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Submission to the Department of Health and Aged Care: Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review

The Royal Australasian College of Surgeons (RACS) welcome the opportunity to provide feedback on the critical considerations for safe and responsible Artificial Intelligence (AI) integration within Australia's healthcare system as part of the Legislation and Regulation Review. As the peak representative of the Australian surgical community, we support the advancement of AI in healthcare while underscoring the importance of robust regulatory measures to protect patients, support clinicians, and enhance outcomes responsibly.

Introduction

The Federal Budget in respect of artificial intelligence (AI) across the Australian economy will help advance and provide an avenue to clearly outline and strengthen the legislative and regulatory framework related to AI. RACS will place an emphasis on surgical applications within the health sector within our submission. RACS is concerned about patient safety, data security, data set biases impacting disadvantaged communities and diverse groups, legislation, professional accountability, and the impact on the environment. The potential benefits and risks require an overview of the key considerations on the application of AI in healthcare.

The clear implications are that AI technology is running ahead of the law in Australia. There needs to be clear regulatory guidelines, and they must be promulgated quickly because that technology is moving so rapidly that even a tardy regulatory response is actually no response. The trap being that Australia may find ourselves playing 'catch-up.' Given this, while a temporary moratorium on some AI applications within healthcare could provide an opportunity to develop appropriate legislation, this is unlikely to be viable. What Australia needs in terms of AI regulation for health is an agile and adaptive framework, one which can move in concert with the rapid development of the technology and provide security for practitioners and patients alike.

The appearance of AI in surgical practice creates in Australia particular problems of professional liability and indemnity. The most serious question arises when a failure of an AI algorithm that a surgeon relied on for clinical decisions occurs. In this respect, will an AI system misinterpret certain data leading to injury cause on a patient and who is liable? It has yet to be established as to who is held responsible. Should it lie with the software developer, with the AI platform provider, or with the surgeon who acted upon AI-generated recommendations? This issue has considerable implications for professional indemnity insurance, especially if liability falls disproportionately on the surgeon, increasing their litigation exposure and affecting the availability and affordability of the indemnity cover.



Committed to
Indigenous health

Another major but related challenge relates to the use of AI in research and clinical publications. This could occur through AI's mistaken interpretation of data in its analyses, or through failure to detect biases in underlying data; the resultant publications may spread inaccuracies. The bottom line could be ill-informed clinical decisions, as other practitioners might base their decisions on faulty or biased research results. As medical literature becomes increasingly reliant on AI-assisted insights, robust safeguards will have to be instituted to ensure integrity of data and appropriate interpretation of AI-generated analyses.

These are risks that the Australian surgical community must weigh in closely, and for which it must advocate policies that clarify accountability in cases of AI error. There needs to be a balance between innovation and protection that AI regulation and compliance can assist with. RACS is committed to continuous improvement in surgical standards and the quality of care for patients throughout Australia. RACS have attempted to answer all 19 questions presented in this Consultation.

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, 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.

1. How can AI benefit healthcare in Australia and how can we measure and deliver these benefits?

AI will enhance Australian health through better diagnostics, personalised treatments, and efficient workflows. For example, AI-assisted radiology can diagnose diseases more precisely and a lot earlier, while predictive analytics can optimise resource allocation in hospitals, thus reducing wait times. In surgery, AI has the potential for preoperative planning and complication prediction. At the same time, these applications need to be carefully validated regarding patient safety.

While it holds great diagnostic promise, for surgery which is complex, it cannot be fully automated. Surgeons must integrate AI insights with real-time, patient-specific conditions. Caution must be taken if there is a heavy reliance on AI. Questions concerning accountability in cases of mistakes and in the absence of rigorous clinical validation can cause harm.¹ Biases within algorithms and data sets may lead to prejudiced outcomes, particularly where predictive models are used.

AI in surgery should be about improving clinical outcomes, and quicker recovery times for patients. Ethical considerations should be founded on transparency, consent by the patient, and surgeon autonomy. The "black-box" nature of many AI systems is not transparent in high-stakes environments like surgery.^{2 3} This raises ethical considerations when dealing with issues of a patient's consent to their usage. AI should augment, not replace, human judgment. It must be instituted on the back of rigorous clinical trials with stringent regulation regarding ensuring safety and efficacy.

¹ Miranda X. Morris, Davide Fiocco, Tommaso Caneva, Paris Yiapanis, Dennis P. Orgill, Current and future applications of artificial intelligence in surgery: implications for clinical practice and research, *Frontiers in Surgery*, vol. 11, 2024, Article 1393898, published online May 9, 2024, doi: 10.3389/fsurg.2024.1393898. PMID: 38783862. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1111929/>

² Linardatos, P., Papastefanopoulos, V., and Kotsiantis, S. (2021). Explainable AI: A review of machine learning interpretability methods. *Entropy* 23:18. doi: 10.3390/e23010018 [Explainable AI: A Review of Machine Learning Interpretability Methods - PubMed](#)

³ Kiseleva, A., Kotzinos, D., & De Hert, P. (2022). Transparency of AI in healthcare as a multilayered system of accountabilities: Between legal requirements and technical limitations. *Frontiers in Artificial Intelligence*, 5, 879603. <https://doi.org/10.3389/frai.2022.879603>

2. Can AI improve access to care, and what regulations could be amended or added to enable this

AI has the potential to improve access to care, particularly in the most rural and underserved areas. These come in the form of telehealth, diagnostic support, and remote monitoring. Proper development and adherence to regulations regarding data privacy, safety, and ethical uses are required.⁴ A framework within which AI-based diagnostics and telehealth platforms operate is needed to ensure patient confidentiality while maintaining high medical standards.

There are obstacles towards the overall successes of AI in these rural settings. Telehealth raises issues of clinical safety and data privacy. AI has also been very limited in complex surgical areas up to now. While AI can support post-operative monitoring, many cases will continue to be subject to in-person evaluation. Artificial intelligence diagnostic tools will, in turn, increase access in those regions where specialist services may be limited. An example is that AI-driven radiology may detect abnormalities as a useful tool to assist decision-making by physicians, but it can't replace clinical decision making.⁵

Clinical trials are very important in ensuring that AI diagnostics introduced within surgery are safe and do not result in life-threatening mistakes. AI systems must be categorised as high-risk medical devices that undergo strict validation. Secondly, regular audits of AI algorithms are very important to prevent biases that might affect underrepresented populations. These will ensure that AI improves access to surgical care in a safe and accountable way through comprehensive regulatory reforms focusing on transparency, patient choice, and ethical standards.

3. What risk does AI pose to patients/consumers or healthcare professionals? Are the risks high or low? What criteria could be used to characterise risk? Should consumers be informed when AI is used in these low-risk ways?

AI in surgery can carry risk such as misdiagnosis, data privacy breaches, and liability issues if a system were to falter. Although AI is relatively good at identifying common conditions, accuracy diminishes with rare conditions⁶. This may become more evident in surgery and other specialities, where a misstep may translate into inappropriate interventions. While AI may be used to help with preoperative planning⁷, trained surgical human judgment will be needed when supplying the accuracy in more complex cases. Data privacy is another issue because AI systems handle so much sensitive patient information that the latter becomes highly vulnerable to breach.

