New Zealand Medical Association
Te Hauora mō ngā Iwi Katoa

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Dr Lance Lawler
President
The Royal Australian and New Zealand College of Radiologists

By email: Kirsten.fitzpatrick@ranzcr.edu.au

RANZCR Position Statement on the Regulation of Artificial Intelligence in Medicine

Dear Dr Lawler

Thank you for inviting the New Zealand Medical Association (NZMA) to provide feedback on the above draft position statement. The NZMA is New Zealand's largest medical organisation, with about 5,000 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders. Our submission has been informed by feedback from our Board and Advisory Councils.

We welcome the development of this position statement on the regulation of artificial intelligence (AI) by the RANZCR. We agree that AI technology in healthcare is rapidly evolving and checks and balances are needed to ensure patient safety. New Zealand has yet to adopt a formal approach to AI in medicine. In the context of this regulatory vacuum, the development of this position statement represents a useful step. While it encapsulates the key principles that should underpin the regulation of AI in medicine, we believe it is most appropriately positioned as an overview of this complex area. In the following paragraphs, we expand on our views on the regulation of AI in medicine and hope that these might inform ongoing discussion and work by the wider sector in this important area.

As a starting position, we believe that it is helpful to consider the use of AI systems / algorithms as therapeutic products. Taking this perspective, the regulatory requirements become much clearer. A regulatory framework for therapeutic products could be adopted as a minimum standard for including AI systems / algorithms in medical care. This would mean that there should be a requirement for Medsafe (or an equivalent entity) to review the evidence on a particular product / system and make a judgement on its suitability for use in New Zealand. Our view is that the Ministry of Health should be the agency that holds stewardship for this process.

Currently, the implementation and use of AI algorithms in clinical care for risk stratification and allocation of resources is essentially an uncontrolled experiment in New Zealand, without even

the necessary structural review elements being included, let alone patient consent. We are aware of at least one DHB that has applied a CanRisk tool to the allocation of genetic testing and mammography for high risk patients where the tool is not being used as per the developer's recommendations, despite original literature warning about limitations in minority ethnic populations. The beta-testing process also showed it is not suitable for use in primary care. We are very concerned that there is no oversight of this process, and the DHB has implemented this programme despite concerns raised by GPs and known risks in Polynesian populations.

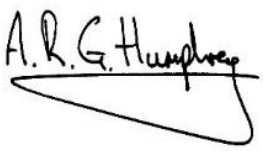
We believe there needs to be much more clarity around the assessment of safety. Our view is that the levels of evidence needed for assessment prior to the implementation of AI systems / algorithms should be mandated rather than left open to interpretation. We suggest this is an area where the draft position statement could be strengthened. As it stands, it could allow anyone selling an AI system /algorithm to deem that having run a model and conducted a small pilot study constitutes sufficient evidence. We believe there needs to be a requirement for controlled trials using real-world prospective data as there is a risk that trials that are run on retrospective data will only further entrench existing bias.

After the assessment of safety, the next tier of regulation is an implementation framework. Our view is that the responsibility for implementation frameworks should sit with Health New Zealand, the new entity which is to take over the functions of the existing DHBs. We believe that individual AI systems / programmes should be required to demonstrate compliance with the implementation framework, including meeting the requirements for audit and safety data. The population-wide systemic problems that can occur with AI systems place massive clinical risk on providers. Lessons should be drawn from experience in other jurisdictions. For example, a widely used hospital sepsis scoring algorithm which determined care in the US was found to have resulted in African American patients substantially less likely to receive important medical treatment than their white counterparts.[1] This example reinforces the need for equity considerations to be part of every stage of regulation. We contend that it is not enough to require a new AI tool to deliver outcomes as good as current outcomes. If current outcomes have been shown to be inequitable, AI tools should not perpetuate existing inequities.

Finally, the governance of AI systems / algorithms should be given careful consideration. Currently, governance is often brought in after key decisions have already been made. Ideally, a governance/regulating body should be established as the first step and entrusted with the responsibility of developing required policies and procedures. Given the highly technical skills required for such work, a sensible approach would be to utilise a trans-Tasman body for this role. It will also be important to ensure that regulatory and governance expertise is appropriately clinically informed.

We hope our feedback is helpful and look forward to seeing the finalised position statement.

Yours sincerely



Dr Alistair Humphrey
NZMA Chair

[1] Obermeyer Z, et al. Dissecting racial bias in an algorithm used to manage the health of populations. Science. 25 Oct 2019;366(6464):447-53