



Department of Health and Aged Care

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

October 2024

Al must support psychiatrists to deliver mental healthcare

About the Royal Australian and New Zealand College of Psychiatrists

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) is responsible for training, educating and representing psychiatrists in Australia and New Zealand. The RANZCP has more than 8500 members, including around 6000 qualified psychiatrists.

Introduction

The RANZCP welcomes the opportunity to contribute to the Department of Health and Aged Care's (DoHAC) consultation on <u>Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review</u> (the consultation). The recommendations contained within this submission are based on consultation with the RANZCP Committee for Evidence Based practice, Committee for Research and the Committee for professional practice, which are made up of (community members and) psychiatrists with direct experience working in mental healthcare. As such, the RANZCP is well positioned to provide assistance and advice about this issue due to the breadth of academic, clinical and service delivery expertise it represents. The RANZCP acknowledges the difficulty balancing Al adoption and legislation. The RANZCP recommends a pragmatic approach that considers the perspective of psychiatrists, GPs, other clinical specialists, consumers and the healthcare system.

Key recommendations

There is an opportunity to support psychiatrists to deliver high quality mental health services with the implementation of AI tools. To ensure that the implementation of AI remains safe and supports the mental health sector, the RANZCP recommends:

- The creation of an AI healthcare oversight body, including representation from psychiatrists and people with lived experience of mental health.
- Al guardrails are used to uphold security and privacy for consumer data, including when used to train Al models.
 - Legislation that outlines the requirements for storage, usage and training of AI tools on consumer health information is required.
 - Offshore storage of consumer health information adds risks due to the differences in data protection and privacy laws.
- All usage in mental healthcare should support psychiatrists to deliver mental healthcare, as opposed to removing their autonomy and agency.
- Psychiatrists and other clinicians must be protected by legislation if they refuse to implement Al tools in their practice.
- Enhanced consent from both the psychiatrist and consumer must be gathered prior to any usage of AI
 in mental healthcare. This includes informing consumers about the difficulty of removing data once it
 exists within the AI tool.
- The creation of a robust regulatory framework that includes evaluation mechanisms and error reporting for AI tools in healthcare.
- Al usage in mental health should be used to improve equitable access to mental health services. Failing
 to do so will only further isolate priority populations, including First Nations people and culturally and
 linguistically diverse communities.

Consultation Questions

1. How can Al benefit health care in Australia and how can we measure and deliver these benefits?

The use of AI in mental healthcare has the potential to benefit the workforce, consumers and health system. A fundamental task that can be supported by AI is administration. Language learning models can take notes based on audio recordings, summarise notes and highlight patterns in records. They can also arrange appointments, plan calendars, write emails and other clerical duties that may be time consuming to clinicians. Outsourcing these tasks to AI may lead to practice where psychiatrists and other clinicians can spend more time supporting consumers during consultations and in team-based care.

Al can be used to provide consumer insight, digital phenotyping and personal sensing utilise an individuals' data and artificial neural networks to infer and contextualise behavioural information.[1] It can be used to link physical activity and movement data to mental health outcomes, informing a clinician's recommendations. This improved monitoring opportunity will provide insights that are otherwise unavailable.

Al can provide 24/7 support through chat bots and Al monitoring tools. Firstly, consumers can seek guidance at any time by conversing with a chat bot, which if trained appropriately can triage the consumer, refer them, or support the consumer with recommendations. Al's can even be trained to administer cognitive behavioural therapy and offer psychoeducation, coping strategies, mindfulness exercises and crisis management.[2]

Auditing mechanisms for AI use needs to be regulated and implemented. Assessment of usage will help to ensure that usage is clinically effective, sustainable ensures usage aligns with ethical standards.

There is a critical need for evaluation and implementation for AI in healthcare. The RANZCP recommends the development of an evaluation framework that establishes the criteria to assess AI tools. A grading system can help clinicians, consumers and practices/hospitals understand the capabilities, robustness and security of different AI tools.

All future policy, strategy and evaluation needs insight from clinicians from psychiatrists and other specialties, and consumers.

2. Can Al improve access to care, and what regulations could be amended or added to enable this?

Remote consultations that are supported/facilitated by AI will help rural, regional and remote consumers access services. Consumers that do not have access to in person consultations due to their geography can be supported by AI through chatbots providing guidance and services.

