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OPINION PIECE

Smartphone apps for skin cancer diagnosis: Implications for patients and practitioners

Lisa M Abbott[1,2] | **Saxon D Smith**[3,4,5]

[1]*University of Sydney, Sydney Law School,* [2]*Skin and Cancer Foundation Australia,* [3]*Department of Dermatology, Royal North Shore Hospital,* [4]*University of Sydney, Northern Clinical School, Sydney Medical School, Sydney, and* [5]*Dermatology and Skin Cancer Centre, Gosford, New South Wales, Australia*

ABSTRACT

A research team at Stanford recently reported that their deep convolutional neural network had learned to classify skin cancer with a level of competence equivalent to that of board-certified dermatologists. It is possible that in time, and using larger datasets, such software may surpass the average doctor in diagnostic ability, and that highly accurate technology may be available to both clinicians and patients via smartphones. This technology is poised to change the landscape of skin cancer diagnosis for both physicians and patients, but whether such changes are beneficial will depend on how they are regulated and implemented.

Key words: artificial intelligence, diagnosis, medical law, skin cancer, smartphone.

INTRODUCTION

While the use of artificial intelligence in dermatology is not new, the high degree of accuracy now possible using deep convolutional neural networks raises questions about the future role of dermatologists in the diagnosis and management of melanoma and other skin cancers.

A research team from Stanford University recently reported that their convolutional neural networks, which had been trained on a dataset of 129 450 clinical images, had learned to classify skin cancer with a level of competence equivalent to that of board-certified dermatologists.[1] The sheer size of the dataset enabled the software to adjust to the variability of zoom, angle and lighting, which could otherwise affect the interpretation of smartphone photography. It is conceivable that in time and in combination with large datasets, this kind of software may surpass the average dermatologist in diagnostic ability, and that highly accurate technology may be available to both clinicians and patients via smartphones.

In the context of Australia's high burden of skin cancer and limited access to dermatological care, particularly in regional and remote areas, improved diagnostic tools offer the potential to improve triage and reduce the time to excision for correctly diagnosed melanomas. They could also reduce the morbidity resulting from unnecessary biopsies and offer an alternative option for monitoring high-risk patients between regular clinician reviews.

However, integrating such software into health systems may give rise to several legal, regulatory and practical issues. For clinicians, rapidly evolving technology may lead to a shift in the standard of care and reshape the role of doctors in skin cancer diagnosis and management. For patients, speedy access to highly accurate diagnostic software may be life saving or life threatening, depending on its accuracy, how it is regulated and how it is used.

USE OF DIAGNOSTIC APPS BY MEDICAL PROFESSIONALS

Several software companies are currently working to integrate artificial intelligence into medical practice via clinics, hospitals and smartphones.[2] Deep learning software will impact upon the role and practice of clinicians in fields that are heavily reliant on image interpretation, including dermatology, pathology and radiology. Whether such developments are interpreted as a threat or an opportunity to improve practice will depend upon attitudes to developing technology and degrees of flexibility in understanding the role of medical practitioners and the effectiveness and accuracy of the technology available.

Given the extent of skin cancer in Australia, even a slight improvement in diagnostic accuracy has the potential to reduce health expenditure radically and to decrease morbidity. Dermatologists in Australia currently excise

Correspondence: Dr Lisa M Abbott, Skin & Cancer Foundation Australia, 121 Crown Street, Darlinghurst, NSW 2010, Australia. Email: labbott@scfa.edu.au

Lisa M Abbott, MBBS. Saxon D Smith, FACD.

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approximately 12 lesions for every melanoma detected,[3] a ratio that rises to 29 benign lesions per melanoma in skin cancer clinics[4] and among general practitioners. As the time dedicated to dermatological education at medical schools in Australia continues to be extremely limited[5] the benefit of immediate feedback to the practitioners may improve dermatological knowledge and result in fewer inappropriate referrals or excisions, resulting in increased access to specialist care for those who require it.

Should diagnostic melanoma apps prove to be accurate and reliable, it is conceivable that it will become standard practice to use them to assess lesions before they are excised, in the same way that medical imaging is considered a requirement before certain types of surgery are performed. The information provided by apps will still need to be interpreted and the results will need to be carefully applied by the practitioner to the patient in front of them, just as medical imaging and pathology tests need to be interpreted and occasionally repeated or reassessed over the process of diagnosis and management.

If the use of such apps does become widely accepted in practice, doctors could potentially be held liable for failing to use available software as an aid to diagnosis (Section 5O of the *Civil Liability Act* 2002 NSW, Australia). Decisions of liability may become complex in situations where the clinician and software come to contradictory conclusions, particularly if an excision is consequently performed in a location of cosmetic significance. However, this alone is not a sufficient reason to shun the opportunities offered by technology to achieve greater accuracy. Rather, it is important to ensure that such software is viewed as a supplement to clinical examination skills and judgement, rather than a replacement.

