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3 July 2023

Meghan Quinn PSM
Secretary
Department of Industry, Science and Resources
GPO Box 2013
Canberra ACT 20601

Dear Ms Quinn,

RE: Discussion paper on Safe and responsible AI in Australia

On behalf of the Australasian College of Dermatologists (ACD), I would like to thank you for the opportunity to comment on the Department of Industry, Science and Resources' discussion paper (the 'paper), *Safe and responsible artificial intelligence (AI)* in Australia.

ACD is the sole medical college accredited by the Australian Medical Council (AMC) for the training and continuing professional development of medical practitioners in the specialty of dermatology. We are the national peak membership organisation, representing over 600 dermatologist Fellows (FACD) and 100 trainees. As the leading authority in Australia for dermatology, we provide information, advocacy and advice to individuals, communities, government, and other health stakeholders on dermatological practice.

Diagnosis and management of dermatological conditions has significantly evolved with rapid advancements in technology and innovation creating new opportunities and risks for patient care. As dermatology is a highly visual specialty, there is increasing interest, both in Australia and internationally in the opportunities for AI, particularly image-based AI, to improve patient access to dermatological care and to enhance quality of care.

ACD's Digital Health Committee have been closely monitoring and advising on these developments - including the opportunities, risks and regulatory considerations - to inform education and guidance for our Fellows (dermatologists), trainees, government and other stakeholders.

We therefore support the intent of this paper to identify potential gaps in the governance of AI in Australia and opportunities to strengthen governance mechanisms to support the safe, ethical and effective development, adoption and use of AI.

This submission provides a brief overview of the context for our work in this area, and the research and recommendations that we have made to date in relation to the development, regulation and adoption of AI technology in dermatology in Australia.

Context: AI use in dermatology

To date in dermatology, there has been a strong focus on the potential for AI to improve detection, diagnosis and monitoring of skin cancer. However, there is growing interest in the utility of AI for other skin conditions particularly inflammatory skin conditions, such as eczema and psoriasis.

While most of these AI products focus on use in the clinical setting to augment general practitioners (GPs) or dermatologists' decision-making, there are direct-to-consumer products available. This has led to new clinical, legal and ethical issues emerging, including consent, data control, practice standards, reliance and liability, communication of accuracy, privacy, data quality and bias, interoperability of systems, consumer and clinician acceptance, as well as the potential positive and negative impact on referral pathways, service demand and delivery models of care.

We are particularly concerned therefore that these AI algorithms and products are developed, trained, designed and adopted to suit the Australian context and deliver ethical, safe and high-quality care for patients, and that development and adoption is underpinned by a robust regulatory and governance framework.

ACD's work to date and published recommendations

In early 2022, ACD's Digital Health Committee undertook a member consultation and literature review on AI which focused on position papers from dermatological professional bodies and other specialities that utilise medical imaging, as well as regulatory guidelines and ethical position papers.

The review findings, published in the Australasian Journal of Dermatology (AJD), provide recommendations for both dermatologists as contributors and adaptors of AI and ACD and aim to guide the development, regulation and adoption of AI in dermatology in Australia. The published paper, *Informing a position statement on the use of artificial intelligence in dermatology in Australia* is available here.[1]

A high-level overview of the key recommendations was published as a College position statement (see ***Attachment A***).[2] In our definition of AI, we note that AI may be referred as augmented intelligence and would encourage the Department of Industry, Science and Resources to consider this in your definition of AI.

Our Digital Health Committee have also consulted with a range of stakeholders, including industry, both in Australia and internationally to gain a better understanding of current and future work in relation to AI in dermatology. Key themes to emerge included:

- The importance of data being representative for the demographic mix, clinical context and market in which it will be used and therefore of undertaking studies in Australia and of real-world studies;
- The challenges in risk classification, for example delineating between what does and does not constitute a 'diagnostic' tool;
- Greater understanding of the point at which AI should be used in the decision-making journey and the impact that may have on clinician decision-making, and taking into account their level of expertise (specialist/non-specialist; level of AI understanding);
- Quality and controls for image data capture;
- Challenges in communicating the concepts of accuracy and sensitivity in a meaningful way;
- Identifying appropriate comparators to establish cost/benefit and how to structure reimbursement mechanisms to support AI that augments patient care; and
- Data security and governance around secondary use.