Accountability in AI-assisted surgery creates challenges, if AI recommendations result in poor outcomes. This creates an “accountability gap”⁸ and poses significant risks in surgical settings, where decisions require nuanced clinical judgment. Transparency will be paramount, and patients must be informed when AI will be used in their care, including any possible benefits and risks. AI holds the potential to bring immense improvements in diagnostics relating to surgery; still, the risks involved need to be addressed with the required safeguards to ensure patient safety, data privacy, and accountability.

⁴ Mathew, S., Fitts, M. S., Liddle, Z., Bourke, L., Campbell, N., Murakami-Gold, L., Russell, D. J., Humphreys, J. S., Mullholand, E., Zhao, Y., Jones, M. P., Boffa, J., Ramjan, M., Tangey, A., Schultz, R., & Wakerman, J. (2023). Telehealth in remote Australia: A supplementary tool or an alternative model of care replacing face-to-face consultations? *BMC Health Services Research*, 23(341). <https://doi.org/10.1186/s12913-023-09265-2>

⁵ Hosny, A., Parmar, C., Quackenbush, J., Schwartz, L. H., & Aerts, H. J. W. L. (2018). Artificial intelligence in radiology. *Nature Reviews Cancer*, 18(8), 500–510. <https://doi.org/10.1038/s41568-018-0016-5>

⁶ Kuo, K. M., Talley, P. C., & Chang, C.-S. (2023). The accuracy of artificial intelligence used for non-melanoma skin cancer diagnoses: a meta-analysis. *BMC Medical Informatics and Decision Making*, 23, 138. <https://doi.org/10.1186/s12911-023-02229-w>

⁷ Takeuchi, M., & Kitagawa, Y. (2024). Artificial intelligence and surgery. *Annals of Gastroenterological Surgery*, 8(1), 4–5. <https://doi.org/10.1002/ags3.12766>

⁸ Heine, K., & Quintavalla, A. (2023). Bridging the accountability gap of artificial intelligence – what can be learned from Roman law? *Legal Studies*, 1–16. <https://doi.org/10.1017/lst.2022.51>

4. What factors are important for rural and regional Australia when assessing the benefits, risks, and safety of AI? Are there other communities that face specific risks when implementing AI-driven healthcare? What considerations should be made to ensure all Australians have access to the benefits of AI?

AI's potential could fill some of the gaps in specialist care for rural and regional Australia. However, there are very real and significant challenges in implementation, including access to reliable internet and data privacy. The risks to Indigenous and remote communities are real, including that of cultural insensitivity from AI algorithms. Meeting these infrastructure and ethical considerations go a considerable way toward fair access to AI benefits.

AI-driven telehealth and diagnostic tools offer the ability to increase access to surgical specialists via remote consultations and enhance preoperative planning. For instance, AI-enabled imaging systems allow urban specialists to diagnose conditions of patients in rural areas.⁹ Several studies have reported that AI-supported diagnostics can dramatically improve early cancer detection rates in these settings.¹⁰ Other potential uses of AI include robotic surgery, which could also potentially support surgeons in rural areas, a point supported by research in India.¹¹ However, surgeons using robots still need know and be trained how to do the procedure without a robot.

Good quality internet infrastructure is, therefore, quite significant in the real implementation of AI in health. Yet so many rural areas have not achieved that access. This is again reiterated in a 2023 review by the Royal Australian College of Surgeons, which points out that telehealth and AI services do need good, constant high-speed connections if they are to be used in real time.¹² In addition, unique health challenges amongst Indigenous Australians¹³ must also be considered by AI systems, to ensure cultural competency and with the involvement of local health experts. With these issues understood and addresses, AI will have an opportunity to reduce healthcare inequity within Australia.

5. Should healthcare professionals have a choice about whether they use AI as part of their work?

Surgeon independence regarding the integration of AI into clinical decisions is critical. If the technology is sophisticated and well-regulated, then surgeons should have choices to utilise AI at their discretion. AI should enhance and not replace surgical expertise, and therefore should allow surgeons to remain in control of its use while making a priority of patient safety and professional integrity. The use of AI will need to be flexible based on clinical scenarios.

While AI is renowned for diagnostic support and data processing, the professional judgment of healthcare professionals should make the final call. However, it is debatable if AI is often superior in diagnosing early signs of cancer compared to human radiologists as it cannot consider complexities in individual patient

⁹ Chandramohan, A., Krothapalli, V., Augustin, A., Kandagaddala, M., Thomas, H. M., Sudarsanam, T. D., Jagirdar, A., Govil, S., & Kalyanpur, A. (2024). Teleradiology and technology innovations in radiology: Status in India and its role in increasing access to primary healthcare. *The Lancet Regional Health - Southeast Asia*, 23, 100195. <https://doi.org/10.1016/j.lansea.2023.100195>

¹⁰ Hunter, B., Hindocha, S., & Lee, R. W. (2022). The role of artificial intelligence in early cancer diagnosis. *Cancers (Basel)*, 14(6), 1524. <https://doi.org/10.3390/cancers14061524>

¹¹ Deo, N., & Anjankar, A. (2023). Artificial intelligence with robotics in healthcare: A narrative review of its viability in India. *Cureus*, 15(5), e39416. <https://doi.org/10.7759/cureus.39416>

¹² Royal Australasian College of Surgeons (2023). *Revised telehealth guidelines: RACS comments on the revised telehealth guidelines released by the Medical Board of Australia*. News, media releases & advocacy, February 20. <https://www.surgeons.org/News/Advocacy/Revised-telehealth-guidelines>

¹³ Verbunt, E., Luke, J., Paradies, Y., Bamblett, M., Salamone, C., Jones, A., & Kelaher, M. (2021). Cultural determinants of health for Aboriginal and Torres Strait Islander people: A narrative overview of reviews. *International Journal for Equity in Health*, 20(1), 181. <https://doi.org/10.1186/s12939-021-01514-2>

cases, like co-morbidities and previous medical history.¹⁴ Thus, AI should support, not supplant, human oversight in clinical decisions. The right training and full understanding of the limitations of AI is essential for ethical and effective surgical practice.

There is evidence that AI improves the outcomes of robotic-assisted surgeries. However, the surgeon should be the chief executor in resolving unforeseeable complications. Likewise, too much reliance on AI can undermine important clinical competencies and be inconsistent with public confidence. Furthermore, surveys conducted among patients demonstrate that they would rather trust a human decision-maker than an AI decision-maker, even if AI decisions were proved more accurate, since such relationships are irreplaceable with built up trust formed in relationships between surgeons and patients.¹⁵

6. What unique considerations are specific to AI in healthcare, and why? Should the government address them through regulatory change?

