



Select Committee on Adopting Artificial Intelligence (AI)

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CONTENTS

Contents

Introduction	4
Key Recommendations	4
CHF's advocacy in automated decision making and artificial intelligence	5
AI Governance	6
Safety and Quality	8
Data, Privacy and Ethics	9
Consumer Engagement	10
References	12

Introduction

Consumers Health Forum (CHF) is the national peak body representing the interests of Australian healthcare consumers and those interested in healthcare consumer affairs. CHF works to achieve safe, quality, and timely healthcare for all Australians, supported by accessible health information and systems. At the heart of CHF's policy agenda is consumer-centred care.

In the context of CHF's commitment to quality improvement in healthcare, CHF supports and recognises the value of automated decision-making and discriminative Artificial Intelligence (AI) technologies, which have been used in healthcare for many decades.

However, the sudden rise of generative word modelling, such as ChatGPT, prompts CHF to raise significant concerns, as many features of generative AI software may pose significant risks to consumers when used in a healthcare setting. As such, CHF welcomes the opportunity to provide a submission to the Select Committee on Adopting Artificial Intelligence (AI). This submission focuses exclusively on generative AI to ensure alignment with the Committee's terms of reference.

While healthcare consumers, healthcare services, and healthcare financing institutions could all potentially benefit from wider adoption of generative AI, the risks are primarily borne by consumers.

In this submission, CHF will guide the committee through the risks that the unregulated adoption of generative AI would have in healthcare. CHF will also provide recommendations on how to mitigate such risks during implementation.

Key Recommendations

1. Government to implement risk-based legislation in which healthcare applications of AI are classified as high-risk
2. Healthcare safety and quality regulatory institutions must work cooperatively with consumers, clinicians, and AI developers to address critical regulatory grey areas.
3. Requirements of AI healthcare software must include the assessment of the employed algorithms against minimum standards of safety and quality.
4. AI algorithms must be vetted against bias. This is a fundamental step to prevent algorithms from exacerbating existing discriminatory practices towards marginalised groups.
5. The government should leverage data and consumer protection legislation to engage with consumers, clinicians, and developers in creating a solid data governance framework for AI software in healthcare.

6. Legislation must protect consumers against data being used for perverse profiteering.
7. Development of resources to increase AI literacy in the Australian population, particularly its applications within healthcare provision.
8. AI integration in healthcare to happen under the stewardship of the Australian Commission on Safety and Quality in Healthcare. The National Safety and Quality Health Service Standards must be amended to address generative AI use and its implications explicitly.

CHF's advocacy in automated decision making and artificial intelligence

CHF has been involved in advocating for consumers regarding Automated Decision Making (ADM) and artificial intelligence for several years, including:

- Advocating for the inclusion of consumer perspectives in the safety and quality of **Electronic Clinical Decision Making Support (ECDS)** software in February 2022¹. Our issue paper - developed through extensive consumer consultation - highlighted the importance of governance and oversight of AI at the federal government level. This ensures that guidelines related to AI (safety, quality, privacy, and security) are developed at a national level.
- Organising webinars to educate and collect feedback from consumers on ADM and AI, such as the June 2022 "**Automated Decision Making and Artificial Intelligence in Health**"² webinar, which focused on the importance for consumers to have solid data guardianship frameworks when their data is collected and utilised by AI software.
- Since 2019, CHF has been a member of the **Australian Alliance for Artificial Intelligence in Healthcare (AAiH)**.³ The alliance presents several priorities for developing regulatory frameworks for AI in healthcare. In October 2023, AAiH released a new updated roadmap, calling for healthcare consumers to be engaged in co-designing AI healthcare services and systems. The roadmap

¹ "GP Data and Electronic Clinical Decision Support | Consumers Health Forum of Australia." 2023. Chf.org.au. June 15, 2023. <https://chf.org.au/publications/gp-data-and-electronic-clinical-decision-support>.

² "Webinar: Automated Decision Making and Artificial Intelligence in Health | Consumers Health Forum of Australia." 2022b. Chf.org.au. June 2, 2022. <https://chf.org.au/events/webinar-automated-decision-making-and-artificial-intelligence-health>

³ Dorricott, Pippa. n.d. "AI Can Revolutionise Healthcare but Only with a National Plan | Ai Health Alliance." <https://aihealthalliance.org/2023/11/16/ai-can-revolutionise-healthcare-but-only-with-a-national-plan/>.

also calls for developing consumer-focused AI healthcare literacy guidelines and resources.

