

Legal and ethical considerations of artificial intelligence in skin cancer diagnosis.

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Abstract

Artificial intelligence (AI) technology is becoming increasingly accurate and prevalent for the diagnosis of skin cancers. Commercially available AI diagnostic software is entering markets across the world posing new legal and ethical challenges for both clinicians and software companies. Australia has the highest rates of skin cancer in the world and is poised to be a significant benefactor and pioneer of the technology. This review describes the legal and ethical considerations raised by the emergence of artificial intelligence in skin cancer diagnosis.

Introduction

Artificial intelligence (AI) is the ability for computer systems to perform tasks that usually require human intelligence.¹ Machine learning, a subset of AI, allows computer systems to self-learn from large datasets and create their own models to predict complex relationships with high levels of accuracy.¹ The algorithms produced by machine learning are often so complex it is not possible to understand how the computer has reached an outcome. This is often referred to as 'deep learning' and utilises multiple layers of artificial neural networks to identify features in data that are difficult for humans to recognise without AI assistance.²⁻

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The use of AI and machine learning has become increasingly prevalent in diagnostic image-recognition fields such as radiology, pathology, ophthalmology and dermatology.²⁻⁵ A recent European survey has found that as many as 20% of radiologists are now routinely using AI in some capacity.⁶ While AI is not currently widely used amongst dermatologists, AI diagnostic accuracy for skin cancers has improved dramatically in recent years and some algorithms now rival diagnoses arrived at by dermatologists when tested in experimental conditions.⁷⁻⁹ With Australia having the highest rates of skin cancer in the world, it is positioned to be an early adopter of AI skin cancer diagnostic technology. The technology faces unique challenges with widespread smartphone use enabling patients to diagnose skin cancer directly via smartphone applications without seeing a doctor. We aim to explore the legal and ethical considerations of both clinician-assisted and patient-directed technology being utilised in Australia.

Liability

In spite of recent advances in AI's diagnostic capability, just like clinicians, AI is not immune to error and there is a risk that it may be relied on excessively by patients and clinicians alike.¹⁰ The major concern is the rate of false negatives, or sensitivity, as there is a potential for inappropriate reassurance about a life-threatening melanoma. In addition, false positives, or specificity, can lead to the overdiagnosis of melanoma with unnecessary excisional surgery and complications including cosmetically disfiguring scarring, wound infection or nerve damage as well as increasing the financial burden to patients and the health system.¹¹

The Food and Drug Administration (FDA) in the United States of America also identifies the potential for technology to be applied to inappropriate populations; being misused by human users; and technology malfunctioning by providing incorrect output.¹²

This leads to the question: who has a duty of care to the users and is legally liable for AI errors? The answers depend on whether the diagnostic software is intended to be used by patients directly or by clinicians to aid decision-making (clinician-assisted).

Clinician-assisted software

In the case of clinician-assisted software, a duty of care is owed by the clinician to the patient. The patient should give consent to the use of AI software and US case law demonstrates that doctors must make "disclosures which a reasonable medical practitioner would make under the same or similar circumstances".¹³ However, with artificial intelligence use in skin cancer diagnosis in its infancy we are still debating what a reasonable medical practitioner should disclose during the consent process for AI technology. In our opinion, the patient must be sufficiently informed to understand, in a broad sense, the risks, benefits and limitations of using the AI software. They should also be aware of significant specific risks, also known as material risks.¹⁴⁻¹⁶

Table 1. Broad risks, benefits and limitations of AI software in skin cancer diagnosis

Risks

- Potential to miss malignancy
- Potential to overcall malignancy and subsequent costs and complications from over-treatment
- Potential for privacy to be compromised

Benefits

- Quick, accessible opinion

Limitations

- Does not take into account full clinical picture
- Performance may vary for rare or unseen cases and for diagnosis of lesions in certain sites (eg. acral, or hair-bearing skin) or skin types

