



## RANZCR Human Rights Commission Submission

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 'Human Rights and Technology' Project Consultation.

### About 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 members in Australia and New Zealand. RANZCR's role is to drive the appropriate, proper and safe use of radiological and radiation oncological medical services. This includes supporting the training, assessment, and accreditation of trainees; the maintenance of quality and standards; and workforce mapping.

Clinical radiology relates to the diagnosis, treatment or monitoring of a patient through the use of medical imaging. Diagnostic imaging (DI) uses plain X-ray, computerized tomography (CT), magnetic resonance imaging (MRI), ultrasound and nuclear medicine imaging techniques to obtain images that are interpreted to aid in the diagnosis and management of disease. In addition to their diagnostic role, clinical radiologists also provide treatments and use imaging equipment in an interventional capacity.

The specialty of radiation oncology focuses on the use of radiation to treat cancer and other diseases. Radiation therapy is an effective, safe and cost-effective method of treating cancer, and is involved in 40% of cancer cures. Unfortunately, while one in two cancer patients would benefit from radiation therapy, only about one in three will actually receive the treatment. One major reason for this is a lack of awareness about radiation therapy.

### Our collective future

We have a collective responsibility in seeking solutions to the challenges we now face. The key factor which sets AI apart from previous technological disruptions is its all-encompassing impact. AI will have an impact on all aspects of our society and will require a collaborative alliance to ensure AI safety, security and fairness. There will be specific roles and responsibilities for government, the private sector, and the research community in supporting this transition. Looking to the early advancements made in other jurisdictions – the US, EU, and UK approach – will be very important.

RANZCR welcomes the collaborative approach by the Australian Human Rights Commission through this consultation to explore the relationship between human rights and technology. The College also acknowledges and welcomes the Federal Government's early commitment to harness the digital transformation through the Digital Economy Strategy. The further \$30 million investment in May 2018 to work through the structural elements includes a Technology Roadmap, Standards Framework, and a national AI Ethics Framework.

Radiology and radiologists will have a key role in the way this technology is applied in the real world. In order to realise its full potential at each stage of the healthcare value chains, the profession needs to lead and, importantly, to collaborate in this transition. It is important to emphasise that we see a promising future with emerging technologies providing new opportunities to create value. But we do not underestimate the challenge ahead and the health workforce will need to be supported to adapt alongside the technology. This will require national leadership to spearhead an agenda which places people and patient safety first.

We've put in place early on our own structures to help guide the gradual transition of its utility in healthcare. In 2018, the RANZCR Faculty of Clinical Radiology formed a Clinical Radiology AI Working Group. This Group has been established to consider the implications of AI and machine learning for the discipline of clinical radiology and work towards providing appropriate education for College members, trainees, stakeholders, and the public. The Group will also

investigate how this technology can be applied appropriately and judiciously in the best interest of patients.

## Introduction

AI in healthcare is already being tested and promoted across a broad range of areas from disease detection, drug discovery and disease management to workflow in the delivery of health services. This submission focuses on how the profession of clinical radiology, and healthcare more generally, need to manage a digital health future and applications of AI ensure patient care and outcomes are best promoted.

One of the key components of success in this endeavour will be in ensuring the right controls are set early through an effective and appropriate regulatory framework. Developing a framework whereby AI solutions can be **developed, tested, deployed and monitored** in a way that assures public trust is vital. The pace of rapidly advancing AI means we need to be proactive about regulation and put in place early some required structures to address both current and future risks. An ethics first strategy is essential with required adaptive governance models underpinned by ethical and human rights principles.

For healthcare, applying a human rights framework in this context requires an approach as rigorous as those already applied to medical research and pharmaceuticals. There is investment initially in the research process to ensure compliance with basic ethical principles and guidelines followed by clinical trials conducted in phases to evaluate safety and effectiveness. Ethical oversight of research involving humans including through drug trials apply controls to ensure same standards of evidence and reasoning behind decisions. Applying a similar approach to AI would bring us closer to the legal and ethical framework required for the safe and effective implementation of AI systems.

Therefore, as a first key step, there is a need to instate a **national advisory committee on ethics** to manage the design, development, and deployment of new AI technologies in healthcare. However, as AI systems evolve over time, there is a greater regulatory requirement to properly manage **post-deployment monitoring**. This is particularly important because AI systems are not static entities, they evolve in response to data and with this their performance may alter. Building in this transparency requires a process whereby performance and any adverse impact are reported and documented. It may also be reliant on an appropriate localisation framework as the datasets used in development may be different to the data reflective of a local population.

Building further integrity measures to ensure these systems are transparent regarding their decision-making processes is important. This is more than the current discussion on algorithm explainability, it extends to which data has been used to make decisions. The unique interplay of AI and data and the potential for erroneous decisions requires an effective regulatory environment. Deciding what is acceptable and ensuring the combination of human and AI interaction is appropriately managed is required to avoid creating or reinforcing unfair bias.