- Two of CHF's **Special Interest Groups** (SIGs), the Digital Health SIG and Safety and Quality SIG, have provided various policy input regarding AI over the years, focusing on the importance of data safety, guardianship and the need for a legislated framework.
- **CHF Australia's Health Panel (AHP)** is an interactive platform dedicated to collecting Australians' views about the state of the nation's healthcare system. CHF is designing a survey through AHP to collect healthcare consumer views and attitudes towards AI in healthcare. This will include trust and confidence in generative AI software aiding clinical decision-making, concerns with using generative AI in healthcare, and assessing current familiarity with generative AI software. The survey will We plan for the findings from this survey to be available before September 2024. CHF will submit the findings of this report in a separate submission to the Select Committee on Adopting AI.

AI Governance

Legislative Frameworks: Australia currently lacks an overarching regulatory framework for using AI. While specific components and uses of AI are regulated by existing legislation, many grey areas must be addressed. Currently, AI is mainly self-regulated, and the limited guardrails are designed by AI technology developers with conflicting priorities. On the one hand, they are eager to avoid legal litigation, but on the other hand, they are driven by profits to increase the scope of use of their software.

It is, therefore, up to governments to ensure that processes are in place to audit AI software. Similar to what happens in cybersecurity – where penetration testing is a standard practice to find vulnerabilities in a computer system – AI auditing should be standard practice and a fundamental step in detecting weaknesses and features that can cause harm to consumers. Additionally, mandatory requirements for AI auditing should also come with clear standards for what counts as an impartial, comprehensive AI audit.

In the case of adverse effects produced by AI, there is currently no clear framework to establish where the responsibility ultimately lies. Should consumers be negatively affected by AI - for example, by receiving wrong health advice - there is no clear pathway for them to report the issue, nor a clear path for institutions to hold AI software developers accountable.

CHF sees a role for developers in participating in the creation of mechanisms that guarantee safety and quality. Developers know their product better than anyone and should be included as essential stakeholders. But self-regulation alone is not enough to ensure that health consumer interests are protected. In an unregulated environment, the vested interests of AI developers would inevitably prevail over consumers. Without safety and quality standards, well-meaning actors trying to use generative AI for positive change would also run the risk of building unethical products. This could happen due to governance groups commissioning generative AI algorithms without a deep understanding of the algorithmic consequences their product may have and the generative AI companies they have hired to build the software defaulting to a profit-driven approach to coding. Government action is, therefore, paramount in ensuring the presence of an independent regulatory body. To be effective – and to ensure they reflect the needs of Australian society – the regulatory framework must be developed in partnering with consumers.

Other nations are at much more advanced stages of establishing such a framework. The EU Artificial Intelligence Act – for example – is a risk-based regulatory framework in which AI is regulated in a way that is directly proportional to the risk it brings to consumers. The Act recognises that AI could harm the health and safety of healthcare consumers and focuses on the importance of preventing and mitigating the safety risks that AI technology may pose⁴.

CHF calls for risk-based legislation to be adopted in Australia, in which healthcare applications of AI are classified as high-risk. Risk-based frameworks are routinely implemented in Australia. The PBS drug scheduling, for example, is a risk-based framework that sees drugs that pose higher risks to consumers being held to stricter regulations⁵. A risk-based framework would allow Australia to maximise AI technology's benefits while minimising risks.

⁴ European Commission. "Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts." Brussels, Belgium: European Union, April 21, 2021 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206>

⁵ Therapeutic Goods Administration. 2022. "Scheduling Basics of Medicines and Chemicals in Australia." Therapeutic Goods Administration (TGA). June 21, 2022. <https://www.tga.gov.au/scheduling-basics-medicines-and-chemicals-australia>.

Safety and Quality

Regulatory grey areas: Currently, Australian regulations only partially protect consumers against the risks of AI use in healthcare.

For example, some technology and software used in clinical settings, such as note-taking software, are exempted from TGA approval⁶ on the assumption that their only function is to collect patient notes. But what happens when AI is introduced? AI can listen to conversations and generate fully formed patient notes. But whose responsibility will it be if the software makes a mistake in generating medical notes? And how will risks related to privacy and security issues be mitigated if AI transmits health information through unknown servers?

CHF recommends that government bodies work cooperatively with consumers, clinicians, and developers to address critical regulatory grey areas.

