Health & Disability Commissioner Te Toihau Hauora Hauātanga
Wellington
New Zealand

Via email: review@hdc.org.nz

29 July 2024

To Whom It May Concern

RANZCR response to the Health & Disability Commissioner on its review to the *Code of Health and Disability Services Consumers' Rights (the Code)* and the *Health and Disability Commissioner Act 1994 (the Act)*

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: by establishing guidelines that help encourage the protection of health and safety.

Thank you for the opportunity to provide feedback to the Health & Disability Commissioner (HDC) on its review to the *Code of Health and Disability Services Consumers' Rights (the Code)* and the *Health and Disability Commissioner Act 1994 (the Act).*

RANZCR has considered this review and would like to provide the following comments in response to select HDC review questions below.

Feedback for topics 1-4

1.1: Did we cover the main issues about supporting better and equitable complaint resolution?
RANZCR would like to emphasise the importance of timely resolution of complaints for clinicians to be able to have the time and focus for their patients in an over-stretched system.
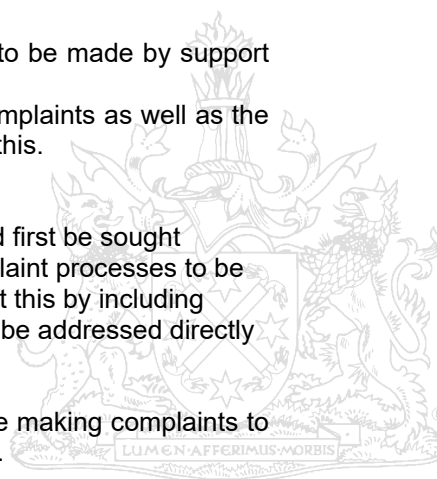
1.c. Clarify the role of whānau:
Clarifying Right 10 (Right to Complain) to explicitly allow for complaints to be made by support people on behalf of the consumer.
RANZCR agrees with the inclusion of whānau being allowed to make complaints as well as the patient. We believe there should be good statements around consent for this.

1.f. Clarify provider complaint processes:
RANZCR wishes to re-iterate the position that complaint resolution should first be sought though the provider. Proposed changes to Right 10 are for provider complaint processes to be streamlined, including promoting the right to complain. HDC could support this by including expectations and guidance that HDC will prioritise referring complaints to be addressed directly with the provider as the first course of action.

Additionally, HDC could support this by promoting and encouraging those making complaints to follow complain processes with providers before escalating these to HDC.

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1.3: What other changes, both legislative and non-legislative, should we consider for supporting better and equitable complaints resolution?

The HDC process can be a prolonged, distressing, drawn out, and intensive process for clinicians involved. Support for clinicians and upholding the mana of clinicians involved in the process is important.

RANZCR also suggests the following improvements:
- Include a statement on strengthening the triage process and focus of resources on significant or concerning complaints. This should acknowledge the reality of the significant time and resources needed to investigate and reply to lower-level complaints.
- Introduce a tracking and reporting system for the complaints in the process. This could provide more clarity and reduce stress for both clinicians and patients in the process.
- Additionally, it is important to manage expectations for patients of what might be achieved by the complaints process as often no 'action' is taken.

4.2: What do you think about our suggestions for considering options for a right of appeal of HDC decisions, and what impacts could they have?

Option A (to introduce a "statutory requirement for review of HDC decisions") appears to place the least burden on the complainant and uses the existing processes/expertise of the HDC to perform the reviews.

Feedback for topic 5

5.g. Expand the requirement for written consent for sedation that is equivalent to anaesthetic

HDC should clearly communicate the expansion of the requirement for written consent for sedation to all imaging providers to ensure that radiologists are fully aware of compliance requirements.

5.3: What are your main concerns about advancing technology and its impact on the rights of people accessing health and disability services?

RANZCR is a leading advocate for the safe application of artificial intelligence (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.