Al could also reduce the amount of required in person consultations for some consumers, as data and insights can be gathered remotely with digital phenotyping and person sensing. This means that when in person consultations are required, more data can be gathered in preparation, reducing subsequent visits.

Outsourcing the administrative duties to AI will reduce the administrative burden on clinicians. In turn this will create more capacity.

3. What risk does AI pose to consumers/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?

The use of AI in the mental healthcare system poses numerous risks that need to be mitigated and navigated with the consultation of clinicians and consumers.

Data privacy and security remains a risk to digital records of any nature. Legislation must ensure that consumer records remain encrypted and secure, as storage of consumer data within AI tools may compromise data security principles. Each state and territory have different health records laws (founded on Australian privacy principles [3]); there needs to be a singular legislation that is implemented nationally.

All systems are trained on 'training data' and the robustness of training data is paramount to performance. By implementing rigorous data quality measures, legislation can help mitigate risks associated with All deployment and enhance trust in these technologies.

Over-reliance on AI could lead to situations that \diminish the role of human judgement and oversight. The RANZCP recommends that legislation ensures clinicians are given authority over AI tools.

Due to the complexity of implementing AI into existing mental healthcare systems, there will be a lag before its support is felt in the system. There are also financial costs associated with customising existing tools to operate within the confines of local regulation. As such, information on costs and impacts needs to be available to consumers and organisations.

Al tools may alter the dynamics of consumer care, potentially diminishing the experience of the consumer and it is important in the mental health sector that consumers feel heard and understood. Although Al tools can mimic human interaction, their presence may have negative impact on consumer experience by reducing trust in clinicians.

4. What factors are important for rural and regional Australia when assessing the benefits, risks, and safety of Al? Are there other communities that face specific risks when implementing Al-driven health care? What considerations should be made to ensure all Australians have access to the benefits of Al?

All chatbots offer an opportunity to improve access for rural, regional and remote communities, though there are technological barriers to implementing them. Internet access is required to engage with All chatbots online and some remote communities do not have the technology to sustain online connections required. Prior to implementing All in healthcare, infrastructure must be improved and made more equitable.

Guardrails and other legislation need to ensure equitable access and representation of First Nations peoples and culturally and linguistically diverse communities within the development of AI tools.

5. Should health care professionals have a choice about whether they use Al as part of their work?

The agency and autonomy of psychiatrists and other clinicians needs to be maintained in organisations that choose to implement AI tools. Legislation should ensure that AI adoption is voluntary for all clinicians and needs to protect them that choose not to use AI tools from the organisations implementing AI tools in mental health care. Clinicians should be protected by legislation if they choose to overrule AI tools. Clinicians that opt to adopt AI tools need to be able to report errors and highlight concerns to their organisation.

6. What unique considerations are specific to AI in health care, and why? Should the government address them through regulatory change?

Unique considerations for use of AI in healthcare includes clinical efficacy, safety of use and informed consent. The RANZCP recommends that legislation and evaluation frameworks are created to ensure that AI tools are improving clinical efficacy, and their use is in the consumers and clinicians' best interests. Clinical efficacy may also impact safe and professional practice. It is important that consumer safety remains the priority of legislation.

Enhanced consent for AI use is a unique consideration for AI in the mental healthcare setting, consumers need to be fully informed of AI usage, including what data will be recorded, how it will be stored and if they what can be done should they revoke this consent. Failing to do so risks compromising consumer confidence and trust in mental health services. In mental healthcare, the trust, confidence and buy in of the consumer can be integral to delivering mental health services, as such it is paramount to mental health that AI guardrails outline consent requirements for AI usage.

7. How does the use of Al differ in healthcare settings compared to general or other sectors such as finance, education, etc.?

The use of AI will require tight regulation to mitigate risks and ensure that consumer safety is prioritised. Given the sensitive nature of mental health assessments and the potential for AI tools to influence treatment decisions, robust oversight is essential to avoid negative outcomes and protect vulnerable populations. AI generates it decisions on aggregated medical research which excludes some groups in individual studies for very good reason) and developers need to be aware of the potential for widening inequity rather than reducing it.

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?

An oversight body should be created with representation from mental health professionals and people with lived experience. This body should advise in policy and legislation relating to the implementation of AI in healthcare. A secondary body may also be required which investigates and evaluates AI usage in healthcare.

