RACGP
Royal Australian College of General Practitioners

Healthy Profession.
Healthy Australia.

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Department of Health and Aged Care
Digital Futures Team
e: DigitalFutures@health.gov.au

Dear Digital Futures team

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

Thank you for providing the Royal Australian College of General Practitioners (RACGP) an opportunity to provide a response to the AI legislation and regulation review. Please see below the RACGP's response to the consultation questions.

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

The RACGP is optimistic about potential administrative efficiencies for GPs, for example in appointment scheduling, billing, and clinical note-taking. This has potential to strip away non-clinical work, which could reduce occupational burnout in GPs and allow them to focus on the delivery of high-quality care. However, inherent to this is the risk that it will actually increase low-value work for GPs through task substitution (eg, checking AI outputs).

Clinical applications could improve diagnostic accuracy and efficiency and enhance personalised therapeutic approaches, though there are caveats to these applications given the risks to patient safety. Measuring and delivering these benefits might involve supporting general practices to embed AI infrastructure.

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

Yes, AI can potentially improve access to care. In general practice for example, this will most likely be through supporting administrative tasks that would free up clinical time. Efforts must be made to ensure that using AI in any healthcare setting does not come at the expense of care quality. Humans must remain in the loop and retain ultimate decision-making responsibility.

There is a risk that the use of AI will push both consumers and healthcare providers to engage in unnecessary testing and treatment. This would place a significant burden on an already overstretched healthcare system, and divert resources away from patients who require medical care.

Efforts to regulate the use of AI within the healthcare context might involve revisions of the Medical Indemnity Act, Health Insurance Act, Healthcare Identifiers Act, My Health Record Act and other legislative instruments as required, with consideration given to the introduction of a new AI Act to provide overarching guidance.

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?

AI is prone to making errors that could affect the meaning and accuracy of information, which poses an obvious high risk to patient safety in a clinical context. Clerical applications in general practice might pose a lower risk,

though there is a chance that they will also handle sensitive data and might be subject to data breaches that could compromise patient confidentiality. Consumers should be informed about a general practice's use of AI applications where their personal data might be collected or used by the tool.

AI systems might be trained on data with inherent biases. For example, particular patient groups might be underrepresented in training data, which could result in the AI making poor or erroneous decisions that affect patient safety. This has particularly serious implications for vulnerable and minority groups.

There is also a risk that healthcare professionals will over-rely upon AI outputs and neglect to check these for errors.

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?

AI has the potential to fill service gaps, increase access to care, and standardise care across health settings, which might be of particular benefit in rural and regional settings. However, AI should be used to supplement existing care pathways; not replace them, as this may entrench existing health inequalities.

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

Yes, this should be the purview of the individual health care practitioner.

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

The risk to patient safety can be high with many clinical applications of AI. Inaccuracy of outputs could contribute to unnecessary, ineffective, or delayed treatment, with potentially fatal consequences. This might be addressed through regulatory change as specified above.

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

As above; the use of AI might pose a greater risk to human safety in healthcare than in other sectors.

7. 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?

The RACGP recommends a dedicated body to oversee the use of AI in Australia in our Position statement on AI in primary care, available at https://www.racgp.org.au/advocacy/position-statements/view-all-position-statements/clinical-and-practice-management/artificial-intelligence-in-primary-care. This new body could be responsible for enforcing regulatory powers outlined in a cross-economy AI Act. The RACGP would like to see GP representatives involved in an advisory capacity.

8. Are there any specific changes to existing healthcare laws that would address AI-related harms or help AI to in be used safely?

As stated in our October 2024 submission to the TGA on their AI regulation consultation paper, the RACGP is in favour of closing regulatory gaps as they apply to software-based medical devices that rely on AI models and systems.

9. Which international approaches should we consider, if any, that are specific to health care?

The RACGP is supportive of international harmonisation approaches to the regulation of AI in healthcare. The EU AI Act should inform this work.

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

Yes, a healthcare practitioner such as a GP should always be able to overrule a finding or decision made by AI if it contradicts their own clinical judgement, for which they will be ultimately responsible under the law.

11. 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?

Having a human in the loop is essential to the delivery of safe clinical care. While AI technologies will improve in their predictions and recommendations over time, research has repeatedly demonstrated their fallibility and all AI outputs should be carefully checked.

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

Errors would have to be communicated to healthcare professionals in such a way that this information can be used at the point of care.

13. Should there be transparency about when AI is involved in health care, and should consent be requested from the consumer or health care professional?

Yes, informed consent should be sought from both the consumer and health care practitioner, and they should be provided an opportunity to opt out of involvement in AI.

14. Generative AI may be developed for general use yet used in health care. Should generative AI developed have any special treatment, regulatory or otherwise?

In our October 2024 submission to the Department of Industry, Science and Resources, the RACGP stated that regulators should consider banning the use of AI models/systems that have not been specifically trained on medical/pharmacological data in a diagnostic/therapeutic context.

15. What protections are needed for patient data used or generated by AI that are different for health care?

Healthcare data is both personal and sensitive and its protections should reflect this.

16. 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?

This might be considered an inappropriate secondary use of data. The RACGP's resource 'Three key principles for the secondary use of general practice data' (available at https://www.racgp.org.au/running-a-practice/security/managing-practice-information/secondary-use-of-general-practice-data) has more information on this topic.

17. 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?

Ideally, sensitive healthcare data should be stored securely in Australia, regardless of whether this impacts our ability to access AI technologies available elsewhere.

18. Are there any specific safety considerations that have not been raised elsewhere?

No.

The RACGP appreciates the opportunity to provide comment on the area of AI in healthcare and related regulatory measures. If you have any questions or wish to follow up on this response, please contact Stephan Groombridge (Manager, RACGP eHealth and Quality Care) at stephan.groombridge@racgp.org.au.

Yours sincerely

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