The integration of AI in surgery will carry critical challenges in patient safety, ethical use, and regulations. Safety for the patient is the first priority, where AI systems in robotic-assisted surgeries can improve precision but also introduce risks of technical failures.¹⁶ These will need strict oversight to make sure that AI enhances and does not replace human decision-making. Whereas this is likely to be much faster with AI-powered diagnostic tools, improper safeguards might misdiagnose diseases and even harm the patients. In turn, it is therefore critical that proper assessments and approval processes take place.¹⁷

Clearly, accountability and transparency issues are paramount: it is always crucial that lines of accountability are quite clear. In addition, it is important that patients have the right to know whether AI has intervened in their care.¹⁸ A further concern is regarding biases that exist in AI algorithms that could lead to inequity in health outcomes, particularly for underrepresented groups in data, such as Indigenous Australians. Consequently, there should be assurances made that training data need to be more varied, and that monitoring for example racial and ethnic biases requires continuous application and vigilance.¹⁹

Robust government regulation about the safety and accountability of AI tools, guided by organisations such as the Therapeutic Goods Administration is needed. Similarly, enhanced privacy protections under *Australia's Privacy Act 1988* become important in terms of protecting patient data used by the AI systems.

7. How does the use of AI differ in healthcare settings compared to general or other sectors such as finance, education, etc.?

¹⁴ Hunter B, Hindocha S, Lee RW. The Role of Artificial Intelligence in Early Cancer Diagnosis. *Cancers (Basel)*. 2022 Mar 16;14(6):1524. doi: 10.3390/cancers14061524. PMID: 35326674; PMCID: PMC8946688.

¹⁵ Robertson C, Woods A, Bergstrand K, Findley J, Balsler C, Slepian MJ. Diverse patients' attitudes towards Artificial Intelligence (AI) in diagnosis. *PLOS Digit Health*. 2023 May 19;2(5):e0000237. doi: 10.1371/journal.pdig.0000237. PMID: 37205713; PMCID: PMC10198520.

¹⁶ Reddy, K., Gharde, P., Tayade, H., Patil, M., Reddy, L. S., & Surya, D. (2023). Advancements in robotic surgery: A comprehensive overview of current utilizations and upcoming frontiers. *Cureus*, 15(12), e50415. <https://doi.org/10.7759/cureus.50415>

¹⁷ Najjar, R. (2023). Redefining radiology: A review of artificial intelligence integration in medical imaging. *Diagnostics*, 13(17), 2760. <https://doi.org/10.3390/diagnostics13172760>

¹⁸ Kooor, J. G., Bacchi, S., Sharma, P., Sharma, S., Kumawat, M., Stretton, B., Gupta, A. K., Chan, W., Abou-Hamden, A., & Maddern, G. J. (2024). Artificial intelligence for surgical services in Australia and New Zealand: Opportunities, challenges and recommendations. *Medical Journal of Australia*. <https://doi.org/10.5694/mja2.52225>

¹⁹ Chin, M. H., Afsar-Manesh, N., Bierman, A. S., Chang, C., Colón-Rodríguez, C. J., Dullabh, P., Duran, D. G., Fair, M., Hernandez-Boussard, T., Hightower, M., Jain, A., Jordan, W. B., Konya, S., Holliday Moore, R., Tyree Moore, T., Rodriguez, R., Shaheen, G., Snyder, L. P., Srinivasan, M., & Umscheid, C. A. (2023). Guiding principles to address the impact of algorithm bias on racial and ethnic disparities in health and healthcare. *JAMA Network Open*, 6(12), e2345050. <https://doi.org/10.1001/jamanetworkopen.2023.45050>

The stakes are higher in healthcare because the impacts pertain to direct patient care. Mistakes in healthcare, unlike finance or education, can cause considerable physical harm. Thus, oversight and safety measures need to be much stricter in healthcare AI.²⁰ Although most failures in financial algorithms may amount to only financial loss, mistakes in AI-run operations can lead to grave injury or even death. There is a potential for AI to cause harm in surgical contexts, if not carefully supervised by human clinicians.

AI tools in surgery, such as robotic platforms, improve precision²¹ but must be kept under strict surveillance. Small errors, such as misjudging real-time data, could lead to disastrous results. Due to these concerns, the AI systems must be "strictly" regulated by the TGA through comprehensive clinical trials and post-market vigilance. Ethical considerations for AI in healthcare are more complex compared to other fields. Patient autonomy and data privacy are of prime importance, needing high-level security regarding this sensitive health information.²² Healthcare AI must have contextual adaptability regarding medical history and comorbidities, which the current AI systems do not address. This compares with AI applied in finance or education, where data are more predictable and decisions less critical to life.

8. Should there be an Australian body specifically dedicated to overseeing AI in healthcare? If so, how would this body differ from a broader organisation like the National AI Centre?

What Australia urgently needs is a specific health sector body leading and regulating AI, particularly in high-risk areas like surgery, on matters pertaining to patient safety, ethics, and clinical validation. Such frameworks or resources, for example, the National AI Centre, do not bear the requisite focus that would contribute to meeting health-specific challenges associated with surgery, where AI systems-robotic platforms-exact incredibly higher demands from clinical trials to subsequent ongoing surveillance. It is here that a specialist body will ensure safety standards for such systems and develop specific regulations necessary to integrate AI into healthcare appropriately.²³ Surgical representation is needed within such a body.

Sensitive ethical issues on patient consent, data privacy, and algorithmic bias are of particular importance in surgery. Guidelines provided by a specialised body would ensure the protection of patient autonomy and transparency where general AI organisations may lag behind. Healthcare AI faces challenges such as real-time decision-making and variability between patients that are unique to their individual anatomies. The body, in particular for AI, would continuously call for updated algorithms so they are accurate and safe.²⁴ It should make adaptations of regulations to suit the needs of Australia's healthcare, including rural areas and indigenous populations. Indeed, international models such as the *AI Act* of the European Union

²⁰ Mennella, C., Maniscalco, U., De Pietro, G., & Esposito, M. (2024). Ethical and regulatory challenges of AI technologies in healthcare: A narrative review. *Heliyon*, 10(4), e26297. <https://doi.org/10.1016/j.heliyon.2024.e26297>

²¹ Reddy, K., Gharde, P., Tayade, H., Patil, M., Reddy, L. S., & Surya, D. (2023). Advancements in robotic surgery: A comprehensive overview of current utilizations and upcoming frontiers. *Cureus*, 15(12), e50415. <https://doi.org/10.7759/cureus.50415>

²² Naik, N., Hameed, B. M. Z., Shetty, D. K., Swain, D., Shah, M., Paul, R., Aggarwal, K., Ibrahim, S., Patil, V., Smriti, K., Shetty, S., Rai, B. P., Chlosta, P., & Somani, B. K. (2022). Legal and ethical consideration in artificial intelligence in healthcare: Who takes responsibility? *Frontiers in Surgery*, 9, 862322. <https://doi.org/10.3389/fsurg.2022.862322>

²³ Gerke, S., Minssen, T., & Cohen, G. (2020). Ethical and legal challenges of artificial intelligence-driven healthcare. In A. Bohr & K. Memarzadeh (Eds.), *Artificial intelligence in healthcare* (pp. 295–336). Elsevier. <https://doi.org/10.1016/B978-0-12-818438-7.00012-5>

²⁴ Amin, A., Cardoso, S. A., Suyambu, J., Saboor, H. A., Cardoso, R. P., Husnain, A., Isaac, N. V., Backing, H., Mehmood, D., Mehmood, M., & Maslamani, A. N. J. (2024). Future of artificial intelligence in surgery: A narrative review. *Cureus*, 16(1), e51631. <https://doi.org/10.7759/cureus.51631>

have proved that a regulatory framework unprecedentedly set for health could avail standards²⁵, assuring equity and safety in AI implementation across diverse populations of patients.