## Radiology and AI

Radiologists play a vital role in patient care by providing accurate diagnoses, information about the stage and extent of disease and safe, effective treatment. As imaging technologies and clinical procedures have become more varied, complex and sophisticated, radiologists have adopted new technologies and modalities of care that benefit patients and support the entire health system.<sup>1</sup> While the role of radiologists will inevitably shift, AI will not replace radiologists,<sup>2, 3, 4, 5</sup> but will instead be utilised to enhance workflow and increase efficiency. AI will become an essential clinical support tool which has the potential to enhance all aspects of radiology.<sup>6 7 8</sup>

The emergence of AI presents its own set of opportunities and risks for the medical professions. Accelerated workflow, diagnostic error prevention,<sup>9</sup> and increases in productivity are just a few ways AI can provide benefit. Although advances in AI offer significant potential for automation,<sup>10</sup>

there are clear limitations. AI is currently a long way from diagnosing disease; however, it is expected the technology will augment clinical care and aid human decision-making in the near future.<sup>11</sup>

Technology has always shaped medicine, and much technological innovation within this field has been driven by patient-centred care.<sup>12</sup> RANZCR appropriately prioritises human rights principles and through a patient safety lens, our vision is to lead best practice in clinical radiology and radiation oncology for the benefit of patients and society.<sup>13</sup>

Human and patient rights are often complementary, and both focus on the importance of putting people at the forefront of decision-making. Determining what benefits AI will deliver is a uniquely human decision and it is essential humans understand how AI determines its output. As leaders in imaging informatics, radiologists are instrumental in safe, valuable AI implementation and are crucial in applying new technologies to practical medical use.

## **Governance model**

The need to create frameworks to ensure that AI training data and outputs are used 'for good' is building increasing policy momentum.<sup>14</sup> This includes practical solutions such as those offered through 'AI and data commons' an agile approach to assemble the required tools and datasets and support knowledge and expertise to launch new AI projects.<sup>15</sup> However, there seems to be less attention on developing a holistic governance framework and proposals instead offer the building blocks towards a more comprehensive approach.<sup>16</sup>

Throughout this submission, we focus on solutions to limit the risks while ensuring AI potential can be realised in healthcare and specifically radiology. We offer suggestions around the development of a national framework leveraging a range of legislative instruments to determine standards including the formation of new regulatory agency to control implementation and place a priority on ethics as the first key step. We place an important emphasis on patient safety as our overarching guiding principle and look to our own discipline and the required standards in radiology to guide. But we acknowledge that AI advancements will rewrite all parts of society and there are others in this space offering early important insights in establishing the required governance structure.

Work undertaken by members of the Ethics and Governance of AI initiative at Harvard University<sup>1</sup> sheds light on the difficulties in pursuing a holistic model at this time. The team offer a conceptual model to help us understand what a holistic governance framework for AI might involve. In this, they propose a layered model for AI governance that describes three layers of different governance approaches: the technical layer, the ethical layer, and the social and legal layer.<sup>17</sup> However, the difficulties in implementing such a model are constrained by a series of structural changes and these experts suggest that a more incremental approach is warranted.<sup>18</sup>

Instead, they suggest a focus on the development of governance elements and strategies, the interplay and interoperability between these building blocks in a layered model. They also focus on ways to build capacity to support policymakers and regulators engaging in the shaping and creation of evolving governance frameworks for AI. They offer principles to address some key areas of concern and provide tools to overcome some of these challenges. These are segmented into four areas of focus: addressing information asymmetries; building public-private partnerships; bridging the digital divide; and sustaining a competitive environment.<sup>19</sup>

This work provides some comprehensive solutions and guidance when working through a complex framework around AI implementation. It is an important contribution and fills many of the current policy gaps currently stalling progress, offering some solutions for policymakers and

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<sup>1</sup> Urs Gasser, Ryan Budish, Amar Ashar, members of the Ethics and Governance of AI initiative by the Berkman Klein Center for Internet & Society at Harvard University and the MIT Media Lab 1, under the direction of the ITU/BDT Regulatory and Market Environment Division, in collaboration with the ITU/BDT Telecommunication Division and under close coordination with the Chief of the ITU/BDT Infrastructure, Enabling Environment, and E-Applications Department.

regulators to bridge the knowledge gaps between governments and the private sector. Importantly it focuses on building capacity and developing knowledge exchange interfaces between regulators and experts and this, in our view, is where the current focus needs to be.<sup>20</sup>

## Consultation Questions

### Theme 1: Human Rights and Technology

#### Policy Summary

AI has the potential to provide benefit to all humans through improving the quality and efficiency of health care. In order to realise this potential, the area of ethics requires much more focus. This should be prioritised early in the design and development of AI applications with an increasing focus on regulatory requirements prior to the stage of post-deployment monitoring. Placing a strong priority now on laying the foundations for the ethical development of AI is vital. A policy imperative has to ensure the technology solves the right problems as the first priority. Important safety aspects to implementation in putting patients and those that understand healthcare (or relevant environments where AI may be deployed) at the forefront of decision making must now dominate the discussion.

