and validation, and the approach used
- monitoring accuracy of outputs
- support product selection that meets the needs of specific populations and health services
- support for implementing AI considering the human-AI team
- support for implementation trials of AI in the clinical setting

Finding 4: Healthcare providers and consumers need access to high-quality, trusted information

A centralised, high-quality and trusted information source would support consumers and clinicians to make informed decisions about AI products. The existence of low-quality and misleading information about AI in health care can adversely impact decision making. Further, the use of AI to generate information about health care can result in poor-quality outputs. Having

access to a trusted source of accurate, reputable, and timely information about AI in health care would support its safe and responsible use.

Finding 5: Realising the benefits

At present there is a lack of evidence to support the potential benefits of AI in health care. Establishing foundational components, such as a benefits framework with a range of qualitative and quantitative metrics, would provide insights into what benefits AI is delivering in health care. This would enable visibility of where AI is most effective in the healthcare system and support investment decisions and equitable distribution of AI benefits.

Finding 6: Data and consent strengthening

Data and consent risks need to be managed across the AI life cycle. Regulation should be clear about when and how data can be accessed and used by AI and who is accountable for the responsible use of patient data. There is a need to clarify who owns patient data and strengthen patient consent practices around the use of data by AI. Governance frameworks will need to address risks relating to bias in data, accuracy of data, data embedding, and data access. Some responses pointed to the implementation of synthetic data resources as a possible mitigation to address some of the challenges associated with data access and representation in healthcare research. Economy-wide mandatory guardrails incorporating data governance measures and supply chain transparency may go some way in mitigating the risks for the use of AI in high-risk settings.

Finding 7: Incentives could support best practice

A framework for incentivising industry to deliver quality AI technologies that are reflective of and applicable to the Australian market could encourage best practice. Incentivising best-practice AI development, and practices that deliver high quality, accuracy, safety and applicability to the Australian market, may support the realisation of benefits for all Australians. It could also help to reduce the risk of harms presented by low-quality products.

Key Themes

Several key themes emerged across multiple stakeholder meetings and written submissions received in response to the consultation paper. These have been broadly summarised below:

AI understanding

Stakeholder understanding of AI is diverse. Many people do not understand AI or base their views on information they receive from the media (including social media). This makes it difficult for people to consider the implications of AI or have nuanced discussions about its risks and benefits. Some who have a good understanding of AI and are eager to highlight risks and problems with the various AI products already in market. These respondents are concerned with protecting consumers and the health workforce from potential risks, and/or improving the AI products to make them safer.

Bias

Bias was a strong theme that emerged consistently throughout many submissions. Most respondents were concerned about the potential for bias, especially where Australian populations are not well represented during the development of AI products. These concerns are reflected in well documented studies demonstrating AI bias and its consequences.

Consent and transparency

Stakeholders expressed concerns about consent and transparency with a specific focus on informed consent. Submissions highlighted a need for the development of principles, governance and consent frameworks specific to health along with education and guidance for workers and consumers. Stakeholders also raised the need for transparency about when AI is being used in the delivery of care and how the AI product works (including how it derives outputs). Stakeholders held varying views about how to improve AI transparency and ensure patients consent to its use.

Data

Data emerged as a major area of focus and stakeholders provided a range of suggestions about how to address associated risks. Aspects of data covered included storage, encryption, ownership, confidentiality and deidentification.

Reidentification of patient data emerged as a key concern. Stakeholders highlighted that, given the many data sources now available, even the most robust techniques for deidentification may no longer be sufficient to safeguard patient privacy. Some respondents pointed out that reidentifying of patient data is a likely outcome. Several clinical stakeholders raised that certain patient data, such as skin scans and genetic data, is impossible to deidentify. In these instances, deidentification cannot be assumed to be a safeguard for patient privacy.

Stakeholders generally agreed that patient data is highly and uniquely sensitive, relative to data in other sectors of the economy. Data ownership was a polarising concept, with some respondents asserting that patients own their health data, while some health service providers said otherwise. Respondents suggested a need for a framework to clarify data ownership and articulate standards around access to patient data, including what kinds of data can be accessed and when. As part of future policy development, it will be useful to examine what lessons can be learnt from genomics.

> ‘Only 38% of Australians trust that companies that use artificial intelligence will protect their personal data.’
>
> ANDHealth

Evidence base

Multiple submissions from diverse sectors highlighted the need for a robust evidence base to inform both the development and implementation of AI in health care. This will ensure AI aligns with existing principles around evidence-based care within the sector. Stakeholders highlighted the need for trials, auditing and monitoring mechanisms to understand how AI performs. Stakeholders pointed to a current lack of evidence for AI performance and proposed that measures need to be implemented to address this. Respondents referred to global research publications which indicate some emerging consensus around potential ways to set standards and measures for AI.

> ‘There must be appropriate evidence-informed measures in place.’
>
> - Advanced Pharmacy Australia

Human in the loop

Almost all respondents identified having a human in the loop as being critically important for patient safety. However, a small number of respondents thought having a clinician in the loop when using AI was either not necessary or impractical. Some submissions discussed the importance of having the right expertise and/or process for a human in the loop, which at times could be a clinician, technical expert or other skilled person.