The decision by a clinician to use AI has been described as a 'moral crumple zone' whereby they become legally answerable for the AI because of their decision to use it:

Absorbing the moral responsibility for errors is a forceful argument for assigning full legal liability to clinicians, yet this is grossly unfair on clinicians as it disconnects accountability from the locus of control. Yet the clinician may act as an independent, knowledgeable intermediary between the software's recommendations and the patient, but in practice is encumbered with the responsibility for computer-generated clinical advice over which they have only limited influence.¹⁷

Case law has previously demonstrated that a medical practitioner owing a duty of care does not necessarily relieve a device manufacturer or supplier of their own duty of care.¹⁸

Direct use patient software

The software developer and distributor are likely to owe a duty of care to the patient in both direct use patient software and clinician-assisted software. The duty of care owed by a manufacturer (or in our case, a software developer) to a consumer has long been settled since in the landmark case, *Donoghue v Stevenson*¹⁹ Lord Atkin ruled that a manufacturer has a duty to take reasonable care to avoid injury to the consumer of its products. In

Australia's largest women's health class action case, *Gill v Ethicon Sarl* (a subsidiary of Johnson & Johnson)¹⁸, pelvic mesh which caused chronic pain (among other symptoms) was placed into thousands of Australian women and Justice Katzmann found that:

manufacturers had a duty to take reasonable care in the design, testing, evaluation, supply, and marketing of the devices. That duty extended to providing accurate information about the performance and safety of the devices, including warnings about potential complications and contraindications.

It may be difficult for software developers to provide sufficient evidence about the design, testing and evaluation of their program because of the inherent nature of AI design. Algorithms do not use programmed rules but rather they create their own set of rules on how to interpret data which constantly change. This issue is referred to as the 'black box' phenomenon. Developers are working on creating feedback controls to improve the transparency of how AI algorithms have reached a decision.

The supplier of a medical device also owes a duty of care to patients. In the same case, *Gill v Ethicon Sarl*¹⁸ Justice Katzmann described that a supplier was expected as part of their duty of care:

to take reasonable steps to ensure that the information they conveyed about the devices was accurate, not misleading, and sufficient to alert both medical practitioners and prospective patients about the true risks associated with the use of the devices.

While this has not been tested in the courts for AI technology, it is likely that the developers or owners of an AI diagnostic skin cancer software would similarly owe a duty of care to patients who foreseeably will use their software.

Medical Negligence

Adverse outcomes for patients may lead to legal claims being brought to the courts against either software developers or doctors. Four basic elements need to be established to result in a finding of medical negligence²⁰:

- the defendant owed a duty of care to the plaintiff;
- the duty of care has been breached;
- as a result of the breach, damage has been caused to the plaintiff; and
- there are no defences which wholly or partially excuse the defendant's negligent behaviour.

The giving of inaccurate or inadequate information to patients and clinicians about the risks of AI skin cancer algorithms is one of the ways a duty of care could be breached. Counselling patients requires provision of information about accurate sensitivity and specificity rates which are reflective of 'real' world conditions rather than using high quality image databases. A recent Cochrane review examining available smartphone apps' ability to diagnose melanoma in direct patient use software found that between 27% and 93% of invasive melanoma or atypical pigmented lesions were not identified, highlighting the significant risk that the apps currently pose.²¹ It may also be difficult for software owners to give accurate up-to-date sensitivity and specificity rates as AI machine learning algorithms can change with the addition of more data.

It is also important that AI software is applied to the intended populations as inappropriate application can change the risk profile. For example, renal transplant patients have up to a 200-fold increased chance of skin cancer and the algorithms based on normal risk populations may not be appropriate or sufficient.²² AI algorithms may also have different diagnostic accuracy in hair-bearing areas or acral sites and again, this needs to be conveyed appropriately to the user.