#### Discussion

The ethical, social and economic facets stretch from transparency to privacy and liability and in managing the social impacts and potential for discrimination through to major jobs disruption and technological unemployment. Key values in building beneficial AI include **transparency**, **accountability**, and **positive impact**,<sup>21</sup> Advancing these values through technical design and collaborative policy leadership will help build morality and value into AI systems.<sup>22</sup> This will be imperative if we want AI systems to reflect our laws, policies, and virtues.<sup>23</sup>

It is clear that the **value of personal data** in the digital economy will continue to pose risks. This is reliant on consumers making informed choices about their personal data and negotiating very complex concepts. In overcoming such barriers, more structured solutions will be required including a need to regulate consumer rights. This would help bring a required focus to both algorithmic governance and consumer empowerment.<sup>24</sup>

**Privacy protections** around data is another key area of concern and this will continue to constrain utilisation of required appropriate data. In looking to solutions, new European regulation, effective May 2018, clearly defines and allows the usage of clinical data for sharing and research applications. This will help facilitate the development of clinically justified AI algorithms.<sup>25</sup>

There are further **integrity and reliability issues** to consider in healthcare whereby there is potential for these technologies to perpetuate existing healthcare inequalities.<sup>26</sup> Overcoming issues around inherent biases in the data used to train these systems is the key area for concern. For example, data used in randomised control trials can potentially be riddled with bias, particularly around gender and ethnicity, and these existing biases in healthcare data could lead to suboptimal results and further inequalities.<sup>27</sup>

The other key area for concern and most critical in healthcare relates to **overreliance** and human bias or the propensity as humans to do what we're told (or what we're told by computers) is problematic. The automation bias risk exists where we replace our own duty of care and vigilance by delegating it to the technology. The issue usually arises when the automation works well. This leads to omission errors or not detecting the issues that weren't found by the system brought about by an overreliance on the technology.<sup>28</sup>

Broader disparities and impacts can relate to knowledge and building consumer's digital trust and inequitable access. The more commonly used term AI refers to a range of different technologies and applications and the language itself may present barriers to understanding. Broader digital inequalities are also relevant as AI is reliant on substantial infrastructure and

data. Those areas with the most data and developed infrastructure are more likely to benefit and those without are more likely to be left behind.<sup>29</sup>

## Theme 2: Reinventing regulation and oversight for new technologies

### Policy Summary

There is a need for a long-term strategy and a broad framework to legislate AI and other new technology. Soft governance will not realise the accountability structure required. Instead, the ideation and development of AI requires a multidisciplinary collaborative approach. There is a need for a structure to connect researchers, developers, clinicians, and policy makers as well as law makers. While machine learning algorithms are still in the early stages of development and deployment, legal protections will be required over time as algorithms increasingly make decisions and these may extend to a right to explanation (while impossible at this time). The latter is the key focus of the EU's new General Data Protection Regulation while not specifically targeting AI.<sup>30</sup>

### Discussion

Forecasting the legal implications of AI in healthcare is made more complex due to the current implementation pace. New deep-learning technologies entering the healthcare space bring with them a host of unknowns. This gives rise to an urgent need for consideration around independent structures to regulate rapid development.

Data from AI poses new regulatory challenges as data from millions of patients will be required to develop and train AI tools. The legal and ethical obligations when **sharing data** and the required frameworks are yet to be established. In addressing these gaps there is a clear need for national regulations in establishing data controls, and in medicine enabling the required discipline oversight to AI implementation will be imperative.

Another key gap lies where we leverage the technology for **clinical decision support** albeit currently very limited. This relates to the interplay between AI and humans and particularly around accountability of decisions. The legal aspects relate to reasonable foreseeability as a key factor for negligence.<sup>31</sup> This is particularly important in healthcare where these systems fail and cause harm.

The potential for overreliance on systems and current opaqueness around where the liability falls when things go wrong- (doctor, developer, marketing entity or future regulator - is a key area for concern. Looking to how other jurisdictions are planning for this, in 2017, the [EU Parliament asked the EC to propose](#) liability rules on AI and robotics and recommended a code of ethical conduct.<sup>32</sup>

The overarching principle which should guide the regulation of AI is the importance of human responsibility. AI in healthcare should be viewed as a tool to assist medical professionals but not to replace them. It should be the doctor's responsibility to provide proper diagnoses and treatment, utilising, but not solely relying on AI results, to decrease the risk of automation bias. Clear ethics goals to guide algorithmic governance is required to advance the development of ethical AI and in establishing human responsibility as a focal point in AI implementation and usage.