Risks

Stakeholders highlighted that AI poses significant, and potentially irreversible risks like physical harm, death, and the long-term pollution of health records. The kinds of risks highlighted ranged from technology risks (arising from AI-specific characteristics) to consequential risks (encompassing the downstream harms that may not be evident at the time of use). Due to the adaptive and probabilistic nature of AI, products that are initially considered low risk may become higher risk over time. The black box quality of AI also increases risk, as it is not possible to see how the AI components have arrived at the conclusion. Some responses identified that the risks associated with AI are disproportionately borne by certain groups, particularly those:

- unable to communicate or give informed consent
- who are underrepresented in datasets, such as women, children, Aboriginal and Torres Strait Islander people, people from some culturally and linguistically diverse communities, and people who are generally underrepresented in the healthcare system
- people unable to operate the AI or override it, such as people with disabilities
- people with other vulnerabilities
- who speak a first language other than English
- younger cohorts such as children and teenagers, for whom the effects of issues may be long term and impact their lives for decades to come.

‘Women were excluded from clinical trials in the US until 1993 and there is still no mandatory requirement for gender balance in clinical trials in Australia.’

- ANDHealth

Background

Artificial Intelligence can help solve urgent and emerging challenges in our healthcare system and support the healthcare workforce to dedicate more time to delivering care. However, along with the potential opportunities of AI in health care, there is community concern about the safety and risks of AI. This includes concerns that current legislative and regulatory frameworks do not adequately mitigate the potential for harm.

There are high-risk use cases for AI in health care. The rapid roll out of AI-powered systems and fast pace of innovation means achieving the right regulatory settings is critical to ensure its safe adoption.

The department has undertaken the **Safe and Responsible Artificial Intelligence in Health Care Legislation and Regulation Review** (the review) which considered the range of legislation that we administer. To understand who is impacted by AI and the relevant regulation, which aspects of AI may need regulation and how this might prevent harms and enable benefits, we have considered regulatory changes and non-regulatory initiatives. The public consultation asked that submissions consider the benefits and risks of AI and potential regulatory changes across Australia's healthcare system. AI has the potential to impact multiple facets of health care, including:

- clinical care
- billing
- insurance
- digital systems
- consent and privacy
- health data
- training, literacy and competency
- liability and responsibility.

Other AI-related initiatives in progress in the Australian Government

The rapid development of commercial AI solutions reveals opportunities for AI to solve urgent and emerging challenges in the Australian health care system. The Productivity Commission's report *Leveraging Digital Technology in Healthcare*, suggested automating low-complexity tasks could potentially free up to 30% of clinicians' time to focus on patient care.

The Australian Government is taking a holistic approach to harnessing the opportunities of AI while addressing high-risk uses. Our work builds on DISR's 2023 consultation on AI, submissions to the Senate Select Committee on Adopting AI in 2024, and considers the Australian Alliance for Artificial Intelligence in Healthcare (AAAiH)'s roadmap.

To build trust in the Australian community, the government is also considering proposed mandatory guardrails for AI in high-risk settings. The Australian Government's consultations on Safe and Responsible AI have shown that our current regulatory system is not fit for purpose. The 2024 consultation on introducing mandatory guardrails for AI in high-risk settings outlines options the Australian Government is considering that introduce preventative guardrails on those developing and deploying AI in Australia in high-risk settings.

We are working closely with DISR, and while the mandatory guardrails proposals paper takes a whole of economy approach to AI, this review addresses the unique risks associated with its use in health care.

The Therapeutic Goods Administration (TGA) conducted a separate legislative review of their framework and how AI is used in the manufacture of therapeutic goods, including medicines. The TGA review sought feedback about strengths of the system, opportunities for improvements and identified issues and areas of concern.

While the TGA consultation specifically relates to products that that come under the therapeutic goods framework, this review by the department covers practice and related issues across the whole portfolio of health and aged care.

Other work that is taking place across government that intersects with AI includes work on privacy, automated decision-making, generative AI in schools, deepfakes, online safety, employment and workplace impacts, competition in digital search and cyber security.

In this review, we have also engaged with DISR, the TGA, the Office for Women, Department of Employment and Workplace Relations, the Treasury, and the Office of the Australian Information Commissioner.

Objectives

This report reflects findings from our legislation and literature review and our public consultation. It describes the current and potential uses of AI in health care and discusses the benefits, risks and possible regulatory solutions.

We need to support the safe and responsible use of AI in health and care settings to ensure that all Australians realise the potential benefits. This includes:

- **human benefits** such as reduced health inequities, a workforce that is supported to work at its full scope of practice, reduced clinical burnout and more time for patient care, and improved population health outcomes
- **cost and productivity savings** that AI could make possible through the automation of low-complexity tasks and the augmentation of care
- **system and economy-wide benefits** as AI plays an enabling role in supporting a sustainable care economy for all Australians.

Scope

We conducted a review of key health portfolio legislation to identify gaps and vulnerabilities in the safe and effective regulation of AI in health care. This review was informed by a consultation addressing:

- the current and potential uses of AI within Australian health care
- the associated benefits and risks
- the impact of AI on the healthcare system, including impacts on people, workflows, and healthcare information
- any potential regulatory changes and non-regulatory supports required to support the safe adoption of AI in health care.

