NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technologies Programme

# Artificial Intelligence technologies for assessing skin lesions selected for referral on the urgent suspected cancer pathway to detect benign lesions and reduce secondary care specialist appointments: early value assessment

## Final scope

October 2023

## 1 Introduction

The topic selection oversight panel identified artificial intelligence (AI) technologies for assessing skin lesions on the urgent suspected skin cancer pathway to detect benign skin lesions and reduce unnecessary secondary care specialist appointments as suitable for an early value assessment (EVA) by the Health Technologies Programme. NICE published a Medtech Innovation Briefing (MIB311) on digital technologies for the detection of melanoma in November 2022. The technologies described in this briefing use AI algorithms to analyse images of suspicious skin cancer lesions to support healthcare professionals in making decisions.

The final scope was informed by discussions at the scoping workshop and assessment subgroup meeting held on 18 October 2023.

A glossary of terms is provided in appendix A.

# 2 Description of the technologies

## 2.1 Purpose of the medical technologies

In the UK, dermatology services receive about 1.2 million referrals a year and about 60% of these are on the urgent suspected skin cancer pathway. Among the urgent suspected skin cancer referrals, only about 6% are converted to a confirmed case of skin cancer. It is, therefore, recognised that a significant proportion of people referred by GPs may not require face-to-face appointments in dermatology departments. The Get It Right First Time (GIRFT) report on dermatology highlighted that there are shortages in the workforce leading to delays in the diagnosis and treatment of skin cancer. Furthermore, experts in dermatology mentioned there is a low threshold for referral because GPs don't receive in-depth dermatology training and many do not have access to dermatoscopes, which are essential for confidently identifying both benign skin lesions and skin cancer.

The  report highlighted the use of digital technology, machine learning and AI as a potential way of helping to deliver effective dermatology services. This early value assessment will evaluate the use of AI software for assessing skin lesions on the urgent suspected skin cancer pathway to detect benign lesions with the aim of reducing unnecessary secondary care specialist appointments. This could help reduce waiting lists and streamline workflows in dermatology. This may also lead to earlier diagnosis and treatment of skin cancer and earlier reassurance for people with benign lesions.

## 2.2 Product properties

MHRA requirements state that any device intended to allow for direct diagnosis should be classified as class IIa. The AI technologies in this scope are intended to be placed in the diagnostic pathway and therefore only those with class II status are included.

### 2.2.1 Deep Ensemble for the Recognition of Malignancy (DERM) (Skin Analytics)

DERM (Skin Analytics) is a UKCA class IIa AI-based skin lesion analysis technology intended for use in the screening, triage, and assessment of suspicious skin lesions. It is indicated for use on dermoscopic images of skin lesions where there is a suspicion of skin cancer in patients aged 18 years or over in any body location except where specific exclusions apply. It is not intended to provide a definitive diagnosis. DERM is not intended for use on skin lesions beneath nails, in eyes or on mucosal surfaces, on soles of feet or palms of hands, on open or ulcerated skin lesions, on lesions which have previously been biopsied, lesions obscured by hair, tattoos or scars, or lesions unable to be entirely imaged within the dermoscopic device used.

DERM is used with the Skin Analytics web-based teledermatology platform Ozone v2. Dermoscopic images must be captured using approved dermoscopic image capture hardware, for example, a smartphone, a dermoscopic lens and an attachment kit. An internet connection to submit images and receive results, and a computer screen to view the results are also needed.

DERM uses AI-based algorithms to provide a suspected diagnosis of the lesion and if applicable, a referral recommendation (for example, discharge and give safety netting advice or urgent referral for suspected skin cancer). DERM can classify lesions as: melanoma, squamous cell carcinoma, basal cell carcinoma, intra-epidermal carcinoma, actinic keratosis, atypical naevus or benign lesions (this includes benign vascular lesion, seborrheic keratosis, dermatofibroma, solar lentigo and melanocytic benign nevus). If a lesion exhibits features of more than 1 lesion type, DERM uses a risk hierarchy to return the more severe suspected diagnosis. The algorithm was trained on a proportion of historical and prospectively collected images from populations in the UK, US, and Italy. DERM uses a fixed algorithm and does not update automatically. Technical software updates and updates to improve performance are only implemented after following software development life cycle

processes, standard operating procedures and will be compliant with regulatory requirements.

