16th October 2024

Mr. Blair Comley PSM
Secretary
Department of Health and Ageing
digitalfutures@health.gov.au

Dear Mr Comley

Re: Submission to Public Consultation on Safe and Responsible AI in Health Care

The Royal Australasian College of Medical Administrators (RACMA) welcomes the opportunity to provide feedback on the "*Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review.*"

The Royal Australasian College of Medical Administrators – RACMA – is the only specialist medical college that trains doctors to become specialist medical leaders and managers. Our education programs, including our accredited flagship Fellowship Training Program, aim to equip doctors with the leadership and management skills needed to influence and lead Australasian healthcare systems with the explicit aim of improving health outcomes for all peoples of Australia and Aotearoa New Zealand.

RACMA has over 1500 Members across Australia, Aotearoa New Zealand, and Hong Kong. The strength of RACMA is its members, who, through the skills of system leadership, clinical governance and workforce management, strive to lead for change and ensure the delivery of safe and quality healthcare for all. The RACMA membership is a highly regarded medical leadership group as demonstrated by our members' roles and responsibilities within those health systems across the Public Service Sector, Private Health, Primary Health Care, Medical Insurance, Tertiary Sector, Military and beyond. Some of the pivotal roles carried out by our Members include Chief Executives, Chief Medical Officers, Medical Directors, Heads of Departments, Regulatory and Quality Assurance Body Executives and Chairs of key industry and research committees.

RACMA members occupy roles in the health system that consider whole-of-system delivery and are unique in their leadership of health and medical professionals, funding and financing, systems and processes. The impact of that leadership is demonstrated in all public and private settings, primary and tertiary settings, and system reform

1. Benefits of AI in Health Care

AI offers substantial potential to revolutionise healthcare by improving efficiency, accuracy, and access. Its ability to assist in clinical decision-making, automate routine tasks, and analyse large datasets holds promise for both healthcare providers and patients.

- **Clinical Efficiency and Decision Support**: AI can streamline administrative tasks, such as managing patient records and automating documentation, which allows healthcare professionals to focus on patient care. AI tools, such as predictive algorithms and diagnostic aids, can enhance clinical decision-making by supporting early detection of medical conditions. AI is already being used in areas like cancer screening and retinal

scans for diabetic retinopathy. AI can analyse data that typically requires specialist input, improving both accuracy and timeliness of diagnoses.

- **Supporting Health Care Workforce**: AI can address workforce challenges by reducing administrative burdens, thereby mitigating burnout and cognitive overload among clinicians. AI scribes, for example, transcribe consultations and prepare care plans, freeing clinicians to spend more time with patients.

- **Access to Care**: AI can enhance healthcare access, particularly in rural and remote areas. Telemedicine and AI-driven diagnostic systems can help bridge healthcare gaps, and AI has the potential to assist populations with language barriers by providing real-time translations of medical information.

However, while the benefits are significant, they must be measured against established health key performance indicators (KPIs) and clinical standards to ensure that AI adoption improves patient outcomes and healthcare delivery.

2. Risks of AI to Patients and Health Care Professionals

The use of AI in healthcare presents unique risks that must be carefully managed, particularly concerning patient safety and data privacy.

- **Patient Safety and Over-reliance on AI**: A key concern is the risk of over-reliance on AI systems by healthcare professionals. While AI can assist in decision-making, it should not replace clinical judgment. AI systems may produce erroneous outputs, particularly when their decision-making process is opaque. This can lead to mistakes if clinicians rely too heavily on AI recommendations without verification. Algorithms trained on biased datasets could disproportionately affect underrepresented populations, leading to misdiagnoses or inappropriate treatment.

- **Ethical and Privacy Concerns**: AI's use in healthcare raises ethical concerns, particularly around informed consent and patient autonomy. The complexity of AI can challenge traditional informed consent models, as patients may not fully understand how AI influences their care. Additionally, AI introduces significant privacy risks, particularly in handling sensitive health data. Robust privacy protections are crucial to safeguard against breaches and misuse.

- **Automation Bias**: Clinicians might defer to AI outputs without critically evaluating them, especially in high-stress environments. Safeguards are needed to ensure that healthcare professionals maintain oversight and accountability when using AI-assisted decision-making tools.

3. Specific Considerations for AI Use in Health Care

AI in healthcare must be governed by principles of safety, privacy, security, and transparency, particularly given the high stakes involved.

- **Clinical Governance and Human Oversight**: AI deployment must be supported by clinical governance frameworks that ensure human oversight. Clinicians should retain the ability to overrule AI-driven decisions, particularly in critical care scenarios. "Human in the loop" must be a standard, ensuring that professionals remain involved in significant AI-supported decision-making.

- **Informed Consent and Transparency**: AI's role in healthcare decision-making must be transparent to both patients and clinicians. Informed consent processes should be updated to reflect AI technologies' complexities, ensuring patients are aware of AI's involvement, its impact on their care, and the risks involved.

- **Data Privacy and Sovereignty**: The handling of health data by AI systems requires stringent privacy protections. RACMA recommends that health data remain within Australia to mitigate the risks of international data transfers and to safeguard against potential cyber threats.

4. Governance and Regulatory Recommendations

To ensure the safe and responsible use of AI in healthcare, the following governance and regulatory measures are recommended:

- **Strengthening Clinical Governance**: AI must be integrated into clinical governance frameworks, with regular audits, risk assessments, and incident reporting to identify and mitigate AI-related risks. These systems should align with existing clinical risk management structures.

- **Creation of a Dedicated Oversight Body**: RACMA supports the creation of an independent body to oversee AI use in healthcare. This body would ensure that AI systems meet stringent safety, ethical, and clinical standards, and certify AI tools for healthcare use.

- **Transparency in AI Reporting**: RACMA advocates for mandatory AI error reporting systems, similar to clinical incident reporting. This will enhance accountability and enable continuous improvement of AI technologies.

- **Data Security and Patient Privacy**: Legislative updates are needed to ensure that patient data used in AI systems is managed securely, and patients have clear rights regarding its use. Certification schemes for AI tools used in healthcare should ensure robust privacy and security measures.

5. Recommendations for Regulatory and Legislative Change

RACMA recommends the following regulatory and legislative changes to address AI-related challenges in healthcare:

- **Amendments to Health Care Legislation**: Health care laws should be updated to address AI risks, especially in high-risk areas such as mental health, emergency care, and data protection. These updates should clarify AI's role in clinical decision-making and protect clinicians from liability in cases where AI malfunctions.

- **Human Oversight in AI Decisions**: Legislation should mandate human presence in AI-driven health decisions. Fully automated systems should not be used in clinical settings where the risks are high.

- **International Benchmarks**: Australia should consider international approaches to AI regulation, such as those from the European Union and North America, to inform the development of local frameworks.

Conclusion

AI in healthcare presents both opportunities and risks. While it can enhance clinical efficiency and patient care, it raises significant ethical, safety, and governance challenges. RACMA stands ready to support efforts to refine AI regulation, ensuring it serves to improve health outcomes while maintaining the highest standards of clinical governance and patient safety.

The Royal Australasian College of Medical Administrators appreciates the opportunity to contribute to this important consultation on the safe and responsible use of AI in health care. We look forward to continued engagement on these issues and welcome any further discussion. Should you require additional information or wish to explore any aspects of this submission in more detail, please do not hesitate to contact us.

Yours sincerely,

Professor Erwin Loh
President
Royal Australasian College of Medical Administrators (RACMA)