In implementing a human rights-based approach to AI and advancing an **ethics in design** approach existing principles enshrined in the EU Charter of Fundamental Rights and UN Guiding Principles on Business and Human Rights will provide direction.

The AI and society work of the Berkman Centre also brings an important discussion to the legal aspects highlighting that we still have a lot of choices to make on the technology side and these can be informed by policy and law. Their work and focus on creating more transparency to increase reliability where AI systems are informing decisions particularly in law and medicine

and the broader human risk of working in autonomous mode.<sup>33</sup> Establishing the required practice parameters for collective decision making with machines to ensure the answer we derive involves human beings is seen as key.<sup>34</sup>

### **Theme 3: Artificial Intelligence, big data, and decisions that affect human rights**

#### **Policy Priorities**

Placing some required limits through regulation should be prioritised in directing machine-learning algorithm development. The policy focus must be on ensuring there is a robust regulatory regime to evaluate this technology and assess the safety implications prior to rollout. Current legislation is not consistent with the logic introduced by these systems. The overarching principle which should guide the regulation of AI is the importance of human responsibility. There is a need for an agreed standard and a clear signal to protect consumers and guide organisations in developing their AI capabilities.

A first key step is to instate a national advisory committee within an institutional framework on ethics for digital technology and AI. The authority needs to make sure there is adequate and safe evaluation before they implement any AI in clinical practice. There need to be clearer pathways in developing and implementing algorithms in clinical practice and, importantly, after deployment, there must be an appropriate process for monitoring the effectiveness of these machine-learning algorithms in practice.

#### **Discussion**

In terms of AI and its decision-making capabilities relevant to healthcare, it is important to note that there is plenty of hype around AI and its impact on the future radiology workforce. However, it is important to understand the limits of AI in health and healthcare. More realistic expectations arise from recognising that at present AI's major function is to automate basic repetitive functions, leaving the high-order cognitive skills to the expert.<sup>35</sup>

Establishing clear AI expectations and promoting appropriate regulatory oversight can help facilitate ethical and accountable practices. Major emphasis should also be placed on ensuring rigorous algorithm validation.<sup>36</sup> Reliable, fair results are fundamental in assuring the safety of patients. That's where establishing an ethical role in machine learning in healthcare is perhaps the most critical. There is a need to set goals shaped by human values for AI systems— what we will and will not allow; those areas where machine learning could be directed or trained to improve patient care.

Setting these limits in collaboration is key and professional leadership, across all medical disciplines, will be important. Building trust and transparency in from the outset to ensure the data inputs and desired outputs are aligned with human values will prioritise safe outcomes. There is a need for an appropriate testing environment to manage patient safety risks and ensure benefits are realised. As these systems evolve we will rely on the right regulatory tools to control and to direct effort to the important task of post-deployment monitoring.

Patients will benefit most from AI if radiologists serve a leading role in guiding the technologies that best enhance medical imaging diagnosis and treatment. It is therefore important that this testing also occurs in the environment in which these systems will be deployed. This will mean the best interests of patients are acted upon and high quality clinical care is provided. Clinical radiologists have a leadership role in terms of directing how the technology is applied and in realising its full potential as well as defining limits balancing efficiency and ethics.

Australia needs a proactive national policy to support the transition and this should be done in partnership. In partnership, there is an opportunity to establish a platform for gathering real-world evidence to determine AI algorithm effectiveness in clinical practice.<sup>37</sup>

Forming the right policy and standards coalitions, including internationally, will help to ensure that Australia is ready for the transition that needs to occur. Collaboration would include

governments, professional organisations, both local and international, and adequate advice and international expertise—this will formalise the structure for decision control and bring in the technology and healthcare professions at this vital early stage.

RANZCR's focus is on establishing standards and ethical processes to ensure the safe and effective use of technology when guiding implementation. This focus extends to practice ethics and supporting the profession and trainees in incorporating this technology into their clinical work. There will be a need for greater due diligence and care by radiologists and a focus on education about the risks and limits of AI is important to support this transition.

Establishing interdisciplinary research institutes with profession-led oversight<sup>38</sup> should be considered as a method of regulating responsible, beneficial AI development and use. The American College of Radiology (ACR) is currently working with the Medical Image Computing and Computer Assistance Intervention to develop AI algorithms to meet clinical needs.<sup>39</sup> Like ACR, RANZCR can bring a strong clinical perspective and experience to developing beneficial AI algorithms in healthcare. Shared expertise in radiology could also be utilised via international collaborations.

## **Contact**

For any questions or requests for further information relating to this submission, please contact the Chief Executive Officer, [REDACTED]

**The Royal Australian and New Zealand College of Radiologists**

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