DERM has been granted a phase 4 accelerated access collaborative AI in health and care award by the NHS AI Lab (formerly known as NHSX) for funding to build evidence and inform recommendations.

### 2.2.2 Moleanalyzer pro (FotoFinder Systems)

Moleanalyzer pro (FotoFinder Systems) is a class IIa CE marked AI-based technology intended to be used by a medical professional for assessment of single skin lesions for the early detection of melanoma. The MoleAnalyzer pro is validated with melanocytic and non-melanocytic malignant types of skin cancer. It should not be used to confirm a clinical diagnosis of melanoma, but rather support healthcare professionals in decision making. The company states the technology can be used in primary care to reduce unnecessary referrals to secondary care and can also be used in the secondary care setting to obtain additional information to support decisions on whether to do a biopsy or excision.

The technology can be used for any age group. Lesions are eligible if they are between 2 mm and 20 mm and are on intact skin without psoriasis, eczema, acute sunburn or hair-covering. Moleanalyzer pro cannot be used for the assessment of peeling skin, mucosa, eyes, or in body orifices.

MoleAnalyzer pro is used with the FotoFinder Universe software platform. The system requires a dermoscopic image. The software can only be used with the FotoFinder dermatoscopes: Dermlite Handyscope (this is compatible with any smartphone or tablet) and Medicam 1000.

Moleanalyzer pro offers manual clinical assessment of a lesion using the 3-point checklist, the 7-point checklist or the ABCD rule to classify lesions (asymmetry, borders, colour and structures). The lesion can also be analysed using a Convolution Neural Network deep-learning algorithm to generate a risk score (also

called the AI score). FotoFinder provides 2 options: online AI where the algorithm is updated continuously and offline AI in which the algorithm is updated annually. The AI score is based on comparisons with images of malignant skin tumours such as: melanoma, basal cell carcinoma, lentigo maligna, squamous cell carcinoma, actinic keratosis, and many others. The AI score indicates how similar a lesion is to these comparison images, therefore it is providing a statistical estimate of the similarity to the malignant lesion images. The AI score is displayed on a colour scale bar which ranges from 0 to 1. A score between 0-0.0.2 indicates the lesion is inconspicuous, 0.21-0.49 indicates further clarification is necessary, and 0.50-1.0 indicates a conspicuous lesion which should be observed with great attention.

A heatmap view is also available (access through online AI only) to visualise which areas of the image are used for the calculation of the AI score, and check if possible confounding factors in the image have influenced the AI score. Moleanalyzer pro software also has an optional professional second opinion service, where a second opinion on the lesion can be obtained from international experts in dermoscopy.

# 3 Target conditions

Skin cancer is the abnormal growth of skin cells and most often develops on skin exposed to the sun. There are 3 major types of skin cancer: melanoma, squamous cell carcinoma, and basal cell carcinoma. Other rare skin cancers may also occur.

## 3.1 Melanoma

A melanoma is a malignant tumour arising from melanocytes in the skin and is usually seen as a pigmented lesion on the skin. There are 4 common subtypes: superficial spreading melanoma, nodular melanoma, lentigo maligna melanoma, and acral lentiginous melanoma (NICE, 2022). Nodular and amelanotic melanomas are rare.

Melanoma is the fifth most common cancer in the UK, accounting for around 4% of all new cancer cases and more cancer deaths than all other skin cancers combined.

On average, between 2016 and 2018, 16,744 new cases of melanoma were diagnosed each year in the UK (NICE, 2022). The incidence of melanoma is projected to increase by 7% in the UK between 2014 to 2035.