What is out of scope?

Our review does not cover the use of AI within the department. It also does not cover the regulation of therapeutic goods like software as a medical device (SaMD), which is the remit of the TGA.

What do we mean by AI?

AI refers to software, websites or apps that use mathematics to predict the most likely answer, unlike more traditional software that has rules programmed into it.

In this review, we are using the definitions used by the DISR in their mandatory guardrails paper as:

> 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.

This definition includes, but is not limited to:

- **Machine learning** – the patterns derived from training data using machine learning algorithms, which can be applied to new data for prediction or decision-making purposes.
- **Generative AI models** – which create novel content such as text, images, audio and code in response to prompts.

What does AI look like in health care in Australia?

AI is already being used in a range of ways in Australian health and care settings.

Examples include, but are not limited to:

- cancer screening – analyses images to detect cervical, breast and prostate cancer
- aged care homes – AI robots for companionship and monitoring
- scribes – generative AI that listens to patient consultations and automatically generates notes, care plans and orders for tests
- clinical decision support – combines information about diseases and treatment pathways and suggests diagnoses and tests based on patient symptoms
- chatbots – assists in finding information on healthcare websites
- AI in surgical tools – helps identify significant polyps during colonoscopy, or to assist in surgery
- skin checks – analyses photographs to check skin health, detect melanoma or other skin cancers
- image analysis in radiology and pathology
- AI in medical records – analyses risks to patients to predict bed usage or surges on the healthcare system.

New AI products are constantly being developed and used within healthcare settings. While these new products and uses have benefits, they also introduce new risks.

Legislation and regulation

What legislation did we review?

Our review focused on examining key departmental portfolio legislation to identify gaps and vulnerabilities in the safe and effective regulation of AI in health care. However, the broader legislative landscape – including Commonwealth whole-of-economy legislation and state and territory health legislation – significantly influences the application of AI in health care and is broadly considered.

We have reviewed legislation which regulates cornerstone federal health infrastructure, including the Medicare Benefits Scheme (MBS), Pharmaceutical Benefits Scheme (PBS), My Health Record, healthcare identifiers, private health insurance and aged care, namely:

1. *National Health Act 1953*
2. *Health Insurance Act 1973, Health Insurance Regulations 2018*
3. *Private Health Insurance Act 2007*
4. *My Health Records Act 2012, My Health Records Regulations 2012*
5. *Healthcare Identifiers Act 2010, Healthcare Identifiers Regulations 2020*
6. *Aged Care Act 2024*

Although it has not been considered as part of this review, the *Therapeutic Goods Act 1989,* administered by the Therapeutic Goods Administration within the health portfolio, plays a key role in regulating the use of AI in therapeutic goods, including medical devices.

The diagram in Appendix A summarises the legislation subject to this review.

Approach to the legislative analysis

We undertook a thematic legislative review in the following manner:

1. Legislation review: reviewing in detail key legislation in the health portfolio to determine the current state of AI regulation.
2. Contextual analysis: evaluating the interaction of health legislation with broader frameworks, such as privacy laws and consumer protections.
3. Thematic findings: identifying recurring themes of AI vulnerabilities and gaps in the broader AI framework, and in specific health legislation.
4. Findings: detailing key findings for the department to consider regarding the regulation of AI in health care.

Legislative review findings

The regulation of health care in Australia is a multifaceted landscape, encompassing both state and national regulatory frameworks. Collectively, these address many of the key concerns about AI in healthcare, such as:

- privacy and data protection (*Privacy Act 1988)*
- consumer rights (the Australian Consumer Law)
- medical devices (*Therapeutic Goods Act 1989*)
- professional conduct (various professional standards and medico-legal obligations).

As technology continues to evolve, efforts across government are underway to ensure this network of laws remains effective and relevant. For example, recent changes to privacy laws will increase transparency about automated decisions that use personal information. Further work is to come on updating privacy laws. Government has agreed in-principle to proposals giving individuals greater choice and control over their personal information, and proposals relating to trading in information and de-dentification of information.

Public consultation reflected heightened concern around data access and disclosure, transparency, bias, and human involvement in decision making where AI is used in health care. Existing frameworks do provide avenues of redress for aggrieved individuals in situations where AI is used in health care. However, difficulties in detection and enforcement support enhancing current protections to include greater pre-market approval requirements and post-market surveillance opportunities for AI products. While the TGA framework already incorporates these measures for regulated devices, whole-of-economy guardrails would provide an opportunity to broaden this style of protection to health products which fall outside the scope of TGA regulation, such as medical scribes and some wearable health products.

Regulatory frameworks administered by the department are narrower in scope and predominantly administrative in nature. Apart from the *Aged Care Act 2024,* the department's health legislation was drafted prior to the development of modern AI technology. Nevertheless, the legislation is largely able to accommodate AI and operate as intended. Minor technical and definitional amendments may be needed to ensure clarity in their application to AI, for example to clarify when and how a definition or offence only applies to human actors. The themes for these possible changes are set out in the table below.

