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27.10.2024

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Submission to the Department of Health and Aged Care, Therapeutic Goods Administration (TGA) Regarding Consultation on: Clarifying and Strengthening the Regulation of Artificial Intelligence (AI)

The Royal Australasian College of Surgeons (RACS) welcomes the opportunity to contribute to the consultation on clarifying and strengthening the regulation of Artificial Intelligence (AI) within Australia's healthcare system and under the auspices of the Therapeutic Goods Administration (TGA). As the peak body representing surgeons, RACS is committed to training, supporting innovation while prioritizing patient safety, clinical effectiveness, and the upholding of high ethical standards in surgical practice.

The "black box" nature of AI decision-making can create huge challenges. Its processes could yield correct results but with the occasional surreal, and wrong outputs. The legal responsibility with respect to such errors are not well understood. Does it lie with the software manufacturer or the doctor who may be unaware of the AI's decision rationale. Laws today are struggling to keep pace with changing technology, and it is for that very reason that RACS needs to proactively become involved in shaping solutions that embrace the potential benefit of AI while determining associated risks and concerns.

Introduction

The rise of Artificial Intelligence (AI) technology and its potential influence has raised both interest and some concerns for the Royal Australasian College of Surgeons (RACS). This consultation provides RACS an opportunity to examine the parameters of AI and its impact on surgical practice in Australia. As the potential for integration of this technology advances, so too the need to provide a strict regulatory framework, transparency, and legislative protection.

The safety of our patients, the effective implementation of AI technology for our surgeons, and the consequential impact on ethical standards for preoperative planning, intraoperative assistance and postoperative care are paramount. The mitigation of risk is RACS's main focus in this submission. AI may involve biased analytics which could then equate to inaccuracies and unintended harm to patients.

The application of Section 41BD of the *Therapeutic Goods Act 1989* will also be interrogated in this response. AI technologies or systems require software and coding. Hence the law must be more cognisant of this fact and not be outpaced by potentially unregulated innovation.

RACS will address the *2024-2025 Budget* measure for *Safe and Responsible AI*. RACS' seeks funding to assist the Australian government investigate both the limitations and strengths associated with AI technology in surgery.

Background

The Royal Australasian College of Surgeons (RACS) is the leading advocate for surgical standards, professionalism, and education in Australia and Aotearoa New Zealand. It represents over 8,300 surgeons and 1,300 surgical trainees and Specialist International Medical Graduates (SIMGs). As a not-for-profit organisation, RACS funds surgical research, supports healthcare standards, and provides surgical education in the Indo-Pacific. The College trains surgeons in nine specialties: Cardiothoracic, General, Neurosurgery, Orthopaedic, Otolaryngology Head and Neck, Paediatric, Plastic and Reconstructive, Urology, and Vascular surgery.

AI in Surgery: Opportunities and Challenges, Australia and Global Comparisons

AI technologies have already entered the realm of robotic surgery, as well as for predictive models, and algorithms for image analysis.[1] Machine learning models have demonstrated accuracy in predicting postoperative complications, such as surgical site infections and readmissions, helping surgeons make more informed decisions.[2] Yet, with these advancements come unique challenges.

Bias in AI Systems, Race and Geography

Bias in AI Systems relating to race and geography could stem from data sets which are not qualitatively substantive. These may lead to the risk of introducing bias to clinical decisions when algorithms are trained on unrepresentative datasets. Vulnerable groups like indigenous Australians can become disproportionately affected if data sets do not encompass the population holistically.[3] In Australia, the complexities due to the divide between urban and rural populations, and the inclusion of multicultural communities will need to be considered. Canada, have been quick to implement specific guidelines ensuring AI systems undergo bias testing for a diverse population in accordance with their *Canadian Human Rights Act* under the Canadian *Artificial Intelligence and Data Act* (AIDA).[4]

Data Privacy and Security

AI relies heavily on vast amounts of patient data to function effectively. This raises concerns about patient privacy, data protection, and the potential misuse of sensitive health information. The regulation must ensure that AI systems adhere to the highest standards of data security. Despite of Australia's legislative history with the enactment of such statues like the *Privacy Act 1988* and the *My Health Records Act 2012*, data breaches have occurred in the past as in the case of the *My Health Record* system which highlights potential vulnerabilities.[5] By comparison, the European Union has in law the *General Data Protection Regulation* (GDPR). The U.S. has the *Health Insurance Portability and Accountability Act 1996* (HIPAA) regulations, but even then, questions still arise if robust protections for health data have been put in place.[6]