AI skin cancer diagnostic apps are already available to patients and take a variety of approaches in helping them interpret their results. Apps freely available to internet users can provide a percentage chance of a photographed lesion being a malignant or benign diagnosis. However, this raw information can be difficult for patients to interpret and may lead to malignant lesions not being excised or excessive excisions of benign lesions in anxious patients which could constitute a basis for a medical negligence action.

Another danger is uncritical deference to AI results in both diagnosis and treatment when greater clinical nuance may be required. This phenomenon has also been described in the risk evaluation context as an ‘atrophy of vigilance’.²³ Subtle clinical factors can be difficult for AI to take into account and clinicians will need to remain vigilant for these factors. For example, patients with barriers to reliable follow-up may be better served with an excisional biopsy even if the suggestion of AI is only to monitor a lesion.

The method of conveying the risks, benefits and limitations is also important. Health apps commonly require user agreements, which are contracts to which a person agrees without any form of face-to-face dialogue. It is doubtful whether due attention is given by many patients to such fine-print agreements.²⁴ The legal effectiveness of ‘fine-print’ disclaimers is also questionable as the Australian Competition and Consumer Commission (ACCC) clearly states that disclaimers cannot be used “as an excuse for a misleading overall message”.²⁵

In the context of AI in skin cancer diagnosis, we have identified that the software developers and suppliers owe a duty of care to patients and that the safety net of clinician input has the potential to constitute negligence if it is not applied in a rigorous and personalised way.²⁶ Much depends on the checks and balances within the AI system, the sufficiency of the adoption of risk mitigation processes and the claims made on behalf of the AI. Future developers will need to help both patients and clinicians to interpret AI results as well as educate patients on when to question the AI results and how to monitor lesions.

Privacy

Privacy is also an important consideration for AI software which will collect, store and use personal information. The type of data collected by AI diagnostic software can range from clinical photos to detailed identifiable information about a patient’s risk factors for developing skin cancer. Most algorithms tend to use demographic and risk factor information as it improves diagnostic accuracy. While AI skin cancer diagnostic algorithms are created using large de-identified datasets of clinical pictures and corresponding histopathology, there is the potential for these programs to continue to improve their accuracy by using patient data. For example, a clinician or patient may photograph a lesion and use the skin cancer diagnostic software. If the lesion is then biopsied, that information

can be integrated into the AI machine learning software to improve its diagnostic algorithm. On occasion, pursuant to data use agreements such records can be transferred without patient permission in order to enhance AI processes, but without explicit permission this may not be lawful.²⁷

In Australia, the *Privacy Act 1988* contains Information Privacy Principles and National Privacy Principles which legally bind non-government organisations in how they can collect, use, disclose and share information. Under Australian Privacy Principle 6 – use or disclosure of personal information - an entity that holds personal information about an individual that was collected for a primary purpose (for example, the diagnosis of skin cancer), must not use or disclose the information for another purpose (for example, improving an AI algorithm) unless the individual has consented.

While consent to improve the AI algorithm could be obtained relatively simply by asking patients who use the app for such permission, software developers should not put the patient under undue pressure to contribute their data. For example, many apps available today, such as Facebook, are ‘free’ but sell users’ information to advertising companies. In the same respect, it is foreseeable that future skin cancer diagnostic apps could be ‘free’ to use in return for contributing data for the improvement of the software.

Patient privacy during the research and development of AI skin cancer diagnostic software is managed by institutional ethics boards which are obliged to comply with the National Health and Medical Research Council guidelines. The guidelines state that all patients should consent “orally, in writing or by some other means (for example, return of a survey, or conduct implying consent)”.²⁸ Interestingly other jurisdictions, including the European Union, have recently amended their guidelines so that personal data can be processed without informed consent when a task is in the public interest.²⁹

De-identification of photographic data is another privacy issue. The *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)* recommends data de-identification where possible and that use of identified data requires clear consent from patients. De-identification of skin imaging is complex and may require more than removal of

facial images, as other identifying marks, scars or tattoos may be present. A breach of a patient's identity has the potential to cause embarrassment, discrimination and/or increased insurance costs. While these risks are still present in routine practice (as doctors often take clinical photographs to monitor lesions), patients should be counselled about the risk before their use of the AI software.

