



# Ethical Principles for Artificial Intelligence in Medicine



The Royal Australian and New Zealand  
College of Radiologists®

# Ethical Principles for Artificial Intelligence in Medicine

RANZCR

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Disclaimer: The information provided in this document is of a general nature only and is not intended as a substitute for medical or legal advice. It is designed to support, not replace, the relationship that exists between a patient and his/her doctor.

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## About the College

The Royal Australian and New Zealand College of Radiologists (RANZCR) is a not-for-profit association of members who deliver skills, knowledge, insight, time and commit to promoting the science and practice of the medical specialties of clinical radiology (diagnostic and interventional) and radiation oncology in Australia and New Zealand.

The College is led by clinicians who are democratically elected by the membership. The ultimate oversight and responsibility for the College is vested in the RANZCR Board of Directors.

The work of the College 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.

### 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.

## INTRODUCTION

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The nine ethical principles outlined below guide the development of professional and practice standards regarding the research and deployment of machine learning systems (ML) and artificial intelligence tools (AI) in medicine.<sup>1</sup> These tools should at all times reflect the needs of patients, their care and their safety, and they should respect the clinical teams that care for them.

These principles are intended to guide all stakeholders involved in research or deployment of ML and AI including developers, health service executives and clinicians. They are also designed to complement existing medical ethical frameworks (referenced on page 3), which do not adequately address the issues likely to emerge from use of ML and AI in medicine.

In order to bridge this gap, RANZCR has developed nine ethical principles specifically to guide the following:

- development of standards of practice for research in AI tools
- regulation of market access for ML and AI
- development of standards of practice for deployment of AI tools in medicine
- upskilling of medical practitioners in ML and AI, and
- ethical use of ML and AI in medicine.

All stakeholders should take heed of all the ethical principles for AI in medicine, noting that some will have greater applicability to them.

## PRINCIPLE ONE: SAFETY

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Although ML and AI have enormous potential, a range of new risks will emerge from ML and AI or through their implementation.

**The first and foremost consideration in the development, deployment or utilisation of ML or AI must be patient safety and quality of care, with the evidence base to support this.**

## PRINCIPLE TWO: PRIVACY AND PROTECTION OF DATA

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Healthcare data is amongst the most sensitive data which can be held about an individual. Patient data must not be transferred from the clinical environment<sup>2</sup> at which care is provided without the patient's consent, approval from an ethics board or where otherwise required or permitted by law. Where data is transferred or otherwise used for AI research, it must be de-identified such that the patient's identity cannot be reconstructed.

**A patient's data must be stored securely and in line with relevant laws and best practice.**

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<sup>1</sup> RANZCR has adopted definitions relating to AI and ML (see Appendix 1), pending publication of an internationally agreed standard.

<sup>2</sup> A clinical environment is any area relating to patient treatment or diagnosis and may include physical or secure virtual environments.

## PRINCIPLE THREE: AVOIDANCE OF BIAS

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ML and AI are limited by their algorithmic design and the data they have access to, making them prone to bias. As a general rule, ML and AI trained on greater volumes and varieties of data should be less biased. Moreover, bias in algorithmic design should be minimised by involving a range of perspectives and skill sets in the design process and considering how to avoid bias.

The data on which ML and AI is based should be representative of the target patient population on which the system or tool is being used. The characteristics of the training data set and the environment in which it was tested must be clearly stated when marketing an AI tool to provide transparency and facilitate implementation in appropriate clinical settings. Particular care must be taken when applying an AI tool to a population, demographic or ethnic group for which it has not been proven effective.

**To minimise bias, the same standard of evidence used for other clinical interventions must be applied when regulating ML and AI, and their limitations must be transparently stated.**

## PRINCIPLE FOUR: TRANSPARENCY AND EXPLAINABILITY

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ML and AI can produce results which are difficult to interpret or replicate. When used in medicine, the doctor must be capable of interpreting the basis on which a result was reached, weighing up the potential for bias and exercising clinical judgement regarding findings.

**When designing or implementing ML or AI, consideration must be given to how a result that can impact patient care can be understood and explained by a discerning medical practitioner.**

## PRINCIPLE FIVE: APPLICATION OF HUMAN VALUES

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The development of ML and AI for medicine should ultimately benefit the patient and society. ML and AI are programmed to operate in line with a specific world view, however the use of ML and AI should function without unfair discrimination and not exacerbate existing disparities in health outcomes. Any shortcomings or risks in ML or AI should be considered and weighed against the benefits of enhanced decision making for specific patient groups.