Table: Legislative Review Findings

Theme	Explanation
Definitions	Current healthcare legislation definitions centre on human providers, offering protection against overzealous use of AI in clinical care. However, as AI continues to evolve, definitions related to health service delivery or professional services and associated terms may need review to accommodate beneficial AI technologies while maintaining necessary safeguards. Terms like 'rendered by a practitioner' and 'clinically relevant service' could be amended in future to create pathways for approved AI assistance in healthcare delivery should it be needed for enhancing patient outcomes and/or system efficiency.
Data access and disclosure	A range of reviewed legislation contains non-disclosure obligations and/or public research disclosure provisions in addition to obligations under the *Privacy Act 1988*. Further consideration can be given to whether disclosures to AI models are appropriately authorised and regulated.
Technical amendments - offences	In some cases, existing non-disclosure and other offences are framed such that conduct will only constitute the offence if information is disclosed to or by a person. In these cases, it is possible that AI models could be used to subvert the offences.
Standards of care	The department is responsible for setting standards of care for aged care and should consider the impact of AI on standards compliance.
Health funding	Existing departmental regulatory frameworks, with technical and definitional amendments, are largely equipped to accommodate AI in health care. For example, funding requirements currently impose conditions around who may deliver health services, supervision requirements and the equipment which may be used. As AI technology continues to evolve rapidly, the department should monitor technological and professional changes to ensure regulatory levers continue to support care delivery models which meet Australia's health policy objectives.
Responsibility and liability	The department notes that the area of professional responsibility and liability in respect of the use of AI is a cause of concern for health professionals and insurers. Noting this, the department continues to liaise with the Australian Health Practitioner Regulation Agency (AHPRA) on these questions. There are multiple aspects to healthcare professional regulation which are outside the scope of the department, including professional standards and medico-legal considerations. The department should ensure the statutory frameworks within its scope which impact professional regulation, such as the Professional Services Review Scheme and compliance with billing requirements, reflect nascent AI norms.

Whole of economy legislative context

The use of AI in health care is currently governed by a mosaic of legislation at the Commonwealth and state/territory levels. Across the Australian economy, the regulation of AI currently falls to multiple legislative frameworks:

- The *Privacy Act 1988* establishes the Australian Privacy Principles (APPs), which set requirements for handling personal and sensitive health information. The APPs apply to all uses of AI in health care including training, testing or deploying AI systems. However, there are limits to the principles' scope (for example they do not impose minimum testing standards for AI models) and depth (for example they do not cover information that is inferred or generated).
- The *Privacy and Other Legislation Amendment Act 2024* received Royal Assent on 10 December 2024. The Act amends the *Privacy Act 1988* including to increase transparency about automated decisions that use personal information. This is the first tranche of amendments in response to the Privacy Act Review Report, with further work to come. Remaining privacy reform proposals to which the Government agreed in-principle include proposals giving individuals greater choice and control over their personal information, and proposals relating to trading in personal information and deidentification of personal information.
- Most states and territories also have privacy legislation that applies to their public sector agencies, such as public hospitals.
- Consumer protections under the Australian Consumer Law have been reviewed by the Treasury and are not detailed in this review.
- Anti-discrimination legislation is framed to be technology-neutral and provides processes for people impacted by AI systems to challenge use or outcomes
- The Department of Home Affairs is currently undertaking a review of the *Security of Critical Infrastructure Act 2018* to strengthen cybersecurity laws which may impact use of AI.

Intellectual property laws, including the *Copyright Act 1968,* can influence the way material in which third parties have intellectual property rights may be used in developing and deploying AI models. The Attorney-General's Department is reviewing how copyright law applies to AI in consultation with stakeholders through the Copyright and AI Reference Group.

State and territory healthcare laws and regulations govern many aspects of healthcare administration, including professional standards and health complaints mechanisms.

The operation of this broader network of legislation directly impacts the use of AI in health care and interacts with the legislation under review. For example, health legislation often refers to the *Privacy Act 1988* in respect of data disclosure provisions. As such, the recommendations from this report should be considered against the broader agenda of work currently underway across government regarding AI in the Australian economy.

International approaches

Australia can draw valuable lessons from the regulatory approaches adopted by other countries, which showcase various strategies for managing the risks and opportunities of AI. For example, the European Union (EU) has adopted a risk-based approach to comprehensive AI regulation in its *Artificial Intelligence Act (AI Act)* and is now focused on implementation with a view to ensuring EU competitiveness. The act provides wide discretion for how individual member states implement health-specific legislation, response to the EU AI Act is still evolving.

The United Kingdom has taken the approach of regulating the most powerful types of AI and has set up an AI Security Institute to enable governance and ensure advanced AI is safe, secure and beneficial. The UK's *AI Regulation White Paper* supports a decentralised model, relying on

existing regulators to govern AI applications in addition to the centralised approach of setting up a dedicated institute. The UK has also funded centres for AI regulation in health care.

