Regulation of Artificial Intelligence in Medicine

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The Royal Australian and New Zealand College of Radiologists®

RANZCR Position Statement on the Regulation of Artificial Intelligence in Medicine

RANZCR

Position Statement

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About RANZCR

The Royal Australian and New Zealand College of Radiologists (RANZCR) is committed to improving health outcomes for all, by educating and supporting clinical radiologists and radiation oncologists. RANZCR is dedicated to setting standards, professional training, assessment and accreditation, and advocating access to quality care in both professions to create healthier communities.

RANZCR creates a positive impact by driving change, focusing on the professional development of its members and advancing best practice health policy and advocacy, to enable better patient outcomes. RANZCR members are critical to health services: radiation oncology is a vital component in the treatment of cancer; clinical radiology is central to the diagnosis and treatment of disease and injury.

RANZCR is led by clinicians who are democratically elected by the membership. The ultimate oversight and responsibility for RANZCR is vested in the Board of Directors. The work of the RANZCR is scrutinised and externally accredited against industry standard by the Australian Medical Council and the Medical Council of New Zealand.

Our Vision

RANZCR as the peak group driving best practice in clinical radiology and radiation oncology for the benefit of our patients.

Our Mission

To drive the appropriate, proper and safe use of radiological and radiation oncological medical services for optimum health outcomes by leading, training and sustaining our professionals.

Our Values

Commitment to Best Practice

Exemplified through an evidence-based culture, a focus on patient outcomes and equity of access to high quality care; an attitude of compassion and empathy.

Acting with Integrity

Exemplified through an ethical approach: doing what is right, not what is expedient; a forward thinking and collaborative attitude and patient-centric focus.

Accountability

Exemplified through strong leadership that is accountable to members; patient engagement at professional and organisational levels.

Leadership

Exemplified through a culture of leadership where we demonstrate outcomes.

Code of Ethics

The Code defines the values and principles that underpin the best practice of clinical radiology and radiation oncology and makes explicit the standards of ethical conduct the College expects of its members.

1. INTRODUCTION

1.1 Purpose and scope

The regulation of medical devices, software and treatments is a cornerstone of safe medical practice. Given the recent technological advances in the field of artificial intelligence (AI) and the possibility of the rapid dissemination of this technology throughout the Australian and New Zealand healthcare systems, the development of an effective and fit for purpose regulatory framework for intelligent medical software must be considered an urgent public health priority.

RANZCR is a leading advocate for the safe application of AI technology in medical practice, holding the position that the use of this technology promises to greatly improve patient care, provided appropriate safeguards are in place.

RANZCR has three streams of work relating to AI in medicine:

- Ethical principles relating to the use of AI in medicine
- Standards relating to the research and implementation of AI in clinical radiology and radiation oncology
- Revisions to the clinical radiologist and radiation oncologist curricula and post-fellowship upskilling to ensure that both specialties are prepared to incorporate AI into their clinical practice.

RANZCR is also a member of the Australian Ethical Health Alliance (AEHA) and therefore collaborates with the AEHA in implementing substantive ethical principles and monitoring its progress against those principles[i].

AI technology is classified by many regulators as a type of "software as a medical device" [ii] [iii] Australian regulators (the Therapeutic Goods Administration) have developed guidance around the regulation of AI technology, which came into effect on 25 February 2021. New Zealand has yet to adopt a formal approach to regulating AI devices, however the Ministry of Health is undertaking some early thinking on this matter. The regulatory environment for AI systems is rapidly evolving and is likely to change further in the future [iv].

The introduction of AI into clinical practice will create opportunities to enhance patient care but will see a range of new risks and responsibilities which need to be clarified. This will inevitably result in new responsibilities for AI manufacturers, practices, hospitals and clinicians. RANZCR is advocating for effective regulation that provides clarity for AI developers and the rest of the healthcare system while safeguarding patient care. Accordingly, outlined below are a set of principles and recommendations to guide the development of a robust regulatory framework for AI technology in medicine. The safe implementation of AI into clinical care is supported by robust RANZCR standards [v] which address the development and deployment of AI tools, safety measures such as governance and audit and patient consent and privacy matters.

1.2 Definitions

College means The Royal Australian and New Zealand College of Radiologists.

Member means a member of the College.

AI specific definitions can be found at Appendix One.