Prognosis is highly dependent on the stage at diagnosis – the most important prognostic indicators are Breslow thickness of the tumour and lymph node status. If a person is diagnosed at advanced stage, it can cause serious morbidity and may be fatal despite treatment. For people with stage 1 melanoma (thickness is 2 mm or less, no sign that it has spread) the 5-year survival rate is almost 100% compared with 30% for people with stage 4 melanoma (spread to distant lymph nodes or other parts of the body).

A person's risk of developing melanoma depends on many factors, including: personal history of skin cancer, melanoma, or atypical naevi; a family history of melanoma; pale skin that burns easily; red or light-coloured hair; high freckle density; light coloured eyes; history of sunburn, particularly blistering sunburn in childhood; a large number of moles, or large congenital naevi; sun exposure; use of tanning beds or sun beds; increasing age; outdoor occupation; immunosuppression; and genetic syndromes with skin cancer predisposition (NICE, 2022).

The NICE clinical knowledge summary for melanoma states that the assessment of people with pigmented skin lesions should include:

- Taking a medical history
- Examining the lesion and the entire skin surface
- Using the weighted 7-point checklist to assess pigmented skin lesions and determine the need for referral. A pigmented lesion scoring of 3 or more on the weighted 7-point checklist is referred to the urgent suspected skin cancer referral pathway.

**Weighted 7-point checklist:**

- Major features of the lesions (scoring 2 points each):

    - change in size
    - irregular shape
    - irregular colour.

- Minor features of the lesion (scoring 1 point each):
    - largest diameter 7mm or more
    - inflammation
    - oozing
    - change in sensation.

The Scottish Intercollegiate Guidelines Network (SIGN) recommend the ABCDE lesion system can also be used to identify signs of melanoma in the SIGN 146 guideline for cutaneous melanoma.

**ABCDE system**:

- asymmetry
- border irregularity
- colour variation
- diameter over 6mm
- evolving (enlarging/changing).

## 3.2 Basal cell carcinoma

Basal cell carcinoma (BCC) starts in the cells lining the bottom of the epidermis. BCC is the most common form of skin cancer and accounts for about 75 in every 100 skin cancers. Approximately 75,000 BCC of the skin are diagnosed each year (NICE, 2021).

People diagnosed with 1 BCC are at an increased risk of having further BCCs diagnosed at the same time, or of developing them subsequently. The main risk factor for BCC is sun (ultraviolet light) exposure, and this is reflected in the number of lesions that people develop and that BCCs most commonly develop in sun-

exposed areas of skin. BCCs also arise in people with a genetic predisposition, for example Gorlin syndrome.

BCC usually appears as a small, shiny pink or pearly-white lump with a translucent or waxy appearance. It can also look like a red, scaly patch. There is sometimes some brown or black pigment within the patch. The lump slowly gets bigger and may become crusty, bleed or develop into a painless ulcer. BCC does not usually spread to other parts of the body, but if left untreated for a long time, they may get larger and grow deep into the skin and destroy skin, tissue and bone. In rare cases BCC can spread to other parts of the body and sometimes become life-threatening (NHS, 2020). Death from BCC is exceptionally rare. The main advantage from early diagnosis is less extensive treatment.

## 3.3 Squamous cell carcinoma

Squamous cell carcinoma (SCC) is the second most common type of non-melanoma skin cancer. It starts in the cells lining the top of the epidermis (outermost layer of the skin) and accounts for about 20 in every 100 skin cancers (NHS, 2020). Approximately 25,000 squamous cell carcinomas of the skin are diagnosed each year (NICE, 2021).

SCC appears as a firm pink lump with a rough or crusted surface. There can be a lot of surface scale and sometimes a spiky horn sticking up from the surface. The lump often feels tender when touched, bleeds easily and may develop into an ulcer. There is a small risk (up to 5%) of SCC spreading to other parts of the body, such as the lymph nodes (NHS, 2020). The risk of spread with SCCs is greater than with BCCs especially for people who are immunosuppressed. Death from SCC is rare. The main advantage of early diagnosis is less extensive treatment (NICE, 2021).

Bowen's disease is a precancerous form of SCC sometimes referred to as squamous cell carcinoma in situ. It develops slowly and is easily treated. The main sign is a red, scaly patch on the skin that may itch. It most commonly affects elderly women and is often found on the lower leg (NHS, 2020).

