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31 May 2019
Strategy, Digital Economy and Business Simplification

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To Whom It May Concern,

RE: Artificial Intelligence: Australia's Ethics Framework

On behalf of the Australasian College of Dermatologists (ACD), thank you for the opportunity to provide comment on the draft framework, *Artificial Intelligence: Australia's Ethics Framework*.

The ACD is the peak medical college accredited by the Australian Medical Council for the training and professional development of medical practitioners in the speciality of Dermatology. The ACD has a national membership of approximately 500 practising specialist dermatologists and 100 trainees across Australia.

Artificial Intelligence (AI) is an exciting and rapidly evolving field with a number of dermatological applications. The ACD is supportive of the need for a national, principle-driven Framework to guide the ethical advancement of AI. The draft framework provides this foundation and the ACD commends the Federal Government for this important initiative.

The ACD welcomes the opportunity for the College to be directly involved in further development of AI policy and ethics. The College is well placed to provide professional input and expert advice, given the rapid progress and potential benefits of AI applications to the field of dermatology and healthcare more broadly.

Please contact Belinda Jackson, Policy Manager belinda@dermcoll.edu.au for further correspondence on this matter.

Kind regards,

A/Prof David Francis MBBS FACD
President
The Australasian College of Dermatologists

ACD Response to consultation on Artificial Intelligence: Australia's Ethics Framework

Introduction
The Department of Industry, Innovation and Science has released a discussion paper developed by CSIRO Data61: *Artificial Intelligence: Australia's Ethics Framework* for public consultation.

The Australasian College of Dermatologists (ACD) welcomes the opportunity to comment on the draft framework. Artificial Intelligence (AI) is an exciting and rapidly evolving field with a number of dermatological applications. The College is supportive of the need for a national, principle-driven Framework to guide the ethical advancement of AI and commends the Federal Government for this important initiative.

The ACD welcomes the opportunity to be directly involved in further development of AI policy and ethics. The College is well placed to provide professional input and advice considering the impact and potential benefits to dermatology and the existing reality and progress in the application of AI.

About us: ACD
The ACD is the peak medical college accredited by the Australian Medical Council for the training and professional development of medical practitioners in the speciality of Dermatology. The ACD has a national membership of approximately 500 practising specialist dermatologists and 100 trainees across Australia.

The College is the leading authority in Australia for dermatology, providing information, advocacy and advice to individuals, communities, government and other health stakeholders on skin health and dermatological practice.

Purpose
The goal of the *Artificial Intelligence: Australia's Ethics Framework* is to create a toolkit of practical and implementable methods that can be used to support core ethical principles designed to assist both AI developers and Australia as a whole.

The eight (8) principles are:
1. Generates net-benefits
2. Do no harm
3. Regulatory and legal compliance
4. Privacy protection
5. Fairness
6. Transparency and explainability
7. Contestability
8. Accountability

These are supported by nine (9) tools:
1. Impact assessments
2. Review processes
3. Risk assessments
4. Best practice guidelines
5. Education, training and standards
6. Business and academic collaboration in Australia
7. Monitoring AI
8. Recourse mechanisms
9. Consultation

ACD Key Points
- The draft framework provides an important foundation for the ethical implementation of AI in Australia.
- Dermatology is a highly visual specialty, often requiring expertise and knowledge in pattern-based recognition for diagnostic acuity. Advances in imaging technology, coupled with AI's ability to interrogate images down to the pixel level, places dermatology in an advantageous position to leverage benefits of this new technology. Optimising AI in this setting may also help to address potential pitfalls, including improper training data, uninterpretable output, and legal challenges[1].
- Within the field of dermatology, recent research in melanoma demonstrates the potential for AI to provide a reliable diagnostic assessment[2], which may in turn drive improvements in patient healthcare access and in standards of care. AI applications include: diagnosis, decision support tool, improved use of limited medical resources, and time optimisation.
- ACD agrees with the overall principles and tools presented in the discussion paper. The rise of potentially AI-driven technologies in the field of dermatology, as well as other health components, requires a system wide response. As such there is a strong case for the development of healthcare sector specific guidelines on how best to manage privacy protection and other ethical considerations with AI. ACD welcomes the opportunity to be involved in the development of policy and ethics associated with AI.
- ACD would like to highlight the importance of ensuring ongoing education and training for health practitioners with respect to understanding AI and its application to better inform their practice. Education and training would help address automation bias and encourage practitioners to actively think and involve themselves with AI derived decisions.
- The inclusion of public consultation as a tool for implementing ethical AI is a welcome addition and will help generate trust and transparency between patients, health practitioners, interfacing institutions, and the general public.