11. Should humans be able to overrule a finding or decision made by AI?

Yes, AI tools should be a supplementary aspect of mental healthcare delivery and not a replacement for human judgement. All psychiatrists must be protected by legislation to overrule findings or decisions 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 Al product?

Human oversight is essential for AI usage in mental healthcare. It is important to maintain consumer safety and clinical efficacy. Identifying errors and misdiagnoses will always be required for AI to operate safely.

13. Should errors made by AI be reported? If yes, how should they be reported?

Reporting of errors needs to be facilitated and supported by legislation. Al tools can generate false outputs and errors. In a clinical setting, errors may cause severe risk to consumer safety and it is paramount that prior to their implementation, evaluation and assessment frameworks are designed and implemented.

In a practice/hospital setting, psychiatrists need to be able to raise concerns and report errors to colleagues and seniors. Were necessary these must be raised to the provider of the AI tools to prompt revision of the AI tool.

At a systems level, clinicians need to be able to raise major or recurring errors to an oversight body that has the power and expertise to investigate the nature of the errors and advise practices and direct the providers to make updates or remove the tool from practice. This legislation needs to be consistent across jurisdictions and not reliant on state and territory legislation.

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?

The usage of AI should be clearly signposted to clinicians, consumers, stakeholders and all other community members when used in mental healthcare. Ethical concerns surrounding fully informed consent must be prioritised, so should the privacy and security of consumer health data. Prior to any AI usage in healthcare, both the clinician and the consumer must be given agency over the usage of AI during throughout a consumer's interaction with the health system. Consent must be informed, and the revocation of such consent must result in immediate termination of AI usage for that consultation. Consumers and clinicians must be protected by guardrails to allow them to revoke consent at any point.

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?

Al usage in mental healthcare must be approached with caution. It is important that the implementation of Al is strictly monitored to maintain consumer safety and data security. Regulations need to be restrictive, with the potential for easing regulation following successful implementation and adoption. Risk mitigation and safe implementation needs to be the focus of the DoHAC.

16. What protections are needed for consumer data used or generated by Al that are different for health care?

Guardrails need to be specific about consumer data due to the sensitivity of health information. Consumer information used as training data must maintain consumer anonymity. Removing personally identifiable information from AI systems once it has been used as training material can be difficult and, in some cases, impossible [3]. As such it is paramount that guardrails ensure enhanced and fully informed consent is required from all individuals whose health information might be used to train AI, with all consent being an 'opt in' approach.

17. Is it acceptable for developers of AI products to use consumer data to develop their products or to sell consumer data collected from use of AI?

The acceptability of using consumer data to develop AI products or sell that data depends on several key factors. First, informed consent is crucial; consumers must be fully aware of how their data will be used, with explicit permission given for development, research, or sale. Additionally, if data is anonymised and cannot be traced back to individuals, its use may be more acceptable, but risks of re-identification still pose a concern.

Regulatory compliance is essential, as developers must adhere to laws like the Privacy Act, that govern data privacy and usage. Ethical considerations also play a significant role; selling consumer data can erode trust in healthcare systems, making consumers wary of how their information is handled. While using data can enhance AI tools and improve health outcomes, the DoHAC must balance these benefits against potential harms to privacy and equity.

18. Should your healthcare information be kept in Australia? If yes, would your view change if this reduced ability to access advances in Al made overseas?

Consumer health information must be handled with strong protections under Australian privacy and data protection regulations. In a scenario where data storage occurs offshore, such as in international research projects, the RANZCP recommends a balanced approach which upholds strict privacy standards. International collaboration must only occur when it is in the best interest of the consumer.

If you have any questions about the use of AI in mental healthcare, please contact Nicola Wright, Executive Manager, Policy, Practice and Research Department via nicola.wright@ranzcp.org or on (03) 9236 9103.

References

- 1. Onnela J-P, Rauch SL: Harnessing smartphone-based digital phenotyping to enhance behavioral and mental health. Neuropsychopharmacology 2016, 41:1691-1696. Fulmer R, Joerin A, Gentile B, Lakerink L, Rauws M. Using Psychological Artificial Intelligence (Tess) to Relieve Symptoms of Depression and Anxiety: Randomized Controlled Trial. JMIR Mental Health. 2018 Dec 13;5(4):e64.
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