Bias: Research has shown that the output of AI is affected by gender and racial biases⁷. Adopting AI in healthcare without vetting algorithms for bias means that high-quality, inclusive services may become less so because of the introduction of AI software. Instead of closing the current gaps, health services risk exacerbating existing discriminatory practices with algorithms that are not equipped to cater to a diverse, multicultural population. Furthermore, the output of AI will likely not be explicit about these biases, presenting their output to clinicians and consumers as plausible and evidence-based (see paragraph below about AI hallucinations).

CHF calls for safety and quality consideration to include the assessment of algorithms, which must be vetted against bias. Standards must be created that will ensure the safety and quality of algorithms used in Australian healthcare, with a particular focus on ensuring that they don't reinforce commonly held biases and health disadvantages, especially towards Aboriginal, Torres Strait Islander and CALD communities.

AI hallucinations: Generative AI is known to "hallucinate," meaning that the language model will generate content that is not verified or accurate. The information that generative AI produces does not come with a warning advising the reader on what

⁶ Therapeutic Goods Administration. 2022. "Is My Software Regulated?" Therapeutic Goods Administration (TGA). June 21, 2022. <https://www.tga.gov.au/resources/resource/guidance/my-software-regulated>.

⁷ Lyell, David, Ying Wang, Enrico Coiera, and Farah Magrabi. "More than algorithms: an analysis of safety events involving ML-enabled medical devices reported to the FDA." *Journal of the American Medical Informatics Association* 30, no. 7 (2023): 1227-1236. <https://doi.org/10.1093/jamia/ocad065>

content has been drawn from highly reputable evidence and what content was simply made up: generative AI relies on the reader's ability to have enough expertise to discriminate between the two. This cannot be assumed when a health consumer reaches out to generative AI for health information, or when a clinician searches online for a solution to a complex issue.

For example, Siontis et al. (2024) have shown how generative AI software Chat GPT (Version 3.5) has recommended the implantation of a subcutaneous defibrillator in a patient immediately after cardiac surgery. Such a step is not something that any cardiac surgeon would recommend, as it would not only interfere with surgery site healing but would also not be able to work appropriately so soon after surgery⁸. When questioned by clinicians on what evidence it used to recommend such a step, Chat GPT provided references to study results and journal articles that did not exist. This is an enormous safety risk for consumers: not only could they be provided with inappropriate care, but they could also follow wrong, harmful health advice at home, which is presented to them as the fruit of rigorous scientific study.

Data, Privacy and Ethics

Data safety and privacy are of paramount importance for consumers. AI is bound to collect extensive amounts of data when utilised in clinical settings, and consumers have the right to know where and how this data is stored and used.

Data safety: Specific legislation that safeguards data collected and used by AI throughout its entire lifecycle, from data collection to storage to data elimination, needs to be implemented. Recent episodes of data breaches in Australia have highlighted how any weakness can result in vast amounts of identified, sensitive data being leaked. The stakes are exceptionally high with healthcare data. As such, CHF calls for the government to leverage protections already in place - such as data and consumer protection legislation – to create a comprehensive data safety framework for AI in healthcare that will protect consumers.

Data guardianship: Legislation must clearly state who can access data collected via AI and how data is collected, stored and used. Healthcare consumers' consent for data use must be informed and dynamic. Informed consent means that healthcare consumers must be notified if the data is about to be used in ways that depart from the original use to which they consented. Dynamic consent means that consumers

⁸ Siontis, Konstantinos C., Zachi I. Attia, Samuel J. Asirvatham, and Paul A. Friedman. "ChatGPT hallucinating: can it get any more humanlike?." (2024): 321-323.
<https://doi.org/10.1093/eurheartj/ehad766>

must be able – at any time – to modify or withdraw their consent for their data being used. Clear procedures must be in place for data disposal, either by ensuring the safe destruction of the data or ensuring that the entity the data is transferred to for custody and ownership also meets all safety and privacy requirements. To do all this, CHF calls for a comprehensive framework of independent data guardianship equipped with the tools to allow for swift, decisive action in case of data and privacy breaches.

Perverse profiting from acquired data: Legislation must also not avoid the challenges of legislating protections that prevent data from being profited from. For example, private health insurers must be denied access to this data, and it should be illegal for a private insurer to refuse a policy or a claim based on AI-collected data. This scenario sounds like a far-removed scenario, but it isn't. In the United States, several health insurers (Humana, Cigna, UnitedHealthcare) are already facing class actions for allegedly deploying AI technology to deny claims⁹.