9. Are there any specific changes to existing healthcare laws that would address AI-related harms or help AI to be used safely?

Legal Reforms in Accountability of AI in Healthcare

AI in surgery and healthcare has thrown some special legal problems considered in need of specific reform in Australia. The major issues pertain to accountability in the case of any error or harm caused by AI, which has not been clearly legislated under the present laws. Traditional civil liability frameworks may not fit. Legal reforms need to address the role of AI in healthcare, laws on accountability for AI-related harm, with sharing of responsibility by both AI developers and healthcare providers.²⁶

Human Oversight and Accountability in AI-Assisted Surgery

The legal framework should guarantee that a surgeon and the developer of AI jointly take up accountability in case an error in surgery happens.²⁷ Transparency of AI decision-making, much like the *General Data Protection Regulation* of Europe, could provide clarity.²⁸ A surgeon must have ongoing oversight to override the AI at any critical situation which may arise with the involvement of patients, to enable them to maintain their ethical commitment. This paper calls for legal reforms by integrating human oversight or “human-in-the-loop”²⁹ into AI-assisted surgery and assures safety by maintaining the ethical commitment of surgeons.

Strengthening Data Protection and Informed Consent

AI-based systems need immensely large datasets, which further raises a number of concerns regarding privacy risks. There is a greater need for protection laws related to data, including encryption and access controls. Reforms should also extend to informed consent by ensuring that a patient understands AI involvement in their treatments.³⁰

Legislative Updates

New medical device classifications specific to AI must be developed under the *Therapeutic Goods Act 1989*, recognising the software and coding component of this technology. The focus needs to be on adaptability and ongoing assessments. The *Privacy Act 1988* needs an upgrade that can protect data better in AI applications through the provision of safeguards and a proper usage protocol for health data. The *Health Practitioner Regulation National Law (2009)* needs further review to cover training in the use of AI during surgery within CPD. Workplace legislation, such as the *Fair Work Act 2009* and the *Work*

²⁵ Schmidt, J., Schutte, N.M., Buttigieg, S. et al. Mapping the regulatory landscape for artificial intelligence in health within the European Union. *npj Digital Medicine* 7, 229 (2024).

<https://doi.org/10.1038/s41746-024-01221-6>

²⁶ Eldakak, A., Alremeithi, A., Dahiyat, E. et al. Civil liability for the actions of autonomous AI in healthcare: an invitation to further contemplation. *Humanities and Social Sciences Communications* 11, 305 (2024). <https://doi.org/10.1057/s41599-024-02806-y>

²⁷ Liu, X., Glocker, B., McCradden, M. M., Ghassemi, M., Denniston, A. K., & Oakden-Rayner, L. (2022). The medical algorithmic audit. *The Lancet Digital Health*, 4(5), e384–e397.

[https://doi.org/10.1016/S2589-7500\(22\)00066-1](https://doi.org/10.1016/S2589-7500(22)00066-1)

²⁸ Lukács, A., & Váradi, S. (2023). GDPR-compliant AI-based automated decision-making in the world of work. *Computer Law & Security Review*, 50, Article 105848. <https://doi.org/10.1016/j.clsr.2023.105848>

²⁹ Quaranta, M., Amantea, I.A. & Grosso, M. Obligation for AI Systems in Healthcare: Prepare for Trouble and Make it Double? *The Review of Socionetwork Strategies* 17, 275–295 (2023).

<https://doi.org/10.1007/s12626-023-00145-z>

³⁰ Naik, N., Hameed, B. M. Z., Shetty, D. K., Swain, D., Shah, M., Paul, R., Aggarwal, K., Ibrahim, S., Patil, V., Smriti, K., Shetty, S., Rai, B. P., Chlosta, P., & Somani, B. K. (2022). Legal and ethical considerations in artificial intelligence in healthcare: Who takes responsibility? *Frontiers in Surgery*, 9, 862322. <https://doi.org/10.3389/fsurg.2022.862322>

Health and Safety Act 2011, will also have to cover job changes, safety risks, and potential redundancies of roles due to the integration of AI.

Litigation and Risk Mitigation

Litigation and mitigation of risk may rise due to AI in the legal complexities associated with liability. However, arguments may exist to the contrary that AI may also be able to reduce mistakes, which in turn could reduce malpractice claims. The laws, therefore, need to spell out accountability both among surgeons, AI developers, and healthcare facilities. In addition, contracts of employment must identify and specify how AI impacts roles and performance expectations within them. The National Health and Medical Research Council (NHMRC) guidelines could be a standard bearer for other organisations to follow and should be updated to include ethical standards for AI use, focusing on bias mitigation, decision transparency, and patient consent.

Legal and Regulatory Implications of AI Scribes in Surgical Practice

While use of AI scribe in surgical consultation will provide opportunities to incorporate more efficiency in documentation, it also reduces administrative workload. Currently, purely transcriptional AI scribes, which only transcribe the interaction of surgeons and patients, are not considered medical devices under TGA regulations. However, as AI scribes evolve clinically, there is the risk that AI may also provide advice to the practitioner while transcribing. Oversight will be in need of ensuring safety for the patients. It becomes a legal liability when AI suggestions actually start influencing medical decisions, which further complicates the clinician responsibility under the Australian *Civil Liability Act*. In addition, any AI transcripts may be subpoenaed in lawsuits over malpractice, which raises questions of their admissibility as evidence under for example the *Electronic Transactions Act NSW*. Data privacy risks further complicate matters as AI systems need to become compliant with the *Privacy Act* to protect sensitive patient data. All of these need reforms in the regulatory framework. The much-needed broadening of the TGA oversight includes the clinical advice provided by AI scribes, security of data, and accountability of the clinicians. The "human-in-the-loop" foundation needs to be maintained wherein AI can support human decisions but not make them. As AI will be more integrated into health, clarity in regulation will be important.