AI in the practice of Dermatology

The specialty of dermatology relies on visual and tactile diagnosis, amongst a wide range of diagnostic tools and methods. Current examples of AI in Dermatology are primarily focused on the use of AI to detect skin lesions using images[3,4,5].

One study published in Nature by Esteva et al took a deep convolutional neural network (CNN) (powered by Google's advanced analytics) and tested its performance against 21 board certified dermatologists. The CNN performed on par with all tested experts, demonstrating an AI

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[1] Schlessinger, DI., Chhor, G., Gevaert, O., Swetter, SM., Ko, J., Novoa, RA. *Artificial Intelligence and dermatology: opportunities, challenges and future directions*. Semin Cutan Med Sug. 2019 Mar 1, 38(1): E31 – 37

[2] Mar, VJ., Soyer, HP. *Artificial Intelligence for melanoma diagnosis: how can we deliver on the promise?* Annals of Oncology, Vol. 29 Issue 8 2018, pg 1625 - 1628

[3] Haenssle HA, Fink C, Schneiderbauer R et al. *Man against machine: diagnostic performance of a deep learning convolutional neural network for dermoscopic melanoma recognition in comparison to 58 dermatologists*. Ann Oncol 2018; 29(8): 1836–1842

[4] Esteva, A., Kuprel, B., Novoa, RA., Ko, J., Swetter, SM., Blau, HM., Thrun, S. *Dermatologist-level classification of skin cancer with deep neural networks*. Nature. 2017 Feb 2; 542(7639): 115 – 118

[5] Lev-Tov, H. *Turning skin "check" into checkmate*. Sci Transl Med. 2017 Mar 1; 9(379)

capable of classifying skin cancer with a level of competence comparable to dermatologists. The study identified the potential for AI enabled smartphones to extend the reach of dermatologists outside the clinic.

Another study by Haenssle et al compared a CNN's diagnostic performance with a large international group of 58 dermatologists. Most dermatologists were outperformed by the CNN. However when given additional clinical information and close up images, the study found an improved diagnostic performance of dermatologists. The data in this study showed that a CNN algorithm could be used as a tool to aid physicians in melanoma detection irrespective of their individual level of experience and training.

These two examples involved an AI program trained using large datasets of clinical images consisting of a range of different diseases. In these settings the AI has been proven to perform diagnosis at a comparable level to dermatologists. However, importantly, their efficacy is yet to be tested in a clinical setting.

Literature[6,7] currently points to a number of AI applications and opportunities for the practice of Dermatology:
- AI has the potential to expand the diagnostic toolbox of dermatologists and enhance access for patients requiring urgent attention.
- AI as a decision support tool "integrated into routine consultation, with clinical examination, photography of suspicious lesions and AI support to assist the clinician reach an appropriate management decision"[8].
- Extend limited medical resources, namely through the use of AI as a triage tool, leading to: "earlier diagnosis, more appropriate referrals to specialists, fewer unnecessary procedures and therefore less morbidity and better outcomes for patients at lower cost to the healthcare system"[9].
- Optimise time consuming tasks and automate repetitive tasks.