What is known is that the technology is outpacing the law. Australia has yet to implement specific AI-related amendments for surgical AI technologies in its legislations. Australia is potentially lagging behind other countries. For example, Germany has legislated AI-specific health data privacy frameworks. Recently it enacted Section 393 SGB V (*Social Security Code – Book V* & proposed "Digital Act" in 2024).[7]

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[1] Habuza T, Navaz AN, Hashim F, Alnajjar F, Zaki N, Serhani MA, et al. AI applications in robotics, diagnostic image analysis and precision medicine: Current limitations, future trends, guidelines on CAD systems for medicine. Informatics in Medicine Unlocked. 2021;24:100596 https://doi.org/https://doi.org/10.1016/j.imu.2021.100596.

[2] Hassan AM, Rajesh A, Asaad M, Nelson JA, Coert JH, Mehrara BJ, et al. Artificial Intelligence and Machine Learning in Prediction of Surgical Complications: Current State, Applications, and Implications. Am Surg. 2023;89(1):25-30 https://doi.org/10.1177/00031348221101488.

[3] Moore CM. The challenges of health inequities and AI. Intelligence-Based Medicine. 2022;6:100067 https://doi.org/https://doi.org/10.1016/j.ibmed.2022.100067.

[4] The Artificial Intelligence and Data Act (AIDA) – Companion document [Internet]. ised-isde.canada.ca. 2023. Available from: https://ised-isde.canada.ca/site/innovation-better-canada/en/artificial-intelligence-and-data-act-aida-companion-document#s7.

[5] Burke W, Stranieri A, Oseni T, Gondal I. The need for cybersecurity self-evaluation in healthcare. BMC Medical Informatics and Decision Making. 2024;24(1):133 https://doi.org/10.1186/s12911-024-02551-x.

[6] Li J. Security Implications of AI Chatbots in Health Care. J Med Internet Res. 2023;25:e47551 https://doi.org/10.2196/47551.

[7] Adem D. Germany enacts stricter requirements for the processing of Health Data using Cloud-Computing – with potential side effects for Medical Research with Pharmaceuticals and Medical Devices [Internet]. Global Policy Watch. 2024 [cited 2024 Oct 22]. Available from: https://www.globalpolicywatch.com/2024/09/germany-enacts-stricter-requirements-for-the-processing-of-health-

The aim of this is to provide minimal security standards for cloud-based IT systems. Those affected are healthcare providers, statutory health insurances, and their contract data processors when using cloud-computing services to hold and process health and social data.

Accountability and Transparency

In recent years, when an AI system is created, the design has been called a "black box" by its critics.[8] This is a term used to describe the opaque decision-making process behind the functionality of the system which is not easily understood by clinicians and patients. For example, where are the data sources? How is the data disseminated? How reliable is the filter for errors? Transparency is key when determining if AI systems should be integrated into a surgical procedure, and the clinical journey of a patient. Surgeons who adopt AI systems could be placed under duress to better justify clinical outcomes.

In Australia, a legal framework for transparency has been left wanting. There is some hope that this Therapeutic Goods Administration (TGA) led consultation will provide some initiatives to progress this. One possible avenue is to reshape the National AI Centre[9] in the hope that it will help enhance transparency. In the U.S. and the EU such initiatives have been set in motion.[10] The EU has proposed the *Artificial Intelligence Act* which placed great emphasis on transparency. Developers are made to make AI systems more explainable, particularly for high-risk areas like surgery.[11]

Therapeutic Goods Act 1989 - Section 41BD

Section 41BD of the *Therapeutic Goods Act 1989* defines a medical device as any instrument, apparatus, software, or other article intended for human use for specific medical purposes, including diagnosis, prevention, or treatment of disease. The following section provides a clear legal framework for regulating AI as a medical device when used in healthcare settings, including surgery.[12] However, AI technology appears to be outpacing the law at present.

While this definition is broad enough to encompass AI systems, there are specific areas where clarification and strengthening of the regulatory framework are required:

1. **Definition of AI as a Medical Device:** It needs to be determined if AI systems used in surgery should be classified as medical devices under Section 41BD. The current definition and TGA's explanation would suggest that there is some scope for encompassing AI software. However, the TGA did make comment that they "do not regulate health and lifestyle apps or other software that does not meet the definition of a medical device."[13] The growth of AI technology goes hand in hand with mobile devices. To ensure rigorous safety, efficacy, and performance requirements of such software, the TGA maybe be compelled to re-examine their stance. Rapid innovation may well dictate how AI technology will be regulated in the future as it will include software and coding.
2. **Risk Categorization of AI Systems:** Risk-based classification for AI technologies will need to be better defined. Surgery can be a high-risk endeavour. Use of AI could influence the decision-making process for not only surgeons but GPs, anaesthetists, radiologist, nurses etc. Stringent evaluation methods like real-time validation and clinical testing are needed. Case studies under close clinical observation will be required before any AI technology can be released for use on

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data-using-cloud-computing-with-potential-side-effects-for-medical-research-with-pharmaceuticals-and-medical-devices/#more-15022 .