2. REGULATORY PRINCIPLES

1. The use of artificial intelligence in medicine should be guided by a strong ethical framework, such as RANZCR's Ethical Principles for Artificial Intelligence in Medicine, with proportionate regulation and robust standards.
2. Current regulatory mechanisms have not evolved alongside recent breakthroughs in AI technology, and may no longer be fit for purpose.
3. RANZCR is committed to ensuring the safety of all patients requiring clinical radiology and radiation therapy tests, procedures or treatments.
4. AI systems, once implemented, are low cost and are more easily adopted on a massive scale compared to other medical technologies and devices. While these systems have the potential to offer significant benefits in healthcare, this must be carefully balanced against potential risks posed by these technologies.
5. RANZCR is committed to strong governance surrounding new and unproven technologies and minimising related medicolegal risks.
6. Regulation for safe use of AI systems needs to be developed in the context of the skills of the medical practitioners who will ultimately be the end users. It must also complement existing regulatory systems, avoiding duplication and not introduce uncertain or impractical requirements. These considerations are essential for safe implementation of these systems and managing the medicolegal implications of this technology.
7. The level of evidence required to demonstrate the safety and efficacy of an AI system should be commensurate to the level of risk associated with the use of that AI system.
8. A robust and fit for purpose regulatory framework is the appropriate mechanism to manage the safety and medicolegal risk of AI systems, relative to their degree of autonomy.

3. RECOMMENDATIONS

Given these principles, RANZCR believes that the regulation of AI systems should ensure the following prior to the AI systems coming to market:

1) AI systems are only applied to clinically justified tasks that enhance patient care, in a fair and equitable manner, as required for the provision of safe and efficient medical care for all patients.

"Clinically justified tasks" are those where the AI system is applied to the provision of safe and efficient clinical practice. Inappropriate uses of medical AI systems may include (but are not limited to):

- Systems which demonstrate undesirable biases leading to inequity.
- Systems which are not required for the provision of healthcare services, such as mining patient records for commercial purposes like targeted advertising.
- Systems which bypass the provision of healthcare services and circumvent the role of medical professionals, such as "direct to consumer" sale of AI systems, particularly where they contradict the recommendations of the clinicians providing patient care.

2) AI systems must be proven to an appropriate standard of evidence and deemed safe for the population and *in the clinical context* in which they are intended to be applied. The level of evidence required to demonstrate the safety and efficacy of an AI system should be commensurate with the level of risk associated with the use of that AI system.

In particular, any AI system which can alter the clinical outcomes of patients should have been explicitly shown, in the clinical context of use, to be safe. Patient outcomes when the AI system is in use must be equal or superior to current clinical practice.

The evidence of safety must be obtained in the clinical context of intended use. There are many scenarios where experimentally proven systems may underperform when applied in a clinical environment, for example due to unexamined interactions between the system and the users [vi].

3) The AI system must be labelled accordingly (with description of its training and testing populations and the clinical context in which it is intended to be used) when placed on the market. It is also important to include the limitations of AI systems when placing them on the market, including the clinical contexts in which the AI system should not be used, and the level of supervision required for users to satisfy medico-legal obligations and professional responsibilities.

End users of the AI system will need to consider the contexts in which the system was trained and tested and assess its suitability for their local patient population. This requires transparency in labelling. The practice or hospital at which the AI system is being implemented will need to define the roles and responsibilities of management, doctors and other members of the clinical team.

There are many possible ways that clinicians and other healthcare workers may interact with AI systems with the misapplication and misuse of these systems leading to possible adverse outcomes. For example, in the setting of mammography, the misuse of computer aided diagnosis systems has been implicated in the poor clinical performance of these tools [vii]. Adequate initial information and assessment will allow an informed clinical decision maker to take into account the reliability of an AI system when considering how it reached a specific conclusion.

All software should be labelled with a version number and regulatory authorities should provide clarity on acceptable mechanisms for updating AI systems and the associated labelling requirements for significant changes to these systems.

4) To ensure safety, the AI manufacturer must provide advice about ongoing monitoring of the systems with clearly defined monitoring responsibilities for both the clinical users and the manufacturers or vendors. This includes a contact point for assistance at the manufacturer.

All medical devices and interventions require ongoing monitoring, but this is particularly important in the case of artificial intelligence systems. These systems are highly dependent on the type and volume of the data used to train them, and if the target population (patients attending the hospital or practice) deviates from the training population, performance can deteriorate. This could occur in clinical environments when the AI system is applied to a new population (for example, if a radiology practice opens a new clinic at another location) or if the existing population characteristics change (population drift, for example as the population ages).