There are a number of issues to be considered with respect to AI in dermatology:
- **Training data needs to be correct** and include a diversity of patient characteristics and skin disease types. AI is only able to perform as strongly as the data from which it learned. Granularity of data provided, regarding data labelling, needs to be considered in order to improve the accuracy and usefulness of the outputs.
- **Algorithm output needs to be interpretable**. The rationale for this concern is that if AI systems are to be adapted as clinical support tools, clinicians will want a way to verify the reasoning that goes into an algorithm's decision. AI should be able to support and explain its diagnostic decision making.
- **Current trials of AI have not been tested in a clinical setting**. Dermatologists performed better than AI when given clinical context regarding the patient[10].

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[6] Ibid 2
[7] Ibid 1
[8] Ibid 2
[9] Ibid 2
[10] Ibid 1

- **AI is capable of undertaking 'super human' tasks however human-patient interaction should always be preserved when necessary**. Diagnosis is not always straightforward in dermatology and therefore requires additional examination and testing; often a macro or holistic view, involving examination of multiple areas of the body, is needed, particularly for inflammatory conditions. Furthermore the human element must be considered. "AI appears unsuited…for tasks that are completely dependent upon the clinician-patient interaction, such as counselling and emotional support"[11].
- **Addressing liability and risks associated with the commercialisation of AI is required**. Any consumer facing diagnostic applications using AI must ensure the ongoing engagement of the medical profession and consumer protection. There are issues already emerging with the use of smartphone applications being used for self-diagnosis for skin cancer, leading to inaccurate diagnosis[12]. Appropriate safeguards and consumer protection mechanisms need to be established in order to mitigate adverse impacts due to the commercialisation of AI.

The Principles

ACD agrees overall with the principles presented in the discussion paper. The ethical principles in the report provide a solid foundation that protects patients and practitioners while laying out practical principles to abide by. The report, supported by the principles, highlight the ongoing need for human oversight of AI to ensure ethical, transparent and accountable processes.

Principle 1 – Generates net-benefits

Generating net-benefits is an important principle, particularly in the context of health and ensuring patient-centric approaches to care. There is an opportunity with AI to improve diagnostic accuracy, minimising inappropriate referrals and unnecessary procedures, leading to better patient outcomes[13].

Principle 2 – Do no harm

This is a fundamental principle for all health practitioners and is important to consider in the context of AI applications in health. Patient safety and quality care is paramount. Any new technology should only be incorporated into everyday practice if there is demonstrated evidence that it improves or contributes to safe and quality healthcare.

Appropriate safeguards must be implemented to ensure diagnosis and decisions generated by AI are both validated, by a trained professional, and have the patient's best interest at the forefront. This can be supported by Human In The Loop approaches as well as ongoing education and training of dermatologists to be able to detect when AI generated decisions are questionable.

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[11] Ibid 2

[12] Cancer Council Australia. Position Statement: Screening and early detection of skin cancer. Accessed on 27th May 2019 at https://wiki.cancer.org.au/policy/Position_statement_-_Screening_and_early_detection_of_skin_cancer#_ga=2.198432303.1499668949.1558677140-746103801.1535090114

[13] Ibid 2

Further medical oversight would help address the risk of misdiagnosis in AI applications. In Australia, melanoma is likely to continue to be the fourth most commonly diagnosed cancer in 2019, with an estimated 15,229 new cases and 1,725 predicted deaths[14]. Incorrect diagnosis of melanoma has implications on treatment and potentially survival. Given the ramifications, the use of AI in this setting will require oversight by trained medical professionals.

Principle 3 – Regulatory and legal compliance

Implementing AI in dermatology will require demonstrating its validity in the eyes of regulatory bodies at an international, federal and state level. If AI is classified as a medical device it would require thorough assessment and compliance with the current, and future, federal and state rules and regulations. The TGA has recently raised these issues more broadly in their consultation on software as a medical device. AI would potentially need to be captured within this or a similar regulatory framework.

