Skin cancer diagnosis apps are unreliable and poorly regulated, study shows

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Smartphone apps used as 'early warning systems' for skin cancer are poorly regulated and frequently cannot be relied upon to produce accurate results, according to new analysis by experts at the University of Birmingham.

Skin cancer detection apps are designed to ensure that the right people seek medical attention by providing a risk assessment of a new or changing mole. These apps use specialised algorithms to try to detect possible skin cancers.

Researchers based in the University of Birmingham's Institute of Applied Health Research in collaboration with the Centre of Evidence-Based Dermatology at the University of Nottingham have analysed a series of studies produced to evaluate the accuracy of six different apps. Their results, published in *The BMJ*, reveal a mixed picture, with only a small number of studies showing variable and unreliable test accuracy among the apps evaluated.

Skin cancer has one of the highest global incidences of any cancer. Early detection and treatment, particularly of melanoma, can improve survival. According to this new analysis, however, apps may cause harm from failure to identify potentially fatal skin cancers, or from over-investigation of false positive results—for example removing a harmless mole unnecessarily.

The research team was also concerned by the quality of the studies themselves, which evaluated apps using images taken by experts rather than by app users. In addition, many studies did not identify whether lesions identified as 'low risk' by the apps were in fact benign, further compromising the conclusions that can be drawn from the evaluations.

Lead researcher Dr. Jac Dinnes, of the Institute of Applied Health Research at the University of Birmingham, said: "This is a fast-moving field and it's really disappointing that there is not better quality evidence available to judge the efficacy of these apps. It is vital that healthcare professionals are aware of the current limitations both in the technologies and in their evaluations."

The authors also drew attention to the regulations governing the evaluation of healthcare apps. Manufacturers can currently apply CE marks to smartphone apps without necessarily being subject to independent inspection by bodies such as the UK Medicines and Healthcare Products Regulatory Agency (MHRA). Although this may change with new Medical Device Regulations coming into force in 2020, the researchers noted that stricter assessment processes in operation in the US has resulted in no skin cancer assessment apps receiving regulatory approval.

Co-author Jon Deeks, Professor of Biostatistics in the Institute of Applied Health Research, adds: "Regulators need to become alert to the potential harm that poorly performing algorithm-based diagnostic or risk monitoring apps create. We rely on the CE mark as a sign of quality, but the current CE mark assessment processes are not fit for protecting the public against the risks that these apps present."

Dr. Dinnes added: "As technologies continue to develop, these types of apps are likely to attract increasing attention for skin cancer diagnosis, so it's really important that they are properly evaluated and regulated. Of course, we also need to emphasise how important it is to go and see your GP if you have concerns—regardless of what an app might tell you."

The team also has made a series of recommendations for future studies of smartphone apps:

- Studies must be based on clinically-relevant population of smartphone users who may have concerns about their risk of skin cancer
- All skin lesions identified by smartphone users must be included—not just those identified as potentially problematic
- Clinical follow-up of benign lesions must be included in the study to provide more reliable and generalizable results.

Hywel Williams, Professor of Dermatology at the University of Nottingham who collaborated on the study, said: "Although I was broad minded on the potential benefit of apps for diagnosing skin cancer, I am now worried given the results of our study and the overall poor quality of studies used to test these apps. My advice to anyone worried about a possible skin cancer is 'if in doubt, check it out with your GP'."

More information: Dinnes, Freeman et al (2020). 'Algorithm-based smartphone 'apps' for assessment of the risk of skin cancer in adults: a systematic review of diagnostic accuracy studies'. The *BMJ*. DOI: 10.1136/bmj.m127

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