Actinic keratoses are dry, scaly patches of skin caused by damage from sun exposure. There is a small risk that the patches could develop into SCC if untreated (NHS, 2020).The patches can be pink, red or brown, and can vary in size from a few millimetres to a few centimetres across. The affected skin can sometimes become very thick, and occasionally the patches can look like small horns or spikes.

### 3.4 Other rare skin cancers

Experts highlighted that there are 45 other types of non-melanoma skin cancers that exist. Merkel cell carcinoma is rarer and more aggressive than melanoma cancer. It starts in hormone-producing cells just beneath the skin and in the hair follicles. It is usually found in the head and neck region. Merkel cell cancer may also be called neuroendocrine carcinoma of the skin. Other types of rare non-melanoma skin cancers can be found in Appendix 1 of the NICE CSG8 guideline.

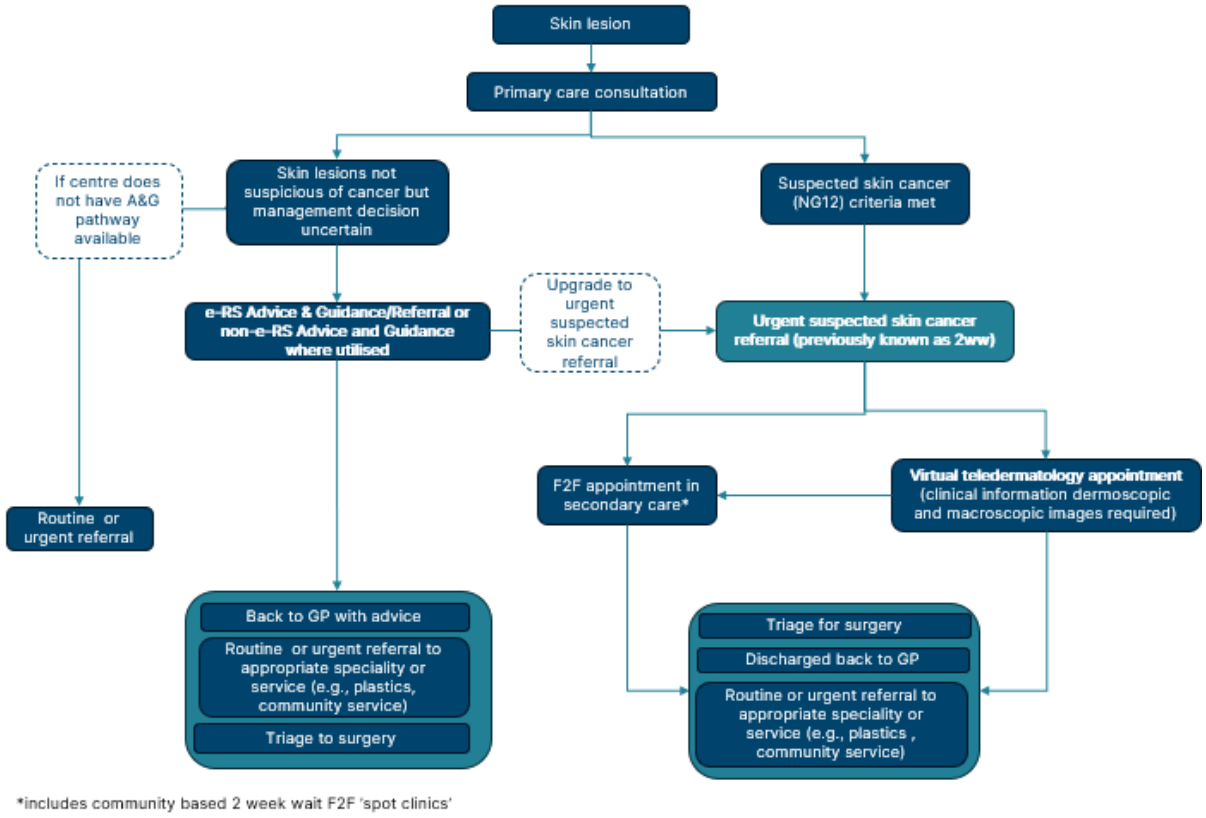
## 4 Diagnostic and care pathway

The initial assessment of a person presenting with a skin condition occurs at the primary care level to determine the appropriate referral pathway. Traditionally, GPs directly referred everyone with a suspicious skin lesion to secondary care through the urgent suspected skin cancer referral pathway where all referrals required people to attend a secondary care dermatology department for a face-to-face appointment with a consultant dermatologist. This pathway continues to exist where other clinical pathways are unsuitable or unavailable and is particularly well suited for people with multiple suspicious lesions, a history of skin cancer and other risk factors.

The NHS England referral and optimisation document describes the use of the NHS e-RS advice and guidance (A&G) service (section 4.1) as the main pathway in primary care for access to specialist services, with the exception of the urgent suspected skin cancer pathway (section 4.2). Figure 1 summarises the current diagnostic and care pathway for skin cancer.

Experts noted there is variation within these pathways and variation in availability and accessibility across the country. If the A&G pathway is not available in a primary care setting, then the person is referred on a routine or urgent referral pathway. Similarly, if a virtual teledermatology pathway is not available, then the person is referred to a face-to-face appointment with a consultant dermatologist in secondary care.

