The Royal Australian and New Zealand College of Radiologists®

19 September 2023

Therapeutic Goods Administration

Via email: devicereforms@tga.gov.au

RANZCR Submission to TGA Audit Framework

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: clinical radiology is central to the diagnosis and treatment of disease and injury and radiation oncology is a vital component in the treatment of cancer.

Software used in medicine has advanced significantly in recent decades, a trend we expect to accelerate. Radiology and radiation oncology have always been at the forefront of technology adoption in the healthcare industry, these being two areas of medicine that are data rich and already using advanced technologies and informatics software. Artificial intelligence (AI) is already proving to be impactful on these disciplines and the technology is evolving rapidly. AI is growing fastest in medical imaging, of the over 500 USA FDA cleared AI devices more than half relate to radiology. RANZCR believes that **AI has enormous potential if used carefully but could also cause significant harm if not appropriately regulated**.

RANZCR appreciates the need to properly balance assessing Software as a Medical Device (SaMD) and ensuring that regulatory requirements are not so onerous that it becomes prohibitive for vendors to release their products and technologies in Australia, thus limiting potential benefits of AI. RANZCR agrees that the current system, using a mandatory audit list may not be the best approach to managing technological advances in SaMD and that a risk-based audit system could provide the flexibility to better respond to complex applications.

RANZCR welcomes the TGA's approach to how the medical device application process can best align with evolving technologies and international practices. While we appreciate that the consultation has a broader range than the specific consideration of AI, RANZCR believes there are specific risks relating to AI enabled SaMD. While we understand the need for the TGA to consider devices from a technologically agnostic perspective, **decision-making devices are inherently different than other forms of medical devices and can pose unique risks to patient safety**. There are several AI specific concerns when assessing the risk factors of AI enabled SaMD that RANZCR would like to highlight in this response.

RANZCR believes that the manufacturer of the SaMD should demonstrate that they have taken an ethical approach when developing SaMD, in line with RANZCR's Ethical Principles for Use of AI in Medicine. Training, testing, validation data and AI performance must be both specified in the interest of transparency. The testing and training population should be representative of the population for which it is intended to be used. Specifically, the safety of Indigenous patients should be considered and if there are population differences, AI performance should be tested on local data.

With more than 90% of medical devices on the Australian Register of Therapeutic Goods (ARTG) supported by overseas approvals there need to be mechanisms in place to ensure that machine learning devices are appropriate for the Australian demographic and that such devices are clearly labelled to ensure that they are able to be used in a clinically appropriate context.

RANZCR is aware that during deliberations the TGA considers determinations by other international regulators and recognises the necessity of this. However, there are some concerns with this practice specifically relating to AI. It has been well documented that **performance of AI systems is related to the population of individuals on which it has been trained.**

Given the reliance of machine learning systems on their training data, it is unclear how to ensure safety in clinical practice. It is unlikely that clinical populations will be sufficiently similar to training populations and clinical populations rarely remain stable over time as demographics and disease distributions change (population drift). At the assessment and audit phase there needs to be consideration of any differences between the data that the machine was trained, tested and verified on, and the Australian population that the device is intended to be used on. This safety consideration is particularly important in relation to our Indigenous population.

The scalability of AI devices also poses a safety risk. Software devices are rapidly scalable (i.e. they can be deployed quickly across multiple systems), with the potential to affect the care of a large number of patients in a short space of time. This is particularly relevant for devices that are intended for screening of common conditions, due to the disproportionate effect they can have at a population level. At a population level, a high-risk but small footprint device only poses a modest risk due to its limited use on patients. Conversely, a low or medium-risk device which is applied to millions of patients can cause multiple incidences of harm, even if the risk to any single individual is low. **The breadth of application of a device must therefore be considered as a risk factor when assessing a medical device with AI capabilities**.
The autonomy of a device must also be considered. For example, a device that can diagnose a life-threatening condition but does so under the supervision of an expert trained in that diagnosis represents a lower risk to the patient rather than a system that autonomously produces a low to medium risk diagnosis.

Devices that “aid a clinician in making a diagnosis” commonly referred to as “computer aided detection or diagnosis” systems, are often categorised as low to moderate risk, which is problematic when considering AI that that can be used in autonomous fashion.
It is important to clearly identify risk categories to avoid a scenario where SAMD is misclassified based on the information provided by the applicant. There is a real danger of AI devices being used outside of their approved scope, for example, machines that are designed to aid a clinician in making a diagnosis being used autonomously. RANZCR believes that in the current landscape**, human in the loop use of AI is the only safe pathway in patient care**. The TGA needs to ensure that labelling is clear so that health providers understand how a machine is, and is not, intended for use. In instances where there may be ambiguity or confusion, RANZCR recommends that a non-compulsory audit is initiated to ensure that the product is appropriately labelled and described prior to approval.

RANZCR believes that 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.

Yours Sincerely,

Dr Gerard Adams
Dean of the Faculty of Radiation Oncology

Dr Rajiv Rattan
Dean of the Faculty of Clinical Radiology