Similarly, Canada has been working towards a more structured regulatory framework with its proposed *Artificial Intelligence and Data Act*. This legislation is intended to regulate the design, development and deployment of AI systems that pose significant risks of harm or biased outcomes. The United States has adopted a multifaceted approach to AI regulation, emphasising innovation while incorporating federal initiatives, state legislation and voluntary industry commitments to address ethical, societal and security risks.

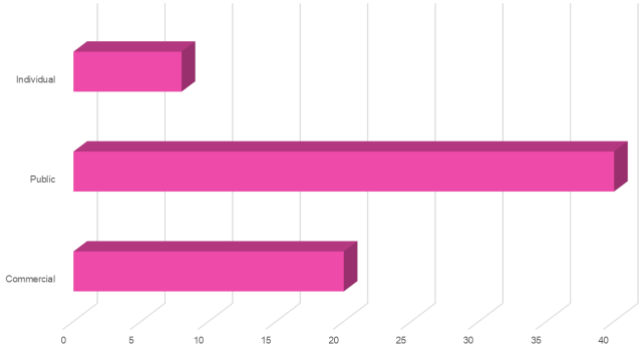
Public consultation

The department published the public consultation paper in September 2024 and received 69 formal written responses and 2 informal written responses. We held a series of meetings with stakeholders across the portfolio from July to November 2024, and 3 public webinars with 338 attendees

We invited stakeholders to share their views and contribute to the review of legislation and regulation for Safe and Responsible Artificial Intelligence in Health Care.

Who responded to the consultation paper?

We received responses from a mix of individuals and organisations. Many are representative bodies. Just under 20 commercial organisations submitted a response.



Number of submissions

Analysis of responses

This section contains a brief synopsis of responses to the consultation paper, which asked 19 main questions, with multiple sub-questions.

Benefits

Responses to the consultation identified a large range of benefits. Many responses were qualified by the need for upfront investment in governance, regulation and safeguards, clarity of accountability and ability to measure real-world impacts. Other responses emphasised the need for quality control and bias management to deliver the benefits, emphasising the current evidence base for benefits is still emerging and small scale.

University of Adelaide stated that:

> AI refers to a set of tools and methods that excel at pattern recognition. Their benefit will be most pronounced where pattern recognition is key to performing a particular task. For example, detection, diagnosis, and risk prediction.

Submissions identified both quantitative and qualitative benefits. These could be broadly grouped into administrative, clinical, discovery, decision support, workflow replacement and remote benefits.

Certain stakeholders identified benefits for people with specific health or communication needs. For example, the Disability Research Network at University of Technology Sydney highlighted that:

> AI will increase the rate at which people with communication disability can express themselves and increase their access to written information through assistive technologies being built into health platforms and enabling multimodal and multimedia communication to be developed (e.g., that don’t rely on reading or typing).

Ideas for how to measure benefits were varied, and included silent trials, clinical studies, focus on clinical impacts and endpoints, patient outcomes and stakeholder feedback. An important factor highlighted was the need to have clarity about how the AI performs when used by clinicians in the clinical setting, compared to development conditions.

Access to care

We asked if AI could improve access to care. One response from the University of Adelaide outlined the relationship between technology and access and emphasised that there should be inclusive non-AI options to access care:

> Potentially, yes. But sometimes technologies can worsen access, and the digital divide is growing. A key safeguard here is having a back-up plan - if you can't or don't want to engage with a chatbot on a website, you have another option to use such as making a phone call.

Risks

Submissions highlighted many kinds of risks ranging from technology risks through to consequential risk. Many responses focused on potential impacts to the different groups of people who use or are affected by the use of AI. Some highlighted that AI may worsen the digital divide or that in seeking benefits, some groups of people may be adversely impacted more seriously than those who receive the benefits. Other groups may face barriers to accessing the benefits due to disability, underrepresentation, geographical, or other factors.

The nature of risk

Some respondents saw that, as with most health tools, there is a mix of high and low risks that arise due to the use of AI, therefore a risk-based approach is critical. The Medical Software Industry Association (MSIA) placed particular emphasis on this point, along with other commercial organisations.

What does 'low risk' look like to stakeholders?

Stakeholders provided many low-risk examples of AI that were dominated by administrative and logistical uses. Some respondents spoke of the difficulty in characterising 'low risk' use. For example, the University of Adelaide stated that, 'defining risk is a challenge. In some cases (for example, AI scribes), something that appears very low risk actually becomes riskier over time and inversely correlated with performance (McCoy et al 2024).'

Seventy-seven per cent of answers indicated that consumers should be informed when AI is used in low-risk ways.

Risk characterisation

While some responses relied on the concept of high, medium and low risk, others suggested more qualitative criteria founded on the particular characteristics of AI in the healthcare sector. Some responses suggested the extent to which the AI product interacts directly with the patient and the clinician should be considered as part of risk characterisation.

The Royal Australian and New Zealand College of Radiologists (RANZCR) noted that they had done substantial work thinking about risk in radiology and that risk characteristics are outlined in their *Ethical Principles of AI in Medicine.*

Other responses suggested accounting for the complexity of the task, the potential impact on patient outcomes, and the level of human oversight involved.

Choice

The majority of respondents strongly believed that healthcare professionals should have a choice about whether to use AI as part of their work.