Without clearly defined mechanisms that address the ongoing monitoring and migration of these systems, a system which was shown to be safe during a regulatory approval process can become unsafe.

5) The AI manufacturer must provide advice on how to address system failures.

The dependence of AI systems on their training data can lead to unexpected adverse events, where an AI system is asked to act on “out-of-context” samples, for example patients with characteristics that were not present in the training data. Severe adverse outcomes such as clusters of incorrect predictions or clinically adverse events with severe complications could occur. Given the likelihood that these events will recur (when similar patients are seen in the future), explicit mechanisms to identify, diagnose, and prevent these failures are required to ensure safety.

As an example, the missed diagnosis of major/central pulmonary embolism should be very low (<1%), as an undiagnosed major embolism has a high mortality rate. A missed obvious pulmonary embolism should be an indication of a severe adverse event.

In such situations a pre-defined process under appropriate clinical governance should be implemented. In the initial phase, consideration should be given to whether the AI system should be taken offline and if so a continuity plan or strategy should be deployed to ensure safe clinical operations when the AI system is offline. The subsequent process plan should include a clinical investigation that involves clinical radiologists, the referrer(s), and any relevant technical staff (including vendor), much like a clinical Morbidity and Mortality process. This process should also engage and provide feedback to the AI system manufacturer/vendor.

An AI tool must operate in such a way that if the AI tool fails, it should not impact on the broader IT systems in the health environment in which it is deployed, including systems such as Electronic Medical Records (EMR) or Radiology Information Systems/Picture Archiving Systems (RIS/PACS).

RANZCR is committed to working with regulators, policymakers and manufacturing stakeholders in Australia and New Zealand to ensure that artificial intelligence can be brought to market safely to enhance patient care.

4. APPENDIX ONE – DEFINITIONS

Technical definitions for artificial intelligence are available from the International Organization for Standardisation (ISO) [viii], general definitions are included below.

Artificial Intelligence:

"An AI system is a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. AI systems are designed to operate with varying levels of autonomy." [ix]

Explainable Artificial Intelligence (XAI)

"A set of processes and methods that allows human users to comprehend and trust the results and output created by machine learning algorithms"[x]

Algorithm

"A series of instructions for performing a calculation or solving a problem, especially with a computer. They form the basis for everything a computer can do, and are therefore a fundamental aspect of all AI systems." [xi]

Bias

"A systematic deviation from the truth." [xii]

Variance

"A random deviation from the truth." [xii]

Expert system

"A computer system that mimics the decision-making ability of a human expert by following pre-programmed rules, such as 'if this occurs, then do that'. These systems fuelled much of the earlier excitement surrounding AI in the 1980s, but have since become less fashionable, particularly with the rise of neural networks." [xi]

Machine learning

"One particular form of AI, which gives computers the ability to learn from and improve with experience, without being explicitly programmed. When provided with sufficient data, a machine learning algorithm can learn to make predictions or solve problems, such as identifying objects in pictures or winning
at particular games, for example." [xi]

Supervised Machine Learning

"A type of ML for which the algorithm changes based on data with known labels. In clinical radiology to evaluate medial images, supervised ML is a repetitive process to match images to existing labels." [xii]

Unsupervised Machine Learning

"In supervised ML the algorithm is fed an unlabelled dataset (i.e. without answers). In this case the algorithm groups the image findings into clusters based on one or more features it "learns"." [xii]

Deep learning

“A more recent variation of neural networks, which uses many layers of artificial neurons to solve more difficult problems. Its popularity as a technique increased significantly from the mid-2000s onwards, as it is behind much of the wider interest in AI today. It is often used to classify information from images, text or sound.” [xi]

Neural network

“Also known as an artificial neural network, this is a type of machine learning loosely inspired by the structure of the human brain. A neural network is composed of simple processing nodes, or ‘artificial neurons’, which are connected to one another in layers. Each node will receive data from several nodes ‘above’ it, and give data to several nodes ‘below’ it. Nodes attach a ‘weight’ to the data they receive and attribute a value to that data. If the data does not pass a certain threshold, it is not passed on to another node. The weights and thresholds of the nodes are adjusted when the algorithm is trained until similar data input results in consistent outputs.” [xi]

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