Another form of compliance is the importance of establishing common industry standards, robust data governance and consistent record keeping. The ACD strongly supports the use of common standards to promote interoperability and common practice. For example ACD have developed draft *Practice guidelines for teledermatology*[15] to ensure a consistent approach to the use of telehealth in the practice of dermatology. While the guidelines do not specifically refer to AI, there are several overlapping considerations, such as image capture, storage and privacy. AI applications in future could feasibly be delivered using a telehealth modality. It is critical should this come into effect, that it be implemented according to the ethical framework.

Principle 4 – Privacy protection

The protection of privacy is a critical element in any application requiring the capture, storage, maintenance and protection of sensitive data, as is the case in the healthcare sector. The rise of potentially AI-driven technologies in the field of dermatology, as well as other health components, requires a system wide response. As such there is a strong case for the development of healthcare sector specific guidelines on how best to manage privacy protection with AI.

An ethical challenge for the application of AI in dermatology is the identification of potentially sensitive information through skin images captured and collected from patients, particularly where there are identifying physical features. In addition, the interoperability and interfacing of one AI to another in a clinical setting has not yet been explored. This supports the abovementioned need for a system wide understanding and response to ensure privacy is protected, whilst generating net-benefits from the use of the technology. A possible solution to this would be the application of 'privacy by design' principles to ensure privacy is upheld without compromising functionality of the AI application[16]. Privacy by design advocates for

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[14] Cancer Australia 2019. Melanoma skin cancer in Australia. Accessed on 28th May 2019 at: https://melanoma.canceraustralia.gov.au/statistics

[15] Currently in draft form only, pending consultation within the ACD. These will eventually be published on the ACD website.

[16] Cavoukian, A. *Privacy by Design; The 7 Foundational Principles; Implementation and Mapping of Fair Information Practices.* International Association of Privacy. Accessed on 30th May 2019, at https://iapp.org/media/pdf/resource_center/Privacy%20by%20Design%20-%207%20Foundational%20Principles.pdf

privacy as the default, ensuring the principles of privacy are proactively implemented rather than reactively responding to lapses in privacy protection. As an end-to-end design feature this approach would engender transparency and trust in the security of patient data.

The discussion paper also points out the "need to consider meaningful consent when considering the input data that will feed their AI systems"[17]. Patient consent is needed for the use of images in the AI training datasets. However this can be difficult to obtain due to the scale (AI requires large datasets[18]) and ethical consent mechanisms that may be required to approve the use of such datasets.

Mechanisms also need to be in place to support patient's choice to opt-out of being assessed and diagnosed by AI. This needs to be further supported by addressing potential intellectual property issues. These may arise from the need to refine AI algorithms using captured data whilst protecting and respecting patient choice.

There must also be a balance between the administrative burden of privacy legislation adherence, technological progress and development and cost effectiveness, particularly when the benefit of the technology outweighs the risk. More needs to be done to adequately address this dilemma and ensure Australians are able to leverage AI for their benefit. Again, this calls for the consideration and implementation of 'privacy by design' principles.

Principle 5 – Fairness
The principle of fairness is linked to addressing potential biases present in the training data and algorithms of AI. Training data needs to be correct and include a diversity of patient characteristics and skin disease types. AI is only able to perform as strongly as the data from which it learned, the adage 'garbage in, garbage out' applies.

The application of AI in dermatology faces the inherent biases in the incidence of skin cancer. Melanoma is more common among those with fair skin than those with darker skin types. It is likely there could be inadequate inputs into the learning system of the AI algorithm which may disadvantage darker skinned patients. The discussion paper rightly points out that "an AI that assesses skin cancer risk would need to take into account skin tone as a factor". Another inherent bias could potentially come from a dataset's geographic location of origin, when acquired from patients with greater exposure to UV. For example in Queensland 1 in 14 people are likely to be diagnosed in their lifetime with melanoma[19].