Australian AI in health care body

Over 70% of those who responded to this question agreed there should be some form of Australian body specifically dedicated to overseeing AI in health care. Suggestions were widely varied as to how this body could differ from a broader organisation like the National AI Centre.

International approaches

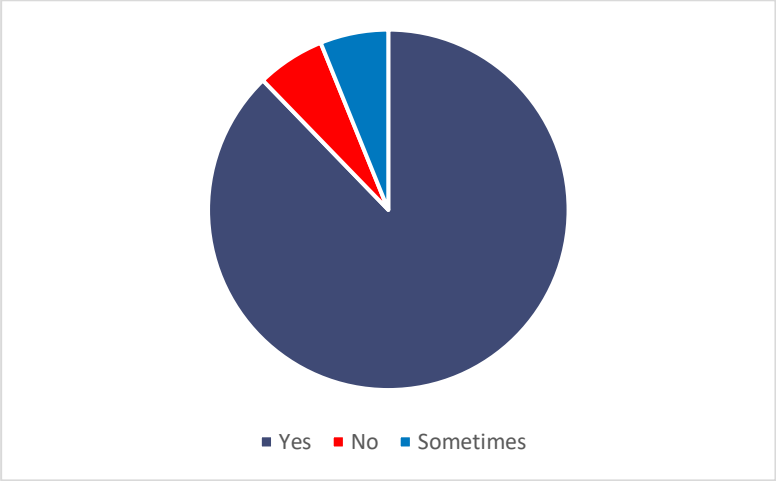
We asked about which international approaches we should consider that are specific to health care. Just under half of responses mentioned European approaches, predominantly including the European Union's *Artificial Intelligence Act (AI Act)* and/or the *General Data Protection Regulation*.

The other half of responses mentioned a mix of international approaches, with some referring specifically to medical device frameworks in other countries, international standards development and the World Health Organization.

Human in the loop

This is often also known as 'expert in the loop' or 'clinician in the loop'. Eighty-eight per cent of responses said there should always be a person or 'human in the loop' to make decisions or deliver a healthcare service. Many responses provided additional commentary and reasons for this view.

Should there always be a person or "human in the loop" to make decisions or deliver a healthcare service?



Many made the point that the human needs to be meaningfully in the loop to be effective. For example, ANDHealth stated that:

> AI may not have the full picture or may be based on limited info in a digital dataset, so some human interpretation and clinical contribution is needed. Trust and reliability of recommendations; a clinician needs to be able to trust the result and understand it. As per all medical technologies, the accuracy, specificity and sensitivity of the tool should be known and validated in robust studies.

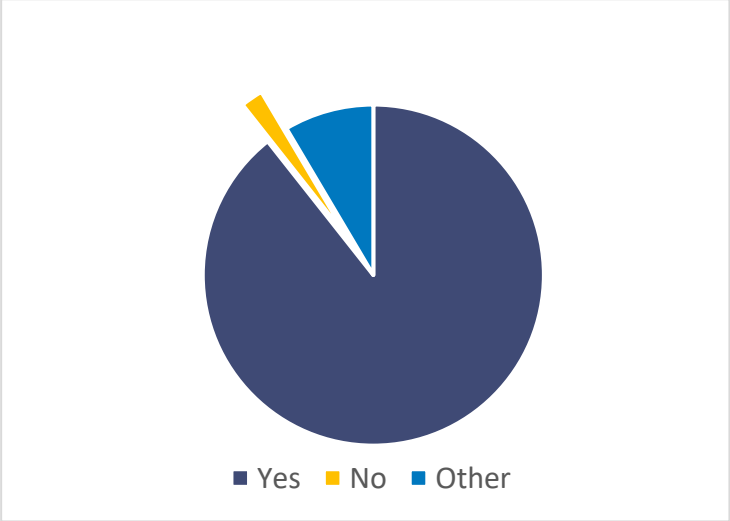
Error reporting

Ninety-three per cent of all submissions said that AI errors should be reported. There were a range of suggestions as to how and where errors should be reported.

Transparency and consent

Only one submission said there should not be transparency about when AI is used in health care.

Should there be transparency about when AI is involved in health care?



We also asked if consent to use AI should be requested from the consumer or healthcare professional, to which 79% of respondents answered yes.

Generative AI

More than 55% of answers were in favour of special treatment for generative AI, with key reasons being uncontrolled inputs and outputs, and training on large datasets containing errors and bias. Suggested treatments included specific governance and regulation.

Advanced Pharmacy Australia stated that:

> Major risk from disinformation from AI tools not intended for healthcare due to lack of guardrails - LLMs are easily and readily available, provide misinformed advice and recommendations for managing diseases/conditions/ailments with no oversight of output.

Data

Many aspects of data emerged as a major area of focus from the submissions, with consistency in the concerns and suggested mitigations. Themes included storage, encryption, ownership, accessibility, accountability, confidentiality, deidentification among others. Pathology Technology Australia, for example, stated that, 'data sovereignty, security and personal protections are paramount in all health care'. The department has published the Framework for Governance of Indigenous Data which sets out specific requirements for all aspects of the data lifecycle.