USE OF DIAGNOSTIC APPS BY PATIENTS

Consumers may find diagnostic apps attractive for a number of reasons, including convenience, immediacy of access and affordability. These issues should not be underestimated in Australia where the burden of disease is high, and access to expert dermatological care is limited. For those who may not otherwise be inclined or able to access dermatological care, the availability of a diagnostic app may increase the likelihood of an earlier diagnosis of skin cancer and increase the users' motivation to seek medical care, leading to greater numbers of excisions at an earlier stage of disease.

Despite these features, using apps in the absence of a surrounding therapeutic relationship is likely to have adverse effects. One is that there is no opportunity for a clinician to take an accurate medical history, conduct risk assessment, provide patient education,[6] ensure adequate follow up and conduct a total body skin examination, as a significant number of skin cancers are incidentally identified on clinical examination.[7] The selection of a lesion for assessment when conducting lesion-directed screening is particularly important, as patients are often ill-equipped to distinguish between cancerous and non-cancerous lesions.[8] Benign diagnoses for poorly selected lesions may offer the patient false reassurance, reducing the opportunity for early detection and treatment. Further, cancerous lesions may only be detected by the patient at a more advanced stage with poorer prognosis,[9] and other lesions in areas not easily visualised, for example the scalp, back and buttocks, may not be assessed at all.

Regardless of whether one believes these apps have a place outside the therapeutic relationship, they are already currently available and vary widely in accuracy. Patients need guidance as to which apps are reliable and accurate, and those that are not should be removed from the market. Should a highly accurate diagnostic app become available, it is theoretically possible to limit access to it by prescribing its use to licenced consumers. However, if the medical profession advocated limiting consumer access to a potentially life-saving tool this would likely be viewed as paternalistic and the motives for doing so met with scepticism. In an age where there is an app for everything and patients prefer to play a greater role in their own health care, the profession's focus should be on removing dangerous and inaccurate products from the market, and supporting and endorsing accurate software.

ACCURACY AND REGULATION OF APPS THAT ARE CURRENTLY COMMERCIALLY AVAILABLE

A recent study of four commercial diagnostic melanoma apps reported sensitivities ranging from 7–98% and specificities from 30–94%, with the best performing program missing 30% of melanomas.[10] Although such apps often include disclaimers and exclusion clauses in their terms of service and advising on the need for consumers to seek medical review, the terms of service are very rarely, if ever, read by the user.[11] Given the potentially fatal consequences of missing a melanoma, relying on patients to assess the accuracy of diagnostic apps is likely to lead to adverse outcomes over time. Effective regulation is clearly required, although it may result in potential slowing of innovation and availability of effective software.

Whether or not the Therapeutic Goods Association, the Australian regulator, has the power to regulate diagnostic melanoma apps depends on whether they fall within the definition of medical devices,[12] as they do in the USA[13] If so, civil and criminal penalties may apply to those who supply and manufacture a diagnostic app that is not registered under the Therapeutic Goods Act 1989. However, the sheer quantity of apps available and the speed with which they are manufactured and updated makes it difficult for a government agency with limited resources to oversee and effectively enforce such a law.

The major digital distribution platforms providing apps for download are in a unique position to assist in the regulation process. It is possible they may in fact be obliged to perform this role, as providing a platform to download a diagnostic app could potentially be considered to be supplying a medical device and constitute an offence under s41MI of the Therapeutic Goods Act 1989. Apple (Apple Inc., Cupertino, California, USA) has recently taken the initiative by issuing developer guidelines addressing

the safety and regulatory concerns of mobile medical device apps.[14] Encouraging such platforms to withhold mobile medical applications until they receive approval from the Therapeutic Goods Association to avoid penalties for a contravention under the Act may be a feasible way to prevent the distribution of unregistered and unsafe apps. Although a small percentage of consumers may nonetheless seek to download apps from an international source, this is less likely to occur if approved apps are available within Australia.

CONCLUSION

Technology is more accessible and socioculturally ingrained than ever. Patients will seek technological solutions to medical problems and expect the profession to keep up to date with technological advances. Rather than advocating app abstinence, the profession should advocate harm minimisation by regulating and endorsing accurate software, incorporating patient education on prevention and detection and including safety features such as preliminary risk assessment algorithms to identify patients at high risk of developing skin cancer, so that they may be directed towards appropriate medical care. The medical profession should take advantage of the improved diagnostic capacity of apps where possible, while ensuring their knowledge and skills are enhanced and utilised alongside advancing technology.

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