10. Which international approaches should we consider, if any, that are specific to health care?

Australia could examine what the *AI Act of the EU* has committed to in their regulation practice. The *AI Act of the EU* regulates AI tools in healthcare along a risk spectrum, submitting those with high risks to strict testing and continuous monitoring, such as surgical diagnostics or treatment tools.³¹ This form of framework could guide AI regulation in Australia. Current concerns revolve upon the reliance of AI in surgery and the importance of proper validation.³²

Australia's unique geography by comparison with the EU requires its own regulatory mould due to specific healthcare challenges faced in rural access and service provisions to a diversified population. Yearly AI validation and clinical trials could create an avenue for assurances on patient safety when working with developers and healthcare providers.³³

³¹ European Union. (2026). Article 72: Post-Market Monitoring by Providers and Post-Market Monitoring Plan for High-Risk AI Systems. In *Regulation (EU) 2021/1223 of the European Parliament and of the Council of 24 November 2021 laying down Union rules on artificial intelligence (AI) that harmonize and unify the law of the Member States relating to AI. Part of Chapter IX: Post-Market Monitoring, Information Sharing and Market Surveillance. Section 1: Post-Market Monitoring*. Date of entry into force: 2 August 2026. <https://artificialintelligenceact.eu/article/72/>

³² Adegbesan, A., Akingbola, A., Aremu, O., Adewole, O., Amamdikwa, J. C., & Shagaya, U. (2024). From scalpels to algorithms: The risk of dependence on artificial intelligence in surgery. *Journal of Medicine, Surgery, and Public Health*. <https://doi.org/10.1016/j.glmedi.2024.100140>

³³ Mahmood, U., Shukla-Dave, A., Chan, H.-P., Drukker, K., Samala, R. K., Chen, Q., Vergara, D., Greenspan, H., Petrick, N., Sahiner, B., Huo, Z., Summers, R. M., Cha, K. H., Tourassi, G., Deserno, T. M., Grizzard, K. T., Näppi, J. J., Yoshida, H., Regge, D., Mazurchuk, R., ... Hadjiiski, L. (2024). Artificial

The EU does continuous monitoring. This helps detect issues such as "data drift" for when AI performance degrades over time.^{34 35} Australia's TGA should adopt this sort of surveillance to keep AI safe for surgery.³⁶ Second, ethics oversight will help prevent bias in AI systems, especially when those systems are trained without data representative of particular groups. Ensuring AI is designed with and for service to Australia's diverse populations-particularly Indigenous communities-will reduce health disparities.³⁷

11. Should humans be able to overrule a finding or decision made by AI?

Surgeons and medical professionals should retain authority on any decision that AI has decided upon, to ensure safety for patients and ethical accountability. Although AI systems can process data with much accuracy, there are plenty of contextual nuances that they may fail to capture, especially when complex surgeries are involved.³⁸ Considering that AI still cannot account for patient-specific factors like rare conditions or comorbidities, it is here that human oversight is paramount in such cases. Besides that, complicated or unusual surgical cases, which AI may not handle satisfactorily, are done by human beings.³⁹ Human judgments become very important in managing certain conditions that might get misinterpreted by the AI and are very rare or uncommon. This will ensure personalised care and will allow surgeons to integrate experiential knowledge with patient-specific factors.

Patient safety is paramount, and although AI may assist in the identification process, it is by no means infallible. The AI-assisted radiology tools sometimes do not pick up atypical cases of diseases; however, such types of errors can be avoided if human professionals override an incorrect interpretation from AI.⁴⁰ In Australia, health practitioners are accountable and must act in the best interests of their patients. Such recommendations need to be under the control of surgeons so that moral, ethical, and legal requirements

intelligence in medicine: Mitigating risks and maximizing benefits via quality assurance, quality control, and acceptance testing. *BJR Artificial Intelligence*, 1(1), ubae003. <https://doi.org/10.1093/bjrai/ubae003>

³⁴ Hillis, J. M., Visser, J. J., Scheffer Cliff, E. R., van der Geest – Aspers, K., Bizzo, B. C., Dreyer, K. J., Adams-Prassl, J., & Andriole, K. P. (2024). The lucent yet opaque challenge of regulating artificial intelligence in radiology. *NPJ Digital Medicine*, 7, 69. <https://doi.org/10.1038/s41746-024-01071-2>

³⁵ Kore, A., Abbasi Bavid, E., Subasri, V., Abdalla, M., Fine, B., Dolatabadi, E., & Abdalla, M. (2024). Empirical data drift detection experiments on real-world medical imaging data. *Nature Communications*, 15, 1887. <https://doi.org/10.1038/s41467-024-46142-w>

³⁶ Kooor, J. G., Bacchi, S., Sharma, P., Sharma, S., Kumawat, M., Stretton, B., Gupta, A. K., Chan, W., Abou-Hamden, A., & Maddern, G. J. (2024). Artificial intelligence for surgical services in Australia and New Zealand: Opportunities, challenges and recommendations. *The Medical Journal of Australia*. <https://doi.org/10.5694/mja2.52225>

³⁷ Mondal, H., & Mondal, S. (2024). Ethical and social issues related to AI in healthcare. In *Methods in Microbiology* (Vol. 55, pp. 247-281). <https://doi.org/10.1016/bs.mim.2024.05.009>

³⁸ Kooor, J. G., Bacchi, S., Sharma, P., Sharma, S., Kumawat, M., Stretton, B., Gupta, A. K., Chan, W., Abou-Hamden, A., & Maddern, G. J. (2024). Artificial intelligence for surgical services in Australia and New Zealand: Opportunities, challenges and recommendations. *Medical Journal of Australia*. <https://doi.org/10.5694/mja2.52225>

³⁹ Bragazzi, N. L., & Garbarino, S. (2024). Toward clinical generative AI: Conceptual framework. *JMIR AI*, 3, e55957. <https://doi.org/10.2196/55957>

⁴⁰ Bernstein, M. H., Atalay, M. K., Dibble, E. H., Maxwell, A. W. P., Karam, A. R., Agarwal, S., Ward, R. C., Healey, T. T., & Baird, G. L. (2023). Can incorrect artificial intelligence (AI) results impact radiologists, and if so, what can we do about it? A multi-reader pilot study of lung cancer detection with chest radiography. *European Radiology*, 33(11), 8263–8269. <https://doi.org/10.1007/s00330-023-09747-1>

are met.⁴¹ Human oversight in AI decision-making ensures the safety not only of the patients but also of ethical standing in surgical care.⁴²

12. Should there always be a person or “human in the loop” to make decisions or deliver a health care service? Are there any circumstances in which it would be acceptable to have fully automated health or care decisions made by an AI product?

AI based decisions in healthcare for specific to complex clinical care requires human involvement. While AI may facilitate and accelerate more administrative processes, such as triage, completely automated surgical decisions require surgical “human-in-the-loop”. AI cannot consider the many subtle, patient-specific factors informing safe surgical decision-making. AI is useful in routine tasks of triage to facilitate efficiency and patient prioritisation, but it always requires human oversight for cases that demand clinical judgment.⁴³

The limits of AI become even more salient in high-stake surgery, where adaptations to unexpected real-time complications are quite often critical. Here, AI systems can go wrong given the fact that their training is on preoperative data. Decisions could be inappropriate, especially on underrepresented groups⁴⁴, thus making surgeons indispensable. This calls for a “human-in-the-loop” approach. Ethical concerns also arise in terms of the autonomy with AI, issues of accountability, and patient trust. The surgeon and other medical professional will be involved to ensure safety for the patients, legal responsibilities, and security in terms of data⁴⁵, especially if AI systems could expose confidential patient information.⁴⁶ Human touch ensures that the treatment provided will be oriented for the patient, ensures ethical accountability, and installs faith in the decisions made by AI.

