



The Royal Australian and New Zealand College of Radiologists®

Response to Australian Human Rights Commission AI Consultation

Thank you for providing the Royal Australian and New Zealand College of Radiologists (RANZCR) with the opportunity to respond to the Australian Human Rights Commission 'Artificial Intelligence: Governance and Leadership' consultation.

About the Royal Australian and New Zealand College of Radiologists

The Royal Australian and New Zealand College of Radiologists (RANZCR) is the peak body advancing patient care and quality standards in the clinical radiology and radiation oncology sectors. It represents over 4,000 medical specialist members in Australia and New Zealand.

RANZCR's role is to drive the appropriate, proper and safe use of radiology and radiation oncology medical services. This includes supporting the training, assessment and accreditation of trainees; the maintenance of quality and standards in both specialties; and workforce mapping to ensure we have the specialists available to support the sectors in the future.

Clinical radiology relates to the diagnosis or treatment of a patient through the use of medical imaging. This includes the use of plain X-ray, computed tomography (CT), magnetic resonance imaging (MRI), ultrasound and nuclear medicine and PET to produce images that are interpreted by a radiologist to aid them and other clinicians in the diagnosis and treatment of their patients. This includes pre-natal care (obstetric ultrasounds), to neonates and children through to the elderly, from dating scans to non-invasive treatment for cancer. Radiology touches people throughout their life.

Radiation oncology is a medical specialty involving the controlled use of radiation to treat cancer either for cure, or to reduce pain and other symptoms that it may cause. Radiation therapy is involved in the treatment of almost all cancers, anywhere in the body, and can benefit one in two cancer patients.

Introduction

Clinical radiology and radiation oncology are two areas of medicine that are already using advanced informatics and technology, and we are ready to adopt and contribute to machine learning (ML) and artificial intelligence (AI) programs, when they are mature and robust. RANZCR agrees that AI has enormous potential if we develop and use this wisely, but could also do significant harm if left unregulated.

RANZCR welcomes the proactive approach taken by AHRC in considering and seeking to manage the far-reaching human rights implications of AI.

RANZCR commenced working on AI in 2017. Our initial focus was to understand the landscape and to inform our membership of advances in artificial intelligence and machine learning and to prepare the ground for the significant changes we foresee. In November 2018, RANZCR organised Australia's first AI in healthcare conference called Intelligence18, which brought together international experts in AI to discuss the latest developments and implications for privacy and the practice of medicine.¹ Also in 2018, RANZCR established an Artificial Intelligence Working Group (AIWG) to consider the implications of machine learning and artificial intelligence on the disciplines of clinical radiology and radiation oncology and plan a response that includes:

¹ <https://www.eiseverywhere.com/ehome/index.php?eventid=349139&>

- how this technology can be applied appropriately and judiciously in the best interests of patients.
- appropriate education for members, trainees, stakeholders and the public

The AIWG has three main streams of work relating to AI including ethics, the development of AI usage standards, and the skills that clinical radiologists and radiation oncologists will need to have to thrive in the future.

RANZCR is proud to be the first professional body in healthcare that has developed a set of ethical principles for AI, through the AIWG. Having reviewed the literature globally and discussed the issues with experts in AI in medicine, the AIWG developed a set of eight ethical principles which are intended to ensure that AI and ML tools at all times reflect the needs of patients, their care and their safety, and they should respect the clinical teams that care for them. The ethical principles cover eight areas which include:

- Safety
- Avoidance of Bias
- Transparency and Explainability
- Privacy and Protection of Data
- Decision-Making on Diagnosis and Treatment
- Liability for Decisions Made
- Application of Human Values
- Governance.

Our draft ethical principles have recently been released for feedback from our members and stakeholders.²

RANZCR would appreciate an opportunity to meet with the AHRC to discuss these issues further and how we might collaborate on this important matter.

One important issue that the AIWG encountered when considering the forthcoming changes is the importance of clearly defining ML, AI, and associated terms to ensure there is a common understanding for deliberations. We have produced a short paper to inform members about the current status of AI, called the State of Play which we will share with the AHRC once finalised.

Consultation Questions

1. What should be the main goals of government regulation in the area of artificial intelligence?

RANZCR believes that current standards and regulations are inadequate to deal with the unique challenges of artificial intelligence in health care, and that robust, AI specific regulation is required to ensure the safety of patients and the teams that care for them.

Australia also needs to embed an ethical approach to use of AI at this early stage which is complemented by regulation and standards applying to relevant industries. We do not wish to stymie robust and proper development of algorithms, ML and AI development, and we feel that there is an urgency to address this now, not at some time into the future.

