NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

EARLY VALUE ASSESSMENT

Equality impact assessment – Guidance development

Artificial Intelligence (AI) technologies for assessing and triaging skin lesions referred to the urgent suspected skin cancer pathway: early value assessment

Consultation

1. Have the potential equality issues identified during the scoping process been addressed by the committee, and, if so, how?

The committee raised equality concerns about the use of AI technologies to detect skin cancer in people with black and brown skin tones.

There was limited evidence on the performance of DERM in people with non-white skin because the low incidence of skin cancers among people from Black, Caribbean, African and Asian ethnic groups makes it difficult to obtain sufficient data to validate AI technologies.

The committee noted that high risk cancers (squamous cell carcinoma and melanoma) are 20 to 30 times more likely to occur in White ethnic groups. But people from Black, Caribbean, African and Asian ethnic groups are more likely to have a worse prognosis because lesions can be detected late. Even when skin cancer is diagnosed at the same stage, people from Black, Caribbean, African and Asian ethnic groups have a greater risk of mortality than people from White ethnic groups.

The external assessment group noted that recent data on Fitzpatrick skin types 5 and 6 showed that no malignancies were missed, which suggests that the accuracy of DERM in people with white skin should be maintained in darker skin tones. The committee emphasized that because the amount of data remains small, further research should be done on the performance of DERM in people with darker skin tones to ensure AI technologies are not incorrectly detecting (false positive) or missing skin cancer (false negative).Experts also advised that studies should measure skin tone with spectrophotometry rather than using the

Fitzpatrick scale because spectrophotometry is a more accurate way of measuring total melanin content in skin. Other potential equality issues noted during the scoping process were:

- AI technologies are not suitable for people with more than 3 lesions and after a certain age it is more likely to find lesions during a total skin examination.
- Outdoor workers may be at higher risk due to longer periods of sun exposure.
- Rural populations may have difficulty with traveling to diagnostic / teledermatology hubs for image capture appointments required for AI assessment.
- DERM is not indicated for use in people under 18.

The committee noted that skin lesions that are not eligible for assessment by AI technology or teledermatology would need a face-to-face appointment.

2. Have any other potential equality issues been raised in the external assessment report, and, if so, how has the committee addressed these?

People with black and brown skin are more likely to have acral lesions (lesions on palms of hands and soles of feet) which have a higher risk of malignancy. Acral lesions are not suitable for AI assessment and would be referred directly for dermatologist assessment.

3. Have any other potential equality issues been identified by the committee, and, if so, how has the committee addressed these?

No other potential equality issues were raised by committee.

4. Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

Skin Analytics state that DERM has primarily been evaluated on patients with Fitzpatrick skin types 1-4, therefore it should be used with caution on lesions of other skin types.

Although there is no statement on restrictions around skin colour in the IFU for Moleanalyzer pro, the EAG's report did note that a large majority of patients in the Moleanalyzer pro studies had lighter skin

tones (Fitzpatrick types 2-3). If AI technologies were adopted in the future for automated use, people with black and brown skin tones may still need a dermatologist review of their skin lesion if the AI technology gave a benign result. All non-benign results would have a dermatologist review.

Because the committee recommended further research on these technologies rather than use while further evidence is generated, access should not be more difficult in specific groups.

5. **Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?**

No.

6. **Are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?**

The committee recommends that further research is needed on the diagnostic accuracy of AI technologies in people with black and brown skin tones

7. **Have the committee's considerations of equality issues been described in the diagnostics consultation document, and, if so, where?**

Section 3.18

Approved by Associate Director (name): Lizzy Latimer

Date: 26/03/2025

Diagnostics guidance document

1. Have any additional potential equality issues been raised during the consultation, and, if so, how has the committee addressed these?

Committee noted that no new data was presented on the performance of DERM in people with black or brown skin and emphasised that the amount of data remains small. The committee understood the challenges of validating AI technologies for people with black or brown skin because there is a low incidence of skin cancers among people from Black, Black Caribbean, Black African and Asian ethnic groups.

The committee emphasised the importance of using AI technologies with a healthcare professional review for people with black or brown skin while further evidence is generated on the accuracy in these groups (See section 3.8 and 3.9 of the guidance and the evidence generation plan).

Committee also noted that people need to give informed consent before AI technology can be used in their care, including for assessing skin lesions. Some people may need extra support to understand the information given to them and help them make an informed decision.

2. If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

Recommendations have changed to support the use of the technology in clinical practice whilst further evidence is generated and provided risk mitigations steps are in place.

There are no barriers to initial access, however committee emphasised the importance of using DERM with an additional healthcare professional review for people with black or brown skin while further evidence is generated on the accuracy in these groups (See section 3.8 and 3.9 of the guidance and the evidence generation plan).

Whilst the technology is used during evidence generation there will remain the variation across the country in which Trusts offer this AI technology as part of the urgent skin cancer pathway.

3. If the recommendations have changed after consultation, is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

Recommendations have changed to support the use of the technology in clinical practice whilst further evidence is generated and provided risk mitigations steps are in place.

We do not expect the recommendations to have an adverse impact on people with disabilities.

People need to give informed consent before AI technology can be used in their care, including for assessing skin lesions. Some people may need extra support to understand the information given to them and help them make an informed decision.

4. If the recommendations have changed after consultation, are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?

An additional healthcare professional review should be carried out following the use of DERM in people with black or brown skin. Further evidence should be generated on the accuracy of the technology on lesions for people with black or brown skin. The evidence generation plan will be reviewed annually to ensure appropriate evidence is being collected as directed by the committee (See section 1.3, 1.4 of final guidance and the evidence generation plan).

Risk mitigations should be in place for the use of DERM in clinical practice whilst further evidence is generated, this should include: appropriate safety net protocols and regular monitoring of DERM's performance to maintain accuracy in order to prevent missed or delayed cancer diagnosis

5. Have the committee's considerations of equality issues been described in the diagnostics guidance document, and, if so, where?

Yes, in section 3.15 of the guidance document.

Approved by Associate Director (name): Lizzy Latimer

Date: 26/03/2025