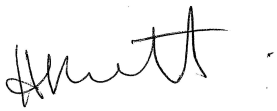
Government engagement

AI models in healthcare in Australia are regulated as Software as a Medical Device (SaMD) by the Therapeutic Goods Administration (TGA). ACD continues to engage with the TGA on opportunities to collaborate and provide expert advice in relation to the development and adoption of AI for dermatology in Australia and to inform development of regulatory and governance mechanisms that support the safe, ethical and effective clinical use.

We welcome the opportunities to be involved in these broader conversations and thank you again for the opportunity to provide input on this consultation.

If you have any questions or would like to discuss further, please do not hesitate to contact Annie Bygrave, Policy Manager at annie@dermcoll.edu.au .

Kind regards,



Dr Haley Bennett

Chief Executive Officer

Attachment A: ACD position statement on the use of Artificial Intelligence in dermatology in Australia

[1] Caffery L, Janda M, Miller R, et al. Informing a position statement on the use of artificial intelligence in dermatology in Australia. Australasian Journal of Dermatology 2022; 64(1): e11-e20.
[2] https://www.dermcoll.edu.au/about/position-statements/

Position statement

THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS

Use of Artificial Intelligence in Dermatology in Australia

Purpose: To guide the development, regulation, and adoption of AI for dermatology in Australia.

Audience: Community

Acknowledgements: This statement has been adapted from Caffery et al. (2022), *Informing a position statement on the use of Artificial Intelligence in dermatology in Australia*. Australasian Journal of Dermatology, Nov 2022[1] by the Australasian College of Dermatologists with permission from the authors.

Endorsement: This position statement has been approved by The Australasian College of Dermatologists' Digital Health Committee.

Disclaimer: This position statement reflects the general views of the Australasian College of Dermatologists at the date of release and may be subject to amendment to reflect emerging clinical and scientific evidence. This information provides educational information and is not intended as a substitute for individual patient assessment. Practitioners are advised to interpret and apply recommendations according to the needs and circumstances of each patient.

First endorsed by ACD: November 2022
Last updated: November 2022

Key messages and recommendations

- The Australasian College of Dermatologists (ACD) supports the development of Artificial Intelligence (AI) to enhance the practice of dermatology in Australia and welcomes future research into how AI can be utilised in dermatological practice, including for skin cancer, skin rashes and inflammatory conditions.
- The rapid advancements in AI and introduction into dermatological practice create a range of new opportunities and risks to patient care.
- This position statement sets out high-level principles and recommendations to guide the safe, ethical and effective development, regulation and adoption of AI technology in dermatology for the Australian context.
- The ACD will continue to monitor the developments in AI relevant to the practice of dermatology in the Australian context and continue to provide more detailed guidance for contributors and adopters of AI.

ACD Position Statement – Use of Artificial Intelligence in Dermatology

Background

Diagnosis and management of dermatological conditions have significantly changed with rapid advancements in technology and innovation, such as Artificial Intelligence (AI). There is increasing interest, both internationally and in Australia, in the opportunities provided by AI to improve patient access to dermatological care and to enhance quality of care.

AI (also referred to as augmented intelligence) involves machine simulation of human intelligence, such as natural language processing, robotics, and computer vision.[2] Computer vision enables AI models to interpret and derive information from visual inputs, including images or videos. In dermatology there is particular interest in using AI to diagnose or predict the risk of skin lesions from inputted images. Also known as image classification, visual pattern recognition has been at the forefront of AI research due to its clinical application.[2] However, there is currently limited evidence to support safe and effective clinical use of AI for dermatological conditions.

Purpose of this position statement

The purpose of this Position Statement on the Use of AI in Dermatology is to provide a high-level overview of the Australasian College of Dermatologists (ACD) key policy recommendations to guide the development, regulation and adoption of AI in dermatology in Australia.

To inform this position statement, the ACD commissioned the University of Queensland (UQ) to undertake a literature review, focused specifically on position papers from dermatological professional bodies and other specialties that utilise medical imaging, as well as regulatory guidelines and ethical position papers. The literature review findings support a set of evidence-based policy recommendations, developed in collaboration with ACD's Digital Health Committee, for ACD and for its members in their capacity as adopters of and contributors to AI.

Further information and the full set of recommendations, including those for dermatologists as adopters of, and contributors to AI are available in the published paper titled, Informing a position statement on the use of artificial intelligence in dermatology in Australia.[1]

Regulation and access in Australia

In Australia, AI models are regulated as Software as Medical Device (SaMD) by the Therapeutic Goods Administration (TGA). A software product is considered a medical device if it fits the definition under Section 41BD of the Therapeutic Goods Act 1989. Direct-to-consumer AI apps may not require TGA approval if they do not meet the definition of a medical device.