Personal health data is highly sensitive

Personal health data was widely agreed to be highly and uniquely sensitive, relative to data in other sectors of the economy. Data ownership was a polarising concept, with some respondents asserting that people own their data, while others had a different view. A framework to clarify ownership and access to personal health data, including what kinds of data and when, was deemed by stakeholders to be an important part of addressing this.

Reidentification is real

Reidentification emerged as a key concern and likely outcome given the many data sources that are now available. Some respondents noted that techniques for deidentification may no longer be

sufficient to safeguard patient privacy, even when robust techniques are used (Rocher et al., 2019). Some clinical groups raised that certain patient data, such as skin scans and genetic data, is impossible to deidentify. In such circumstances, deidentification should not be assumed to be a safeguard. This also extends to low dose CT scanning where 3D reformation can reproduce a person's face from scans. One response highlighted that the consequences may be more serious for people in small communities.

Irreversible consequences

The consequences of mishandling or exposure of personal health data may be long lasting and irreversible, leading to the potential for mental and physical harm and, in some cases, death. Data leakage is one way where the breached data generally cannot be retrieved or deleted, so the damage may continue for years after the original exposure or leakage. For children, who are not able to consent initially, the impacts may be felt for the long term. There is also the possibility of AI introducing changes to patient records that are difficult to reverse or irreversible, such as errors arising from 'hallucinations' or inaccuracies.

Data is needed to develop AI and mitigate risks

The Productivity Commission and others highlighted the need for a nationally consistent approach to data that enables use in order to mitigate bias in AI, to clarify a consistent set of principles and to ensure that the Australian population benefits from AI, and in particular that governance of indigenous data and indigenous data sovereignty are explicitly addressed, noting the Framework for Indigenous Data Governance.

It's possible to get benefits from AI without sending data overseas

Multiple submissions from technical experts highlighted it is not necessary to physically send data to other jurisdictions to process and produce a result since there are technical solutions available locally.

Using or selling personal health data, including patient data

There were polarising views about who owns personal health data, what is acceptable use, and whether people should be remunerated when their data is sold. Some respondents expressed the necessity of using personal health data.

Keeping personal health data in Australia

Fifty-four percent of respondents indicated that personal healthcare information should be kept in Australia.

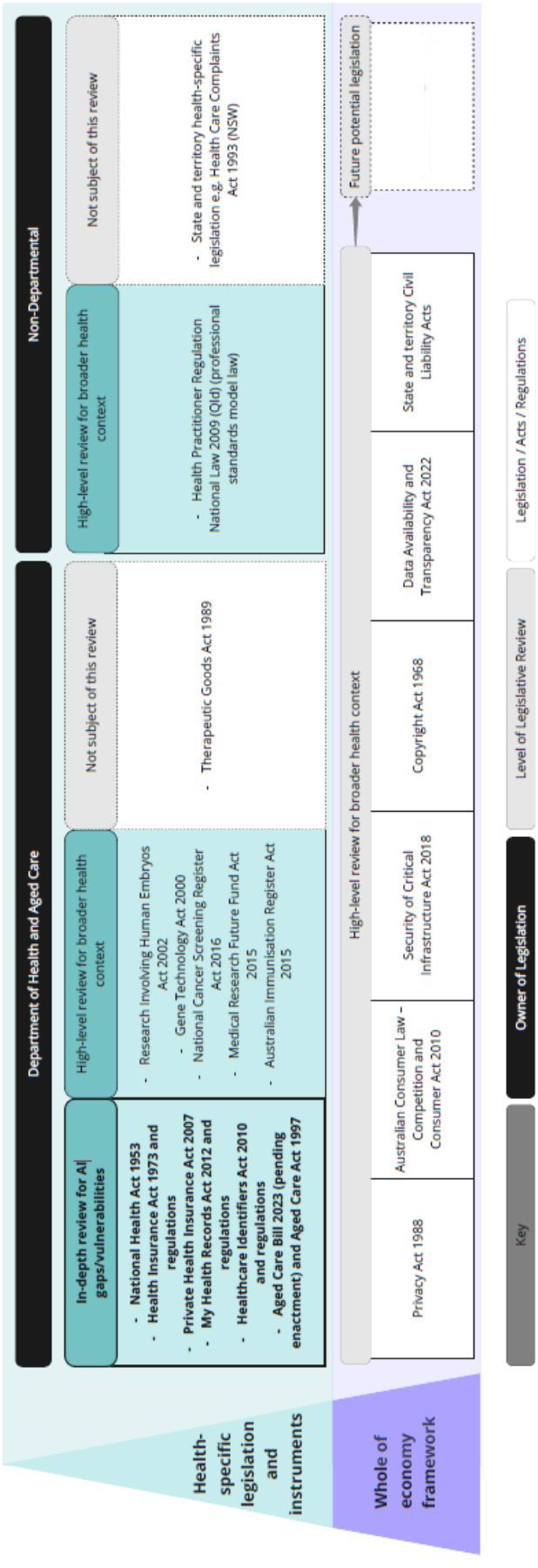
Conclusion

The rapid pace at which AI technologies are evolving and being implemented in health care necessitates an evidence-based approach to design, development and deployment. AI technologies may present a significant productivity and public benefit opportunity for the Australian health, disability and aged care ecosystem and it is essential that these benefits are equitably realised through targeted innovation pathways and appropriate assurance mechanisms. Given health and care are high-risk settings for the deployment of AI and the rapid adoption of AI technologies across the sector have given rise to risks that must be responsibly managed to protect Australians and support safe use.