**Figure 1: Diagnostic and care pathway**




## 4.1 Advice and guidance service

The advice and guidance (A&G) pathway is a two-way dialogue channel provided by the NHS e-Referral Service (eRS) which allows the referrers (typically GPs) to seek input from specialists (GPs with special interest [GPwSIs] or consultant dermatologists) primarily to provide a diagnosis but also for a number of other reasons:

- Ask for advice on a treatment plan and/or the ongoing management
- Clarification (or advice) regarding test results
- Seek advice on the appropriateness of a referral
- Identify the most clinically appropriate service to refer to.

The most widely used model of eRS A&G is teledermatology where images of a lesion and clinical information are attached to A&G requests. If this is not available, non-eRS A&G is used. A specialist can advise the GP through a secure rapid digital communication channel. Potential outcomes through A&G can be either:

- convert the A&G request to a routine or urgent referral in the appropriate speciality or service (e.g., plastics, community dermatology service). This option is limited to centres that use eRS
- respond back to GP with advice only; the GP can then either manage the person in primary care or redirect to a community dermatology service where available if the person has a low risk lesion
- book direct for surgery with a pre-operative phone consultation.

An A&G request can be recommended to upgrade to an urgent suspected skin cancer referral if required.

## 4.2 Urgent suspected skin cancer referral pathway

A person on the urgent suspected skin cancer referral pathway should receive a diagnosis or ruling out of cancer within 28 days of being referred. This was formerly known as the 2 week wait pathway. For further details, see NHS England's webpage on faster diagnosis of cancer. NICE guidelines (NG12) on recognition and referral of skin cancer outlines the appropriate investigations in primary care and selection of people to refer on this pathway. Section 1.7 of the NG12 guideline describes the criteria that needs to be met to make a referral through this pathway for melanoma, SCC and BCC. These are summarised below in sections 4.2.1 to 4.2.3.

Experts highlighted that if NG12 criteria are met, the person is referred on the urgent suspected skin cancer pathway either for an urgent face-to-face appointment in secondary care, or an urgent virtual teledermatology review. If a primary care centre does not have a virtual teledermatology pathway available, the urgent face-to-face appointment pathway is used.