13. Should errors made by AI be reported? If yes, how should they be reported?

From an Australian surgical perspective, a robust national reporting system for AI errors is needed to ensure patient safety, accountability, and continuous improvement of AI performance in healthcare.⁴⁷ The opportunities for AI in surgery are endless, from aiding diagnosis to intraoperative decisions with medical practitioner oversight, but precise and prudent control needs to be considered. Reporting of AI errors via

⁴¹ Mennella, C., Maniscalco, U., De Pietro, G., & Esposito, M. (2024). Ethical and regulatory challenges of AI technologies in healthcare: A narrative review. *Heliyon*, 10(4), e26297.

<https://doi.org/10.1016/j.heliyon.2024.e26297>

⁴² Naik, N., Hameed, B. M. Z., Shetty, D. K., Swain, D., Shah, M., Paul, R., Aggarwal, K., Ibrahim, S., Patil, V., Smriti, K., Shetty, S., Rai, B. P., Chlosta, P., & Somani, B. K. (2022). Legal and ethical consideration in artificial intelligence in healthcare: Who takes responsibility? *Frontiers in Surgery*, 9, Article 862322. <https://doi.org/10.3389/fsurg.2022.862322>

⁴³ Samantha Tyler, Matthew Olis, Nicole Aust, Love Patel, Leah Simon, Catherine Triantafyllidis, Vijay Patel, Dong Won Lee, Brendan Ginsberg, Hiba Ahmad, and Robin J Jacobs. "Use of Artificial Intelligence in Triage in Hospital Emergency Departments: A Scoping Review." *Cureus* 16, no. 5 (2024): e59906. Published May 8, 2024. <https://doi.org/10.7759/cureus.59906>.

⁴⁴ S.L. van der Meijden, M.S. Arbous, B.F. Geerts, "Possibilities and challenges for artificial intelligence and machine learning in perioperative care," *British Journal of Anaesthesia*, vol. 23, no. 8, pp. 288-294, August 2023. DOI: 10.1016/j.bjae.2023.04.003. Available on ScienceDirect. Copyright © 2023 British Journal of Anaesthesia. [https://www.bjaed.org/article/S2058-5349\(23\)00067-7/fulltext](https://www.bjaed.org/article/S2058-5349(23)00067-7/fulltext)

⁴⁵ Ibrahim Habli, Tom Lawton, and Zoe Porter, "Artificial Intelligence in Health Care: Accountability and Safety," *Bulletin of the World Health Organization* 98, no. 4 (April 1, 2020): 251–256, <https://doi.org/10.2471/BLT.19.237487>.

⁴⁶ Shiva Maleki Varnosfaderani and Mohamad Forouzanfar, "The Role of AI in Hospitals and Clinics: Transforming Healthcare in the 21st Century," *Bioengineering* 11, no. 4 (April 2024): 337, <https://doi.org/10.3390/bioengineering11040337>.

⁴⁷ Carter, S. M., Aquino, Y. S. J., Carolan, L., Frost, E., Degeling, C., Rogers, W. A., Scott, I. A., Bell, K. J. L., Fabrianesi, B., & Magrabi, F. (2024). How should artificial intelligence be used in Australian health care? Recommendations from a citizens' jury. *Medical Journal of Australia*, 220(8), 409-416. <https://doi.org/10.5694/mja2.52283>

systems and bodies like the National AI Centre or Therapeutic Goods Administration will ensure incidents are documented and analysed.

The collaboration between AI developers, healthcare providers, and regulatory bodies is very critical. Most AI errors are systems-related, such as mismatched or incongruent data generated by AI and any pre-existing clinical background.⁴⁸ A national reporting system would prompt transparency and rapid correction of errors. Learning from mistakes can help improve AI performance, especially for high-stakes environments such as surgery. Full reporting will allow detection of patterns, which upon being taken up by the developers, can be addressed and hence enhance AI safety over time.

The international best practices include, among others, the Food and Drug Administration Medical Device Reporting system in the United States⁴⁹ and the European Union's *Medical Device Regulation*. In return for reporting their errors transparently, the AI surgical ecosystem would provide public trust and patient confidence by informing them of adverse events involving AI, just like it would happen in the case of traditional medical errors. Such a system is quite important in ensuring accountability, continuous improvement, and patient-centeredness in AI-driven surgery.

14. Should there be transparency about when AI is involved in health care, and should consent be requested from the consumer or health care professional?

AI use in healthcare, especially in Australian surgery, calls for serious transparency and informed consent for the protection of trust and ethical standards. Transparency would mean that both the patient and health professionals have a good understanding of where AI is intervening to make clinical decisions to promote trust and reduce anxiety. In surgery, where patient confidence is very important, clear communication about the function of AI should be informed to avoid mistrust.⁵⁰

When AI functions at the influencing level of diagnosis and treatment in critical decisions, the possible surgical risks require explanation. The legal principle of “informed consent” in Australia grew from the landmark case of *Rogers v Whitaker [1992] HCA 58*. Hence following the general principles stipulated in this case, the patient should, by necessity, be informed of any involvement by AI and its possible consequences on their health. This becomes more critical in high-stakes surgeries where AI's influence may have consequences over the long term. The limitations and potential biases of AI require surgeons to be able to override AI where necessary and reinforcing professional human judgment.

It is here that the regulatory frameworks in Australia should introduce the element of transparency and consent in line with an *AI Code of Medical Ethics*. The regulatory bodies should ensure that the patients and clinicians are well-informed; the consent should, therefore, be a dialogue rather than a formality. In this respect, transparency and consent will not only protect patient autonomy but also ensure that AI is deployed responsibly within our Australian healthcare system.

15. Generative AI may be developed for general use, yet used in health care. Should generative AI developed have any special treatment, regulatory or otherwise?

Generative AI will continue to show promise for healthcare. However, it will have to be strictly regulated against the real risks that errors in surgical care may pose on patient safety and clinical decision-making. Though generative AI has the potential to leverage diagnostics, treatment planning, and administrative

⁴⁸ Evans, H., & Snead, D. (2024). Understanding the errors made by artificial intelligence algorithms in histopathology in terms of patient impact. *NPJ Digital Medicine*, 7, Article 89. <https://doi.org/10.1038/s41746-024-01093-w>

⁴⁹ Vokinger, K. N., & Gasser, U. (2021). Regulating AI in medicine in the United States and Europe. *Nature Machine Intelligence*, 3(9), 738–739. <https://doi.org/10.1038/s42256-021-00386-z>

⁵⁰ Esmaeilzadeh, P., Mirzaei, T., & Dharanikota, S. (2021). Patients' perceptions toward human–artificial intelligence interaction in health care: Experimental study. *Journal of Medical Internet Research*, 23(11), e25856. <https://doi.org/10.2196/25856>

efficiency, its adoption into medical practice raises concerns over bias, hallucinations, or even the generation of incorrect information, and accountability for errors.