The Safe and Responsible Artificial Intelligence in Health Care Legislation and Regulation Review found that the department's legislation is largely able to accommodate AI. However, minor and technical amendments may be required for clarity and, where gaps do exist, economy-wide guardrails and non-regulatory initiatives could enhance safeguards.

The public consultation highlighted that there are varying degrees of AI understanding among the sector and the public. It has also drawn attention to key considerations around bias, consent, personal health data, automation, workforce, the importance of human oversight, and the need for evidence-based decision making about AI products and the outputs they produce. To ensure Australia realises the potential benefits of AI in health care we must recognise its limitations and mitigate potential harms.

Appendix A – Legislative framework overview



Appendix B - Consultation

B1 Consultation questions

We invite stakeholders to provide input by responding to the following questions:

1. How can AI benefit health care in Australia and how can we measure and deliver these benefits?
2. Can AI improve access to care, and what regulations could be amended or added to enable this
3. What risk does AI pose to patients/consumers or health care professionals? Are the risks high or low? What criteria could be used to characterise risk? Should consumers be informed when AI is used in these low-risk ways?
4. What factors are important for rural and regional Australia when assessing the benefits, risks, and safety of AI? Are there other communities that face specific risks when implementing AI-driven health care? What considerations should be made to ensure all Australians have access to the benefits of AI?
5. Should health care professionals have a choice about whether they use AI as part of their work?
6. What unique considerations are specific to AI in health care, and why? Should the government address them through regulatory change?
7. How does the use of AI differ in healthcare settings compared to general or other sectors such as finance, education, etc.?
8. Should there be an Australian body specifically dedicated to overseeing AI in health care? If so, how would this body differ from a broader organisation like the National AI Centre?
9. Are there any specific changes to existing healthcare laws that would address AI-related harms or help AI to be used safely?
10. Which international approaches should we consider, if any, that are specific to health care?
11. Should humans be able to overrule a finding or decision made by AI?
12. Should there always be a person or “human in the loop” to make decisions or deliver a health care service? Are there any circumstances in which it would be acceptable to have fully automated health or care decisions made by an AI product?
13. Should errors made by AI be reported? If yes, how should they be reported?
14. Should there be transparency about when AI is involved in health care, and should consent be requested from the consumer or health care professional?
15. Generative AI may be developed for general use yet used in health care. Should generative AI developed have any special treatment, regulatory or otherwise?
16. What protections are needed for patient data used or generated by AI that are different for health care?
17. Is it acceptable for developers of AI products to use patient data to develop their products or to sell patient data collected from use of AI?
18. Should your healthcare information be kept in Australia? If yes, would your view change if this reduced ability to access advances in AI made overseas?
19. Are there any specific safety considerations that have not been raised elsewhere?

B2 Consultation responses

In total, 69 written submissions were received in response to the public consultation paper. Of these, some respondents elected to remain anonymous while giving permission to publish their response. Several other respondents preferred to not have their submission, name or organisation (where applicable) published.

The list below shows those organisations and individuals who gave permission to publish their details.

Respondent
Advanced Pharmacy Australia (formerly known as The Society of Hospital Pharmacists Australia (SHPA))
Amazon
ANDHealth
Attrayee Chakraborty
Australasian College of Dermatologists (ACD)
Australian Alliance for AI in Healthcare
Australian Centre for Health Engagement, Evidence and Values (ACHEEV), University of Wollongong, and Australian Institute of Health Innovation, Macquarie University
Australian College of Rural & Remote Medicine
Australian Dental Industry Association
Australian Healthcare & Hospital Association
Australian Institute for Machine Learning, and Royal Adelaide Hospital
Australian Institute for Machine Learning, University of Adelaide
Australian Institute of Digital Health
Australian Medical Association
Australian Psychological Society
Australian Research Data Commons
Avant
Cancer Council Australia
Canteen Australia
Catholic Health Australia
Consumers Health Forum of Australia
Design Tobias
Digital Health CRC
Dr Fiona Van Leeuwen
Dr Joe McTigue
Dr Kim Drever
Faculty of Medicine, Dentistry and Health Sciences, The University of Melbourne
HCLTech
Individual
Medical Software Industry Association
Medical Technology Association of Australia
Medicines Australia
Olympus

Optometry Australia
Pathology Technology Australia
Productivity Commission
Queensland Nurses and Midwives' Union
RMIT University
RMIT University
Roche Products
Royal Australasian College of Physicians
Royal Australian & New Zealand College of Ophthalmologists
Royal Australian and New Zealand College of Radiologists
Royal Australian College of General Practitioners
Royal Australian College of Medical Administrators
Royal Australian College of Surgeons
sike.ai
Stephen Brancatisano
The Pharmacy Guild of Australia
The Social Policy Group
University of Technology Sydney

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