Experts noted that the face-to-face appointment pathway also includes community based 'spot clinics' which are present in a few areas across the UK. People with a single suspicious lesion may be assessed through this pathway to be triaged into the correct pathways. Triage is undertaken by a specialist (a consultant dermatologist or a GPwSI). These clinics may include a mix of urgent and non-urgent referrals. At the spot clinic, the specialist can review a higher number of patients (about 24 consultations in 2 hours) than they can at a typical outpatient clinic, as they are assessing specifically for triage. The outcomes for a spot clinic can include:

- treatment such as cryotherapy (done same day in some models where a senior dermatologist is present at the spot clinic)
- discharge back to the GP with or without a treatment plan
- a booking directly for surgery
- a routine or urgent referral to the appropriate speciality or service

Experts also noted that virtual teledermatology is expanding across the NHS and replacing the traditional face-to-face interaction. Where teledermatology does not exist, the face-to-face appointment referral continues to be used. Teledermatology refers to the use of static digital images and relevant patient information to triage, diagnose, monitor or assess skin conditions remotely. Experts noted that virtual teledermatology has an exclusion criterion where it cannot be used for lesions on difficult sites such as palms, soles, scalp and intimate areas, people with multiple skin cancers and/or multiple lesions. It was also noted that virtual teledermatology would not be used for children and they would be sent directly for a face-to-face appointment. If a person is referred through the urgent teledermatology referral

pathway, the clinical information along with a high-quality macroscopic image (taken with a smartphone or DSLR camera) and dermoscopic images (taken with a dermatoscope device and light source to magnify the image 10 times) of the skin lesion are required, and the images should be taken by a healthcare professional trained in medical photography. For lesions that are raised from the skin, an extra close-up image is taken to show the lesion in profile. Labelling of the images are also needed. Experts highlighted that image capture to support teledermatology is currently being done in the following settings:

- a GP surgery
- a community diagnostic centre (CDC) photography hub close to a person's home
- a teledermatology clinic based in secondary care.

Images are sent to be assessed by a consultant dermatologist using the teledermatology service and are stored in the person's record. The person can be either be:

- booked directly for surgery
- discharged back to their GP
- referred for a routine or urgent referral to the appropriate speciality or service.

### 4.2.1 Referral for suspected malignant melanoma of the skin

The NICE clinical knowledge summaries (CKS) covers the initial assessment and management for melanoma.

In the initial assessment of melanoma, the GP takes a detailed medical history and examination of the lesion in good light, with or without magnification. The person's entire skin surface (including the scalp and mucous membranes) should be examined and lymph nodes in the regional drainage area should be palpated if the lesion is suspicious of melanoma.

Sections 1.7.1 to 1.7.3 of NICE guideline NG12 recommend that the urgent suspected skin cancer referral pathway for melanoma is needed if:

- they have a suspicious pigmented lesion that has a weighted 7-point checklist score of 3 or more,
- dermoscopy suggests melanoma,
- they have a pigmented or non-pigmented skin lesion that suggests nodular melanoma.

Additional criteria from the British Association of Dermatologists' UK guidelines for the management of cutaneous melanoma (Marsden et al. 2010), BMJ Best practice guidelines for melanoma and the NICE guidelines on improving outcomes for people with skin tumours including melanoma (CSG8) recommend urgent referral if:

- any new persistent skin lesion, especially if growing, pigmented, or vascular in appearance and the diagnosis is unclear,
- a new pigmented line in the nail (especially if there is associated damage to the nail), or a lesion growing under the nail,
- there is any doubt about the lesion, or there is a history of recent change,
- a biopsy has confirmed the diagnosis of malignant melanoma. Note: if a lesion is suspected to be melanoma, an urgent referral to a dermatologist or other suitable specialist with experience of melanoma diagnosis should be made, and excision in primary care should be avoided.
- a pigmented or non-pigmented skin lesion suggests nodular melanoma,
- any major features in the 7-point checklist, or any features of the ABCDE system.

The BAD guidelines on the prevention, diagnosis, referral and management of melanoma of the skin produced in joint collaboration with the Royal College of Physicians have also listed additional criteria for when an urgent referral to dermatology is required:

- a new mole which is growing quickly over the age of puberty
- any mole which has 3 or more colours or has lost its symmetry
- a mole which has changed in appearance and is also itching or bleeding.