There are a range of factors that can affect the equitable access if AI is involved in the diagnosis or treatment of patients (as AI systems also have the potential to impact health consumers on a larger scale):
- **Algorithmic Bias**: AI tools are limited by their algorithmic design, interpretation process and the data they have access to making them prone to bias. AI tools trained on greater volumes and varieties of data should generally be less biased.
- **Sampling Bias:** Can occur when algorithms are trained and validated on underrepresented populations (eg ethnic groups, persons with disabilities, socioeconomic groups) are under-sampled or excluded from training datasets, meaning algorithms may not be accurate in these populations. In the case of advancing technologies, these patient groups may be left behind in being able to access the benefits of these technologies.
- **Cultural and Linguistic Barriers:** May impact the ability of certain populations to access telehealth or other digital technologies (eg health records online, electronic forms). There must be measures in place to allow these consumers access to patient care.
- **Technological literacy**: Lack of technological literacy can limit or preclude consumers from accessing digital and AI health technologies.
- **Financial prohibitions and biases**: These can limit certain groups from benefiting from technological advances. This may be due to the cost of the services, or the expenses of the necessary hardware platforms. This can limit access to healthcare services, especially for lower socioeconomic populations.

RANZCR supports adhering to best practice and local governance requirements for patient anonymisation and secure data storage.

5.4: What changes, both legislative and non-legislative, should we consider to respond to advancing technology?

Legislative:

The use of AI in medicine offers opportunities to improve the quality, safety, and efficiency of healthcare delivery. However, the adoption and use should be guided by a strong ethical framework, such as RANZCR's Ethical Principles for Artificial Intelligence in Medicine[i], alongside proportionate regulation and robust standards. RANZCR has developed a Position Statement on the Regulation of Artificial Intelligence in Medicine[ii] which outlines key principles and recommendations to guide to safe oversight of AI in medicine. RANZCR believes 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.

Key recommendations include:

1. AI systems are only applied to clinically justified tasks that enhance 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.
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.
4. 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.
5. The AI manufacturer must provide advice on how to address system failures.
6. Healthcare is a complex, safety-critical domain. Failures in either the performance or clinical implementation of AI can lead to patient harm. The HDC should consider the complex nature of accountability when an AI system causes patient harm, specifically for the AI system's vendors, the practice, and the individual clinician, and the HDC should develop best practices for a restorative approach when it identifies there has been a breach of the Code caused by the use of an AI system.

Non-legislative:

Several non-legislative measures are available that should be undertaken to ensure that the AI in medicine can be safely harnessed to the benefit of all New Zealanders.

Interoperability and Infrastructure: Interoperability between digital health systems is imperative for the adoption of AI, including in the training of AI tools and implementation across diverse sites. Functional, supported and interoperable infrastructure will support the provision of high-quality patient care.

RANZCR recently published a Digital Health White Paper[iii] outlining the following priorities required for New Zealand to maximise the benefits of digital health, and build the foundation for AI integration:
1. Interoperable language;
2. interoperable systems for radiology imaging, reporting and storage; and
3. electronic referral systems that support patient choice and advancements such as clinical decision support.

Additional feedback

HDC "promotes the rights of all people in New Zealand who use health and disability services." As such, HDC acts as the advocate for people using health services, and also provides determinations on assessments of whether a health provider has breached the rights of health service users. As such, as HDC acts as both advocate and judge, this raises the issue of
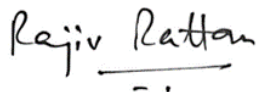
impartiality when HDC decides on the resolution of patient complaints. Some information or statement on impartiality would be useful to include.

Both clinicians and consumers will require education on the risks and benefits that the use of AI in healthcare provides.

RANZCR looks forward to further collaboration on all and any other related health matters with HDC.

For queries or further information, please contact ████████████████████████ ████████████████████████████████.

Yours sincerely

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[i] RANZCR's Ethical Principles for Artificial Intelligence in Medicine (2023) [Cited 2024 July 1] Available from: https://www.ranzcr.com/documents/4952-ethical-principles-for-ai-in-medicine/file
[ii] RANZCR Regulation of Artificial Intelligence in Medicine (2022) [Cited 2024 July 1] Available from: https://www.ranzcr.com/documents/5579-ranzcr-position-statement-on-the-regulation-of-artificial-intelligence-in-medicine/file
[iii] RANZCR's Towards Interoperability in Aotearoa New Zealand: Clinical Radiology Forging the Path Ahead 2024) [Cited 2024 July 1] Available from: https://www.ranzcr.com/index.php?option=com_edocman&task=document.download&id=2217