For example, models of AI that have been trained using databases in which the data is not representative may lead to biased results when treating patients from different backgrounds, particularly of minority populations.⁵¹ Freely available generative AI at present gains insight from data sourced from the internet and hence there are many examples of bias and stereotyping, both racially and regarding gender. Several studies have documented that even minor errors by AIs may have serious consequences in clinical settings. It, therefore, calls for clinical validation, ongoing safety testing, as well as ethical protections.⁵²

Australia needs a regulatory framework involving AI applications in healthcare into a high-risk category. Transparency, accountability, and standards of accuracy would be expected to be maintained, considering the draft presented by the *European Union's AI Act*. Along with legal reform around accountability, developers of AI and health professionals need to be held liable for AI-induced medical errors. This shall, therefore, guarantee that AI acts in the context of one of the safest and most reliable health systems in the world: Australia's.

16. What protections are needed for patient data used or generated by AI that are different for health care?

AI-generated patient data in healthcare is highly sensitive and fraught with risks; therefore, it needs strong protection.⁵³ In surgical contexts, AI tools often process or create information related to diagnosis, treatment outcomes, and predictive analytics, all of which are absolute necessities for strong data protections. Any misuse or breach of such information could lead to infringed privacy or compromised patient care, thus undermining the use of AI systems.⁵⁴

Traditional ways of data security cannot work for AI-driven data in view of the fact that continuous learning and large data increase the risks of cyberattacks. Instead, what is needed is enhanced encryption with real-time monitoring and tighter controls over access. Further, even the prevailing legislation, such as the Australian *Privacy Act 1988*, cannot cope with all the issues arising when considering AI, such as algorithmic transparency and illegal use of data. We may well see AI itself be used in cybersecurity, but to what capacity and effectiveness is yet to be known.⁵⁵

Key ethical challenges include patient consent, data ownership, and commercial use of AI insights. Patients need to be informed about the use of their information, and regulation should specify who owns AI-generated insights—patients, healthcare providers, or developers of AI. The use of tailored regulations about these issues will ensure the safe and ethical employment of AI-generated patient data in Australia and will protect the rights of the patients while enabling AI-driven advancements in healthcare.

⁵¹ Norori, N., Hu, Q., Aellen, F. M., Faraci, F. D., & Tzovara, A. (2021). Addressing bias in big data and AI for health care: A call for open science. *Patterns*, 2(10), 100347.

<https://doi.org/10.1016/j.patter.2021.100347>

⁵² Naik, N., Hameed, B. M. Z., Shetty, D. K., Swain, D., Shah, M., Paul, R., Aggarwal, K., Ibrahim, S., Patil, V., Smriti, K., Shetty, S., Rai, B. P., Chlosta, P., & Somani, B. K. (2022). Legal and ethical consideration in artificial intelligence in healthcare: Who takes responsibility? *Frontiers in Surgery*, 9, 862322. <https://doi.org/10.3389/fsurg.2022.862322>

⁵³ Murdoch, B. Privacy and artificial intelligence: challenges for protecting health information in a new era. *BMC Med Ethics* 22, 122 (2021). <https://doi.org/10.1186/s12910-021-00687-3>

⁵⁴ Williamson SM, Prybutok V. Balancing Privacy and Progress: A Review of Privacy Challenges, Systemic Oversight, and Patient Perceptions in AI-Driven Healthcare. *Applied Sciences*. 2024; 14(2):675. <https://doi.org/10.3390/app14020675>

⁵⁵ Jada, I., & Mayayise, T. O. (2024). The impact of artificial intelligence on organisational cyber security: An outcome of a systematic literature review. *Data and Information Management*, 8(2), 100063.

<https://doi.org/10.1016/j.dim.2023.100063>

17. Is it acceptable for developers of AI products to use patient data to develop their products or to sell patient data collected from use of AI?

RACS does not agree that patient data should be sold for commercial purposes. The use of AI developers with patient data raises ethical, legal, and privacy concerns in the health sector. Specifically, what is required from an Australian surgical perspective is that any use of a patient's data by AI developers for training algorithms or other commercial use needs explicit consent from the patient. Any breach will impact public confidence in an AI-driven healthcare system with collateral damage to all medical practitioners, like surgeons.

It has often been seen that deidentification is a solution for privacy, but research has identified the existence of a number of risks of reidentification, especially for large data sets.⁵⁶ This is a direct implication that strong safeguards are required to safeguard patient privacy. Finally, selling patient data-even de-identified data involves ethical risks related to exploitation and the misuse of data for nonhealthcare purposes.⁵⁷

These are challenges that the current state of privacy laws in Australia, such as the *Privacy Act 1988*, may not comprehensively address and thus require stricter regulation. Stronger frameworks, similar to the *General Data Protection Regulation* instituted by the European Union, could ensure more transparency, accountability, and compliance, but this needs to be evaluated in Australia first. Patients have a right to know how their data will be used and to opt out. After all, guaranteeing ethical, secure, and transparent use of patient data in AI development will go a long way in ensuring that trust is maintained in the facilitation of innovation within Australian healthcare.

18. Should your healthcare information be kept in Australia? If yes, would your view change if this reduced ability to access advances in AI made overseas?

From an Australian surgical perspective, health data should be housed on-shore in respect of the requirements of Australian privacy law to ensure the sanctity of patient confidentiality, and maintaining data sovereignty. Stringent regulations under the *Privacy Act 1988* and the *My Health Records Act 2012* include security regarding the handling of such data, and the need for accountability. Overseas data storage may expose patient information to foreign laws, such as the *US CLOUD Act*, which allows government access, raising concerns over privacy and national security. The current Australia-US CLOUD Act Agreement was design for communication platforms based overseas which are used to “commit a range of serious crimes, such as terrorism, child sexual abuse, and cybercrime.”⁵⁸ Privacy protections and safeguards may have to be revisited in light of the potential commercial abuse of patients and surgeons' data.

There may be those instances when accessing advanced AI-driven tools from abroad will contribute to the betterment of patient care, but this has yet to be clearly defined. International AI tools developed from countries such as the U.S. and EU may provide exceptional medical innovations. In these instances, stringent governance and data-sharing agreements need to make certain that Australian standards are met. International data storage for these purposes could be allowed provided strong safeguards in this regard would include reciprocal obligations of foreign AI providers to adhere to Australian privacy laws. The balance between innovation and protection of data is a question of trust in the health system while taking advantage of technological development.