Granularity of data provided, regarding data labelling, needs to be considered in order to improve the accuracy and usefulness of the outputs, as well as the diversity and breadth of training and validation sets. This also needs to be balanced against several other principles, including privacy protection (principle 4), transparency and explainability (principle 6), and accountability (principle 8).

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[17] Dawson D and Schleiger E, Horton J, McLaughlin J, Robinson C∞, Quezada G, Scowcroft J, and Hajkowicz S(2019) Artificial Intelligence: Australia's Ethics Framework. Data61 CSIRO, Australia.
[18] Esteva et al in their study used a training dataset of 129,450 clinical images, consisting of 2,032 different diseases
[19] QLD Health 2016. Skin Cancer Prevention Strategy. Accessed on 27th May 2019, at https://www.health.qld.gov.au/__data/assets/pdf_file/0020/663032/health-wellbeing-strategic-framework-skin-cancer.pdf

Principle 6 – Transparency and explainability

AI decisions need to be transparent and explainable, and this is intertwined with the accountability principle. This is vital not only for the patient but for the treating health practitioner to ensure the decision is supportable and valid. Building trust in AI and the resultant decisions requires education and engagement of patients and health practitioners.

There is further risk associated with this principle with respect to the quality of the initial training data provided to the AI and the potential for the AI generated decisions to be biased, as described above. Therefore an ability to demonstrate transparent decision making and processes within AI is key to addressing this in an ethical manner. The inclusion of public consultation as a tool for implementing ethical AI is a welcome addition and will help generate trust and transparency between patients, health practitioners, interfacing institutions, and the general public.

Principle 7 – Contestability

This principle would apply in dermatology in situations whereby a clinical classification generated by the AI system varies from the dermatologist's classification. This is pertinent given that current trials of AI in dermatology have shown AI generating more accurate, and quicker, diagnosis than human dermatologists. This requires a standardised approach to classification, which can be extremely challenging. Nomenclature is constantly being reviewed, based on new consensus and/or research findings. AI algorithms will need to incorporate a mechanism to continually update when changes are made to ensure currency of the classifications they generate.

Algorithm output also needs to be interpretable[20]. The rationale for this concern is that if AI systems are to be adapted as clinical support tools, clinicians will want a way to verify the reasoning that goes into an algorithm's decision. AI should be able to support and explain its diagnostic decision making.

Principle 8 – Accountability

Accountability is a crucial principle, particularly given the examples provided in the discussion paper. Accountability for errors and ensuring this is communicated to patients and those interacting with AI is important. Those responsible and their roles in the application of AI algorithms and tools should be identified prior to implementation.

Accountability is especially relevant in the area of commercialisation of AI in dermatology. There are issues already emerging with the use of smartphone applications being used for self-diagnosis for skin cancer, leading to inaccurate diagnosis[21]. Although not directly AI algorithms, there is potential in the future for AI to be incorporated into smartphones. Appropriate safeguards and consumer protection mechanisms need to be established in order to mitigate adverse impacts due to the commercialisation of AI, and ensure clear lines of accountability.

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[20] Ibid 6
[21] Ibid 12

The proposed tools

ACD supports the proposed tools put forward in the paper. The ACD is supportive of the creation of further guidance for the development of standards to help govern designers of AI systems, particularly when dealing with complex systems such as healthcare.

ACD would like to highlight the importance of ensuring ongoing education and training for health practitioners with respect to understanding AI and its application to better inform their practice. Education and training would help address automation bias and encourage practitioners to actively think and involve themselves with AI derived decisions.

Conclusion

The ethical principles, and tools, outlined in the discussion paper apply to the use of AI in dermatology. The ACD would welcome the creation of a healthcare specific framework to address the ethics of AI in health more thoroughly, using the ethical principles and tools set out in this report to guide the development of such a framework.

The ACD welcomes the opportunity to be directly involved in further development of Artificial Intelligence policy and ethics, considering the impact and potential benefits to dermatology and the existing reality and progress in the application of AI.