Before an AI model can be legally supplied in Australia it must have TGA pre-market approval. TGA approved products are listed on the Australian Register of Therapeutic Goods. AI models are subject to both pre- and post-market regulatory oversight. ACD recognises the current limitations of risk assessment and clinical assessment that may occur with the regulation of AI up to this point and has made recommendations to mitigate this.

The TGA is currently undertaking reform of the regulation of SaMD to be consistent with the International Medical Device Regulators Forum (IMDRF) regulation of SaMD. Since February 2021, all new SaMD applications for regulatory approval will be assessed using the new risk assessment processes, including the purpose of the device and whether the intended user is a health care professional or a patient. The ACD supports this approach.

Ethical use of Artificial Intelligence

Currently, there are several guidelines on the ethical use of AI. An international review identified 84 published ethical guidelines.[3]

While comparability of guidelines is difficult due to variations in ethical principles and definitions, the principles of transparency, justice and fairness, non-maleficence, responsibility and privacy are consistent among several published ethical guidelines. Therefore, ACD will promote the ethical use of AI based on these five principles.

Key policy recommendations

ACD acknowledges that there are multiple stakeholders involved in ensuring the safe, ethical and effective clinical use of AI in dermatology.

- **Augmenting care:** ACD supports the development of AI to enhance the practice of dermatology.
- **Ethical use**: the ACD recommends that dermatologists use AI ethically – this involves beneficence, non-maleficence (including ensuring patient privacy and confidentiality is maintained), transparency (informing patients that the diagnosis was augmented by AI); and utilising AI models that have attempted to reduce bias, where possible.
- **Equity:** ACD supports the development of AI that can enhance skin health outcomes for Aboriginal and Torres Strait Islander peoples.
- **Collaboration:** ACD recommends ongoing collaboration with regulators, policymakers and industry stakeholders, and clinicians and consumer groups to help ensure appropriate AI policy, regulation and education to support safe and effective use of AI in clinical dermatology to improve patient care.
- **Real-world evaluations**: ACD recommends prospective, real-world evaluations that demonstrate AI to be equivalent or superior in performance to clinicians, or significantly enhance the performance of clinicians are required to support clinical adoption of AI.
- **Patient safety:**
    - ACD recommends only AI models which have regulatory approval by the TGA using the reformed (post- 25 February 2021) risk assessment model are used in clinical practice.
    - ACD does not endorse the use of direct-to-consumer AI models that do not have regulatory approval as a medical device.

- ACD recommends utilising approved AI devices to aid dermatologists in reaching a diagnosis; that is, AI should be used to augment, but not replace clinical judgement.

Transparency and traceability: ACD recommends that all artefacts of AI workflows, such as model output and saliency maps be traceable and auditable through incorporation into the patient's medical record and stored for the retention period prescribed in relevant legislation.

Recommendation for adopters and contributors to Artificial Intelligence

As adopters and contributors of AI, dermatologists will need to develop knowledge and skills in the selection, use and monitoring of AI, while upholding the ethical principles outlined above. The specific recommendations for dermatologists as adopters of, and contributors to AI are available in the published paper titled, Informing a position statement on the use of artificial intelligence in dermatology in Australia. [1] ACD will continue to build on these recommendations through future education and guidance.

ACD Position Statement – Use of Artificial Intelligence in Dermatology

References

1. Caffery, LJ, Janda, M, Miller, R, Abbott, LM, Arnold, C, Caccetta, T, et al. Informing a position statement on the use of artificial intelligence in dermatology in Australia. *Australas J Dermatol*. 2022; 00: 1– 10. https://doi.org/10.1111/ajd.13946
2. Du-Harpur X, Watt FM, Luscombe NM, et al. What is AI? Applications of artificial intelligence to dermatology. Br J Dermatol. 2020; 183: 423-30.
3. Jobin A, Ienca M and Vayena E. The global landscape of AI ethics guidelines. Nat Mach Intell. 2019; 1: 389-99.

This position statement is also available online. For more topics, visit dermoll.edu.au or scan the QR code.

About us

Dermatologists are doctors who are the medical specialists in skin health. The Australasian College of Dermatologists (ACD):

- Trains and supports dermatologists
- Advocates for better skin health for our communities
- Sets the clinical standard in dermatology

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