⁵⁶ Farzanehfar, A., Houssiau, F., & de Montjoye, Y.-A. (2021). The risk of re-identification remains high even in country-scale location datasets. *Patterns*, 2(3), 100204. <https://doi.org/10.1016/j.patter.2021.100204>

⁵⁷ Chiruvella, V., & Guddati, A. K. (2021). Ethical issues in patient data ownership. *Interactive Journal of Medical Research*, 10(2), e22269. <https://doi.org/10.2196/22269>

⁵⁸ Australian Government, Department of Home Affairs. (2024). *Australia-United States CLOUD Act Agreement*. <https://www.homeaffairs.gov.au/about-us/our-portfolios/national-security/lawful-access-telecommunications/australia-united-states-cloud-act-agreement>

19. Are there any specific safety considerations that have not been raised elsewhere?

The consideration of safety for the integration of AI in healthcare from an Australian surgical perspective arises in a number of critical areas that impact patient care, principally in terms of how biases are propagated in AI systems, and accountability when decisions result in harm. These systems, which often learn from historical data, incorporate biases on the basis of race, sex, and socioeconomic status. If AI algorithms are not properly validated, they may actually exacerbate, instead of mitigating, existing health disparities by providing inequitable treatment, thus eroding trust that people have in technology. That's why AI surgical systems should be modelled with diverse data to ensure equal care for all patients.

There is also accountability with AI systems making adverse decisions. These legal frameworks will have a hard time locating where the autonomous systems are making bad decisions. RACS advocates for new frameworks to clear up these complexities. There must be the drawing of clear lines of responsibility by those who develop AI, healthcare providers, and institutions. In this regard, regulation and mechanisms of oversight will be required to improve the development of standards that ensure diversity in data on which such systems are trained, with conditions allowing for accountability, and performance reviews. Indeed, the adoption of best practices will go a long way in placing Australia at the forefront in ensuring that AI technologies in surgical practice are safe and effective, focusing first and foremost on patient care.

Commentary: AI in surgery from the environmental sustainability perspective

While AI intervention in surgery holds promise for higher precision, speed, and patient outcome, the development also comes with huge resource utilisation in terms of energy and personnel that can be harmful to the environment. This has only been recognised in 2024 with for example numerous investigative reports conducted by the U.S. National Public Radio (NPR). For example, it was reported that "Google says its total greenhouse gas emissions climbed nearly 50% over five years, mostly due to electricity that powers AI data centers."⁵⁹ Only recently it was reported that Constellation Energy and Microsoft have signed a power deal to help resurrect a unit of the Three Mile Island nuclear plant in Pennsylvania to provide power to Microsoft's proliferating artificial intelligence operations.⁶⁰

According to recent commentary made by researchers from the University of Technology Sydney⁶¹, since ChatGPT launched in November 2022, AI development has accelerated at an unprecedented rate, with increased investment and social concern. The environmental impact, however, is cause for alarm. AI applications can use as much as ten times more energy than traditional searches, while generative AI consumes 33 times more. This, in turn, increases energy demand and leads to increasing carbon emissions, stretching already stressed electricity grids amid climate change. In 2023, data centres hosting AI applications were using between 1–1.5% of all global electricity use; similarly, company reports, such as that from Microsoft, attributed large jumps in emissions due specifically to AI. Microsoft's emissions rose from 12.2 million to 17.1 million tonnes of CO₂ from 2020 to 2023. These centres also use a lot of water for cooling, putting stress on the resource in water-stressed areas. With records of extreme heat increasing due to climate change, data centres are in competition for resources with the local population; hence, the need for IT managers to take up the mantle of education and training regarding impacts on sustainability.

⁵⁹ Dara Kerr, "Artificial Intelligence's Thirst for Electricity," *U.S. National Public Radio (NPR)*, July 10, 2024, 5:09 AM ET, heard on *Morning Edition*, <https://www.npr.org/2024/07/10/nx-s1-5028558/artificial-intelligences-thirst-for-electricity>.

⁶⁰ C. Mandler, "Three Mile Island Nuclear Plant Will Reopen to Power Microsoft Data Centers," *National Public Radio (NPR)*, September 20, 2024, <https://www.npr.org/2024/09/20/nx-s1-5120581/three-mile-island-nuclear-power-plant-microsoft-ai>.

⁶¹ Gordon Noble & Fiona Berry, "Power-hungry AI is driving a surge in tech giant carbon emissions. Nobody knows what to do about it," *The Conversation*, July 8, 2024, 4:26 PM AEST, <https://theconversation.com/power-hungry-ai-is-driving-a-surge-in-tech-giant-carbon-emissions-nobody-knows-what-to-do-about-it-233452>.

By this measure, the effectiveness of artificial intelligence systems in healthcare requires working on real-time decision-making for surgeries. This would require colossal computational power and data processing. The high demand for energy-guzzling servers and cloud infrastructure results in a higher carbon footprint which may be offsetting the benefits brought about by AI-enhanced surgical procedures. As much as AI can facilitate workflow processes and reduce human errors in the performances of operations, AI requires specialised training for surgeons and other support personnel. That kind of training takes time and hence calls for extended training periods with considerable use of advanced technology to increase the total environmental impact of hospital operations. AI in surgery could also lead to increased volumes of disposable materials, like sensors and sterile coverings for AI-powered machinery, adding to the already important medical waste problems. While AI has immense potential with respect to enhancing surgical precision and, consequently, surgical outcomes, the demands this places in terms of resources raise very serious challenges in terms of sustainability. Health services need to consider the ecological cost arising from such benefits and be mindful of finding greener technologies and renewable energy solutions that could reduce the ecological footprint of AI.

Conclusion

RACS is of the opinion that ultimately broad regulations encompassing safety, accountability, and transparency of the use of AI in Australian healthcare are needed to maximise its benefits while minimising the associated risks. Other measures of priority involve rigorous clinical validation of the AI tool, data privacy, and sensitivity to diverse cultural contexts. Investment in training for health professionals that will facilitate smooth translation of AI into practice is also very important.

For that reason, oversight would have to be extremely strict. RACS proposes a regulatory body for AI in health care, reform of accountability laws, and enhanced data protection. Besides this, human oversight of decisions is required. We advocate using international frameworks as a guide, like the EU's *AI Act*, to promote ethical non-clinical AI development and deployment.

The introduction of a national AI error reporting system will greatly benefit patient safety. Transparency and informed consent of AI use in healthcare are demanded. Generative AI needs inclusion in the category of high risk with relevant stringent regulations. Data protection laws urgently need strengthening, with a ban on selling patient data without explicit consent. Patients may give consent but not know what they are consenting to or unforeseen outcomes. Lastly, increasing diversity in training data would go a long way toward avoiding biases. Continuous assessment of the ecological impact by servers and hardware designed to maintain AI technology requiring monitoring.

RACS welcome continual engagement with government in the use of AI in healthcare and its impact on both medical specialists like surgeons, and patients alike.

Yours sincerely,

Professor Mark Frydenberg
Chair, Health Policy & Advocacy Committee