**The doctor must apply humanitarian values (from their training and the ethical framework in which they operate) to any circumstances in which ML or AI are used in medicine, but they also must consider the personal values and preferences of their patient in this situation.**

## PRINCIPLE SIX: DECISION MAKING ON DIAGNOSIS AND TREATMENT

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Fundamental to quality healthcare is the relationship between the doctor and the patient. The doctor is the trusted advisor on complex medical conditions, test results, procedures and treatments who then communicates findings to the patient clearly and sensitively, answers questions and provides advice on the next steps.

**Whilst ML and AI can enhance decision making capability, final decisions about care are made after a discussion between the doctor and patient taking into account the patient's presentation, history, options and preferences.**

## PRINCIPLE SEVEN: TEAMWORK

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ML and AI will necessitate new skill sets and teams forming in research and medicine. It is imperative that all team members get to know each other's strengths, capabilities and integral role in the team.

**In order to deliver the best care for patients, each team member must understand the role and contribution of their colleagues and leverage them through collaboration.**

## PRINCIPLE EIGHT: RESPONSIBILITY FOR DECISIONS MADE

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Responsibility for decisions made about patient care rests principally with the medical practitioner in conjunction with the patient. Medical practitioners need to be aware of the limitations of ML and AI, and must exercise solid clinical judgement at all times. However, given the multiple potential applications of ML and AI in the patient journey, there may be instances where responsibility is shared between:

- The medical practitioner caring for the patient;
- Hospital or practice management who took the decision to use the systems or tools; and
- The manufacturer which developed the ML or AI.

**The potential for shared responsibility when using ML or AI must be identified, recognised by the relevant party and recorded upfront when researching or implementing ML or AI.**

## PRINCIPLE NINE: GOVERNANCE

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ML and AI are fast moving areas with potential to add great value but also to do harm. The implementation of ML and AI requires consideration of a broad range of factors including how the ML or AI will be adopted across a hospital or practice and to which patient groups, and how it might align with patients' goals of care and values.

**A hospital or practice using or developing ML or AI for patient care applications must have accountable governance to oversee implementation and monitoring of performance and use, to ensure practice is compliant with ethical principles, standards and legal requirements.**

## BROADER ETHICAL FRAMEWORKS

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Other ethical frameworks cover the expected approach and behaviour of medical practitioners when delivering care to patients and provide general guidance relating to the development and adoption of new technologies in medicine.

Medical practitioners in Australia are expected to practise in accordance with the Medical Board of Australia's Good Medical Practice: A Code of Conduct for Doctors in Australia and the <sup>3</sup>Australian Medical Council's Good Medical Practice.<sup>4</sup>

Medical practitioners in New Zealand are expected to practise in accordance with the New Zealand Medical Council's Good Medical Practice <sup>5</sup> and the Code of Ethics set by the New Zealand Medical Association.<sup>6</sup>

RANZCR has also developed a more explicit Code of Ethics for clinical radiologists and radiation oncologists.<sup>7</sup>

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<sup>3</sup> Medical Board of Australia (2014) <https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>

<sup>4</sup> Australian Medical Council (2009) <http://www.amc.org.au/about/good-medical-practice>

<sup>5</sup> New Zealand Medical Council (2016) <https://www.mcnz.org.nz/about-us/publications/good-medical-practice/>

<sup>6</sup> New Zealand Medical Association (2014) <https://www.nzma.org.nz/publications/code-of-ethics>

<sup>7</sup> RANZCR Code of Ethics <https://www.ranzcr.com/documents/3958-ethics/file>

## APPENDIX ONE: DEFINITIONS RELATING TO AI

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### Artificial Intelligence

“Technologies with the ability to perform tasks that would otherwise require human intelligence, such as visual perception, speech recognition, and language translation”.

From: Department for Business, Energy and Industrial Strategy, *Industrial Strategy: Building a Britain fit for the future* (November 2017), p 37 <sup>8</sup>

### 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.”

From: AI in the UK: Ready, willing and able? <sup>9</sup>

### 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 fueled much of the earlier excitement surrounding AI in the 1980s, but have since become less fashionable, particularly with the rise of neural networks.”

From: AI in the UK: Ready, willing and able?

### 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.”

From: AI in the UK: Ready, willing and able?

### 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.”

From: AI in the UK: Ready, willing and able?

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<sup>8</sup> Department for Business, Energy and Industrial Strategy. Industrial Strategy: building a Britain fit for the future [Internet]. GOV.UK. 2017 [cited 28 March 2019]. Available from: <https://www.gov.uk/government/publications/industrial-strategy-building-a-britain-fit-for-the-future>

<sup>9</sup> Select Committee on Artificial Intelligence. AI in the UK: ready, willing and able? [Internet]. Parliament.UK. 2017 [cited 28 March 2019]. Available from: <https://publications.parliament.uk/pa/ld201719/ldselect/ldai/100/100.pdf>

## 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.”

From: AI in the UK: Ready, willing and able?