² <https://www.ranzcr.com/documents/4821-ranzcr-ethical-principles-for-ai-in-medicine-consultation/file>

The government has a broader role in this area, and regulation can only be considered alongside robust and proportionate standards which is a major focus for RANZCR in all its facets, the implications for healthcare management and reimbursement (the role of the Federal Department of Health), and the difficult issue of medicolegal liability around AI. These issues can inform the development of regulatory frameworks, and regulations in turn can guide practice in these areas.

A further consideration is workforce readiness, which is more of a policy consideration but may also require regulation.

2. Considering how artificial intelligence is currently regulated and influenced in Australia:

a. What existing bodies play an important role in this area?

In healthcare, the TGA regulates the market access of medical devices and medicines and will have responsibility for AI tools being brought to market. The TGA has two main roles; to determine which AI tools are allowed to be marketed in Australia, and to define the regulatory requirements of safe, effective, and ethical AI.

The TGA is currently consulting on the need for specific regulations around software as a medical device, and AI. RANZCR will provide a response.³

b. What are the gaps in the current regulatory system?

RANZCR has spoken to a range of government bodies about AI over the past two years. We have been disappointed at the lack of readiness to tackle the challenges and capitalise on the opportunities that AI will bring. The current regulatory system is completely unprepared to deal with these challenges. All regulators have a central role in protecting users, preventing discrimination, ensuring transparency in algorithmic design, and safeguarding personal data and privacy. RANZCR strongly believes it is time to move beyond just principles to get explicit on rights and responsibilities and in particular there is an urgent need to consider the safety of patients, the protection of their personal data and the safety of the teams that care for them.

In relation to healthcare, RANZCR is pleased that the TGA has commenced work on regulation of AI used in medicine.²

RANZCR would welcome all major government departments and agencies being asked to consider the implications of AI and to develop a plan for how it will be utilised in their industries.

3. Would there be significant economic and/or social value for Australia in establishing a Responsible Innovation Organisation?

As is indicated above, RANZCR feels there are gaps that needs to be addressed, therefore we strongly support creating a Responsible Innovation Organisation.

AI is different from previous cycles of innovation and requires an entity with overarching responsibility to govern it. Over the past two years, RANZCR has noticed a significant gap in AI readiness across government departments and agencies that we engage with.

³ <https://www.tga.gov.au/consultation/consultation-regulation-software-including-software-medical-device-samd>

Regulation of AI requires a comprehensive approach across many professional bodies, industry groups, and governmental organisations. As mentioned earlier, regulation in AI is not only concerned about user safety and rights, but also diverse issues such as standards, funding and reimbursement, and medicolegal responsibility. RANZCR would like to see the proposed 'Responsible Innovation Organisation' bringing together all of the relevant stakeholders in this area, and providing the leadership that is currently lacking in this discussion.

RANZCR agrees that the Responsible Innovation Organisation could add value as described on page 13 of the consultation document, and with the proposed functions and powers on page 16.

4. Under what circumstances would a Responsible Innovation Organisation add value to your organisation directly?

RANZCR anticipates the RIO adding value by:

- supporting and enabling the adoption of an ethical approach to the use of AI in medicine,
- supporting the development of a robust regulatory framework to protect the public (and patient safety in healthcare),
- assisting with complaints resolution for AI in healthcare,
- supporting the development and adoption of standards for AI research and deployment,
- advising government on the legal framework, particularly in relation to the distribution of medicolegal responsibility between AI vendors (the developers), clinicians (the users), and healthcare governance groups (the purchasers).
- supporting the development and adoption of standards for data management and privacy, and
- advising health regulators in relation to AI adoption and deployment.

5. How should the business case for a Responsible Innovation Organisation be measured?

Not applicable to our response.

6. 6. If Australia had a Responsible Innovation Organisation:

- a. What should be its overarching vision and core aims?
- b. What powers and functions should it have?
- c. How should it be structured?
- d. What internal and external expertise should it have at its disposal?
- e. How should it interact with other bodies with similar responsibilities?
- f. How should its activities be resourced? Would it be jointly funded by government and industry? How would its independence be secured?
- g. How should it be evaluated and monitored? How should it report its activities?

Given that AI will be used across a range of established industries, there is considerable scope for overlap with existing regulatory authorities and agencies. The Responsible Innovation Organisation must prioritise collaboration with regulators and standard setting bodies across multiple sectors of the economy. RANZCR would

especially like to see it working effectively with healthcare regulators and stakeholders to provide advice and support relating to the research, adoption and deployment of AI and ML tools in health.