[8] Shaikh TA, Mir WA, Sofi S. Decrypting the Black Boxing of Artificial Intelligence Using Explainable Artificial Intelligence in Smart Healthcare. In: Mishra S, González-Briones A, Bhoi AK, Mallick PK, Corchado JM, editors. Connected e-Health: Integrated IoT and Cloud Computing. Cham: Springer International Publishing; 2022. p. 53-82.

[9] https://www.industry.gov.au/science-technology-and-innovation/technology/national-artificial-intelligence-centre

[10] Fehr J, Citro B, Malpani R, Lippert C, Madai VI. A trustworthy AI reality-check: the lack of transparency of artificial intelligence products in healthcare. Front Digit Health. 2024;6:1267290 https://doi.org/10.3389/fdgth.2024.1267290.

[11] EU Artificial Intelligence Act, "Categorization of the Transparency Rules under the EU AI Act," EU AI Act, accessed October 1, 2024, https://www.euaiact.com/key-issue/5.

[12] Therapeutic Goods Act 1989, Section 41BD https://classic.austlii.edu.au/au/legis/cth/consol_act/tga1989191/s41bd.html.

[13] Therapeutic Goods Administration., Understanding regulation of software-based medical devices, Australian Government, Department of Health and Aged Care, Published 21 June 2022, Last updated 9 May 2024, https://www.tga.gov.au/resources/guidance/understanding-regulation-software-based-medical-devices.

the public. The usage of AI systems used in high-stakes surgeries must meet the highest safety standards.[14]

3. **Post-market Surveillance:** Continuous monitoring of AI systems in surgery is essential to detect and address any emerging risks. Section 41BD should be supplemented with requirements for robust post-market surveillance of AI technologies, including regular updates (and substantive changes), auditing, and ongoing clinical validation to ensure they remain safe and effective throughout their lifecycle. In any case, this process should at least be incorporated within the functional parameters of the National AI Centre (NAIC) for quality control. The rate at which AI companies are being formed will put pressure on any regulatory body to maintain compliance.

Recommendations

RACS recommends the following actions to clarify and strengthen the regulation of AI in surgery:

1. **Review Section 41BD:** Medical device classification needs to be reviewed considering the software and coding that AI technologies readily use, especially when considering risk-based classification for surgery.
2. **Strengthen Pre-market and Post-market Evaluation:** Ensure that all surgical AI systems undergo rigorous pre-market evaluation and are subject to continuous post-market surveillance, with specific requirements for high-risk AI applications in surgery.
3. **Establish a Surgical AI Advisory Group:** The reshaped National AI Centre should include a surgical AI advisory group, composed of medical and surgical professionals, to guide policy development and regulatory oversight of AI in healthcare.
4. **Allocate Funding for AI Research in Surgery:** A portion of the *2024-2025 Budget* allocation for Safe and Responsible AI should be directed towards research into AI safety, transparency, and effectiveness in surgical applications by RACS. RACS would then provide funding to its research area 'Research, Audit and Academic Surgery (RAAS)' to conduct further intensive research into AI and surgery over the next five years.

Conclusion

RACS would like to acknowledge that commitment through the TGA is essential to patient safety, surgeon's professional protections, and public confidence. The clear development of regulatory guidelines will be key in supporting the responsible integration of AI technologies into the surgical field. RACS is committed to ongoing constructive work with the Department of Health and Aged Care and the TGA to further developing these regulations, core to patient safety and the protection of surgeons in the advancement of AI applications in health.

Yours sincerely,

Associate Professor Kerin Fielding
President, RACS

Professor Mark Frydenberg
Chair, Health Policy & Advocacy Committee

[14] Therapeutic Goods Administration., Artificial Intelligence (AI) and medical device software, Australian Government, Department of Health and Aged Care, Published 21 June 2022, Last updated 9 May 2024, https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/manufacture-specific-types-medical-devices/artificial-intelligence-ai-and-medical-device-software.