

Further evaluation is required for smartphone-aided diagnosis of skin cancer



Whether technological advances have the potential to transform skin cancer diagnosis has gained considerable interest, particularly in countries such as the UK and USA, where the incidence of skin cancers is rising. Although skin cancers are common, especially the keratinocyte cancers (such as basal cell carcinoma and squamous cell carcinoma), these cancers can be challenging for patients and doctors to differentiate from benign lesions. Therefore, patients might present late, primary health-care professionals might refer or excise lesions too readily, and there might not be enough dermatologists available to triage the numbers of patients with suspicious lesions to provide diagnosis and treatment or reassurance. This burden on patients and health-care systems could be lessened by new digital approaches aimed at encouraging people at high risk of melanoma and other skin cancers to consult primary care clinicians earlier to more accurately distinguish benign lesions from possible skin cancers. This approach is a health-care priority because evidence suggests that a timely diagnosis for melanoma, and the more common keratinocyte cancers, results in excellent survival rates.

The randomised controlled trial by Monika Janda and colleagues¹ in *The Lancet Digital Health* is a welcome addition to the literature since little rigorous evidence exists to support claims for new technological approaches. Skin self-examination using a smartphone fitted with a dermatoscope (a magnifying device with a polarising light source, routinely used by dermatologists) was compared with naked-eye skin self-examination. Adults were eligible if they were at increased risk of skin cancer (ie, they had at least two self-reported skin cancer risk factors) and had to own or have access to an iPhone compatible with a dermatoscope attachment. 234 enrolled adults were randomly assigned to monthly mobile teledermoscopy-enhanced skin self-examination (n=116) or naked-eye skin self-examination (n=118), and both groups had an in-person whole-body clinical skin examination within 3 months of their last skin self-examination. Sensitivity for detecting skin cancers was lower in the intervention group than the naked-eye skin self-examination group:

at the lesion level, sensitivity for lesions clinically suspicious for skin cancer was 75% (95% CI 63–84) in the intervention group and 88% (95% CI 80–91) in the control group (p=0.04). Specificity was 87% (95% CI 85–90) in the intervention group and 89% (95% CI 87–91) in the control group (p=0.42). At the individual level, the intervention group had a sensitivity of 87% (95% CI 76–99) compared with 97% (95% CI 91–100) in the control group (p=0.26), and a specificity of 95% (95% CI 90–100) compared with 96% (95% CI 91–100) in the control group (p=0.96). The authors concluded that “further evidence is necessary for inclusion of skin self-examination technology for public health benefit”. The trial findings are similar to those from a UK trial in which patient assessments done by trained primary care clinicians and using the digital MoleMate system (SIAscopy with primary care scoring algorithm) were compared using The National Institute for Health and Care Excellence guidance on good practice (clinical history, naked eye examination, 7-point checklist). No differences in sensitivity were identified between the intervention group and the usual care group, but the lower specificity resulted in more referrals from the intervention group reflecting an increased burden on specialist care.²

Several factors might have contributed to the findings of the trial by Monika Janda and colleagues.¹ First, types of skin cancer might not have been sufficiently defined, and the dermoscopic approach might have been more suitable for detecting possible melanoma rather than keratinocyte cancers. Second, the trial recruited people from the general population who self-reported two or more risk factors for skin cancer and potential participants were excluded if they had a history of melanoma within the past 5 years. Similar studies commonly exclude people who have ever had any skin cancer (melanoma, squamous cell carcinoma, or basal cell carcinoma). Participants were a self-selected sample who were possibly more aware of the features of skin cancer than the general population and might have had well-developed skin self-examination skills as a result of previous skin cancer treatment, thus reducing the ability to detect any intervention effect. Third, the

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See [Articles](#) page e129

follow-up period was relatively short (3 months), and although this time period might be sufficient to identify undiagnosed prevalent skin cancers, it might not be sufficient to detect changing lesions over time. Longer follow-up might have resulted in significant trial results.

The incorporation of artificial intelligence deep learning algorithms into clinical diagnostic aids has gained substantial interest in the past 5 years;^{3,4} a 2019 study reported that a deep learning algorithm outperformed dermatologists in a head-to-head classification of dermoscopic images of melanoma.⁵ However, most diagnostic tests remain unsuitable for use due to inadequate performance in real-world, low prevalence populations, such as primary care or the general community. Therefore, these algorithms need rigorous, prospective validation among the populations who are intended to use them, to determine whether they lead to earlier detection and improve patient safety and quality of care, while minimising overinvestigation and overdiagnosis.⁶⁻⁸ Only once validated should these algorithms be incorporated into smartphone apps for patients or clinical decision support for primary care health-care practitioners.

Digital diagnostic aids represent a rapidly advancing research field that is of great interest to clinicians, patients, and the public. Despite the recommendations of the 2019 Topol Review, which stated that the National Health Service England should make the most of innovative technologies such as digital medicine and artificial intelligence, the results from this trial suggest

that a cautious approach continues to be required when evaluating new technological approaches that aim to promote timely skin cancer detection, while improving patient safety and quality of care.

We declare no competing interests.

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For more on the 2019 Topol Review see <https://topol.hee.nhs.uk/>