Consumer complaints: Consumers must be able to raise complaints to the regulator when negatively affected by AI.

Consumer Engagement

Raising consumer AI literacy: As discriminative and generative AI become increasingly established as productivity tools, it will become crucial to provide consumers with the tools to learn what AI can and can't do for them.

Generative AI poses significant challenges and concerns, as it can churn out vast amounts of information, which is presented very confidently but is not necessarily accurate as it might be affected by biases and hallucinations described earlier in this submission. This poses a risk, particularly in the context of health information, as consumers may be influenced to make decisions about their health on data that seems credible but is potentially false or even harmful.

As AI becomes increasingly popular, first-time users will attempt to use generative AI without knowing its capabilities and associated risks. Countries like Finland have started to build tools to minimise such risk: the University of Helsinki's "Elements of AI"¹⁰ course – for example – is attempting to bridge that gap with six learning

⁹ "AI Lawsuits against Insurers Signal Wave of Health Litigation." n.d. News.bloomberglaw.com. <https://news.bloomberglaw.com/health-law-and-business/ai-lawsuits-against-insurers-signal-wave-of-health-litigation>.

¹⁰ "A Free Online Introduction to Artificial Intelligence for Non-Experts." n.d. English. <https://www.elementsofai.com/>.

modules that explain what AI is, what issues it can solve, its real-world applications, how it works and how it mimics neural networks as well as its implications.

CHF recommends that a similar free course be developed in Australia or adapted from similar tools already developed overseas, with a specific focus on the benefits and limitations of AI in healthcare. This is necessary to ensure that the content is widely accessible to Australia's diverse communities and that its contents are tailored to Australian society. By providing accessible and understandable information about AI, consumers can navigate the digital landscape more confidently, making informed decisions about their health and well-being and avoiding major pitfalls.

If provided with the appropriate resources, an independent health consumer peak body such as CHF would be best placed to ensure that the themes of such a learning tool are relevant to consumers and written in accessible language.

Clinicians must understand AI and engage with consumers about AI: They must familiarise themselves with AI and how it can be used in healthcare. This would allow clinicians to use AI to benefit healthcare consumers by providing more accurate diagnoses, more streamlined decision-making processes, and more personalised care. Better AI literacy in clinicians would also positively impact the safety of AI: familiarity with AI will ensure clinicians can critically evaluate the recommendations and processes generated by the AI software. Just as with other technological advancements, clinician active engagement is paramount in ensuring that the benefit of new technology is utilised safely and effectively.

Healthcare providers will also play a pivotal role in bridging the gap between the complexities of AI and healthcare consumers' understanding. As trusted sources of medical expertise, clinicians can provide a safe place to have informed discussions with consumers regarding the impact of AI on their healthcare journey. Clinicians can empower consumers to navigate through these changes and allow consumers to actively participate in determining their treatment plans.

For all the above reasons, CHF recommends that efforts be made to ensure that generative AI is introduced under the stewardship of the Australian Commission on Safety and Quality in Healthcare. CHF recommends that the National Safety and Quality Health Service Standards (NSQHS)¹¹ be amended to reflect and explicitly address generative AI use and its implications.

¹¹ Australian Commission on Safety and Quality in Health Care. 2021. "National Safety and Quality Health Service Standards (Second Edition) | Australian Commission on Safety and Quality in Health Care." Australian Commission on Safety and Quality in Health Care. May 2021.

Generative AI is bound to produce considerable change in how health services run, encompassing every facet of the NSQHS standards, from clinical governance to risk management to how health services communicate and partner with consumers. As such, the NSQHS standards would be the first port of call for health services wanting to find guidance on safely integrating generative AI into their processes.

Lastly, the amendment of the NSQHS standards must happen in partnership with consumers. Chapter 2 of the NSQHS establishes that the healthcare workforce must partner with consumers in planning, delivering, measuring and evaluating systems and services and that consumers must be partners in their care to the extent they choose. Therefore, establishing standards of use of generative AI in healthcare must also be consistent with this approach.

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1 Dorricott, Pippa. n.d. “AI Can Revolutionise Healthcare but Only with a National Plan | Ai Health Alliance.” <https://aihealthalliance.org/2023/11/16/ai-can-revolutionise-healthcare-but-only-with-a-national-plan/>.

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