Regulation

In Australia, the Therapeutic Goods Administration (TGA) is responsible for the regulation of AI skin cancer diagnostic software. The software is defined as a medical device provided it is used for the 'diagnosis, prevention, monitoring, prediction, prognosis or treatment of a disease'.³⁰ Software developers are seen as manufacturers under the *Therapeutic Goods Act 1989* and the product must be approved by the TGA before entering the market. Currently, AI skin cancer diagnostic software is classified by the TGA as moderate risk (Class IIa) for clinician-assisted software or Class IIb for direct use patient software.³⁰ They are required to undergo a series of assessments which include, but are not limited to, a review of the product design, packaging, labelling and possible inspection of the product.³⁰ Medical device efficacy claims are also regulated by Section 18 of the Australian Consumer Law which states that '*a person must not, in trade or commerce, engage in conduct that is misleading or deceptive or is likely to mislead or deceive*'.³¹

The system is not perfect with a recent international journalism investigation finding that 170 Australians had died from failed medical devices in the last 10 years a further 8,500 had been injured.³¹ The Australian TGA system relies heavily on private companies in the European Union (EU), called 'notify bodies', to assess medical devices with over 90% of Australian devices having assessments in these facilities. This 'off shore' testing exposes the Australian system to risk as the TGA doesn't have direct oversight of EU notify bodies. As of 25 February 2021, the TGA has implemented reforms to the regulation of software-based medical devices (as against lifestyle apps) which will require reclassification of some apps as medical devices to improve regulatory accountability.³²

Outside of the Australian regulatory environment, diagnostic software is freely available over the internet in many jurisdictions, highlighting both the need for the adoption of

suitable cybersecurity protocols to ensure patient safety is prioritised and that users are not misled regarding diagnostic efficacy in a relatively unregulated cyberspace environment.^{26,}
³³ Promisingly, in an effort to regulate this rapidly changing field, organisations such as the World Health Organisation and International Medical Device Regulator Forum are working to create comprehensive and cohesive international medical device regulation guidelines.

Implications for Practice

Based on the abovementioned legal considerations and evidence to date, we propose the following recommendations for the use of diagnostic AI:

- Clinician-assisted AI software, as opposed to AI software used directly by patients, is a safer modality to deliver diagnostic skin cancer technology to patients;
- Software developers and suppliers have a responsibility to inform clinicians and patients about the accuracy, risks, benefits and limitations of the software;
- Clinicians should be aware of the risks, benefits and limitations of the software and not use it as a substitute for expert clinical judgement;
- Clinicians should inform the patient of their intended use of AI and gain consent by ensuring patients understand the broad risks, benefits and limitations of the AI diagnostic software being used;
- Clinicians should only use AI diagnostic software which has been approved by the Therapeutic Goods Administration, unless for research purposes;
- Software developers and suppliers of AI skin cancer diagnostic software directly used by patients should take all reasonable precautions to ensure patients are not harmed through the misuse or misinterpretation of the software results ;
- AI skin cancer diagnostic software developers require consent from patients to use de-identified patient data to improve diagnostic accuracy;
- Regulators and stakeholders in the skin cancer diagnosis field should develop clear, specific guidelines addressing the use of AI in skin cancer diagnosis;
- Hospitals and medical practices should develop specific policies regarding the use of skin cancer AI diagnostic software at their institutions.

Conclusion

AI technology is rapidly progressing with AI diagnostic algorithms already, at least in experimental settings, outperforming clinicians in the diagnosis of skin cancer. With the highest rates of skin cancer in the world, Australian patients have the potential to benefit significantly from its introduction. However, it is important that patients are protected from potential harm by appropriate industry regulation and that clinicians and patients understand the ethical and legal limitations and ramifications of AI-influenced diagnosis and treatment before its widespread implementation.

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