### 4.2.2 Referral for suspected squamous cell carcinoma

Section 1.7.4 of NICE guidelines NG12 recommends a person is referred to the urgent suspected skin cancer pathway if they present with a skin lesion that raises the suspicion of squamous cell carcinoma. NICE defines this as a mass or lesion that has an appearance or a feel that makes the healthcare professional believe cancer is a significant possibility.

### 4.2.3 Referral for suspected basal cell carcinoma

Section 1.7.5 to 1.7.6 of NICE guidelines NG12 recommend a routine referral for people if they have a skin lesion that raises the suspicion of a BCC. An urgent suspected skin cancer pathway referral should only be considered for a lesion that raises suspicion of BCC if there is a particular concern that a delay may have a significant impact, because of factors such as lesion site or size.

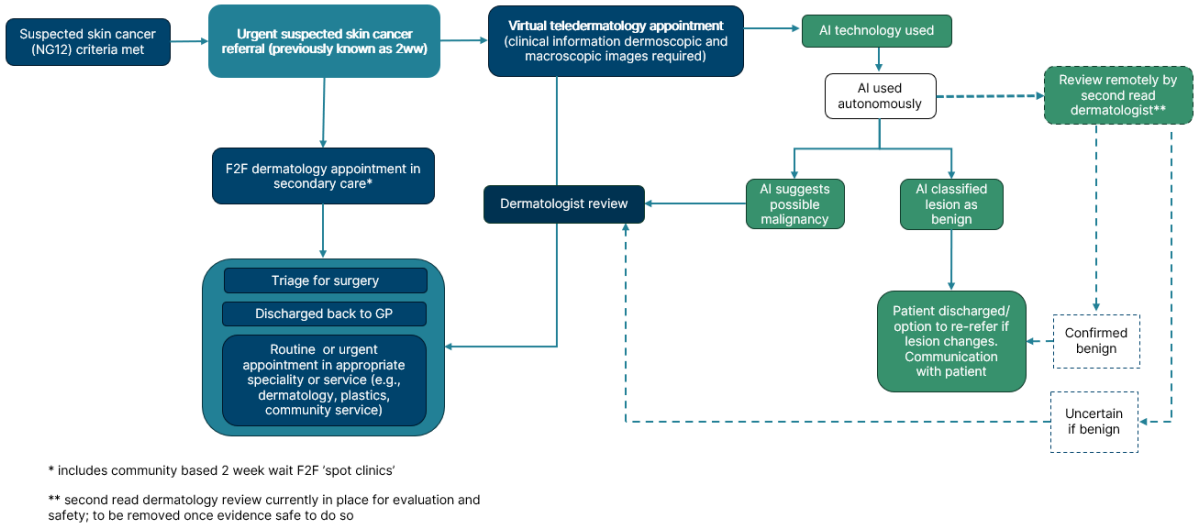
## 4.3 Proposed positioning of AI technologies

Experts noted that the current unmet need in dermatology is in primary care within the pre-referral setting (see section 4.3.3). However, it is expected that there would be limited evidence in this setting and therefore the scope of this assessment will focus on the use of AI technologies in the post-referral population (after being referred by the GP on the urgent suspected skin cancer pathway). This post-referral assessment could identify those with benign lesions who can be discharged from the urgent suspected skin cancer pathway.

Within the post-referral setting, AI technologies could be used with a second read dermatologist review (see section 4.3.1) or they could be used autonomously (without the second read; see section 4.3.2).

The proposed positioning of AI technologies in the current pathway is described in Figure 2.

**Figure 2: Proposed positioning of AI technologies in post-referral setting**




* includes community based 2 week wait F2F 'spot clinics'

** second read dermatology review currently in place for evaluation and safety; to be removed once evidence safe to do so

### 4.3.1 Post-referral setting with second read dermatologist

If AI technologies are used with a second read dermatologist review, a dermatologist employed by the company reviews all cases that the AI technology has identified as benign. This is done through virtual teledermatology with the aim of minimising false negative results (that is, cancerous lesions missed by the AI technology). Experts noted that the second read dermatology review is currently in place for evaluation and safety and the long-term plan is to remove this and for AI technologies to work autonomously.

If the lesion is confirmed to be benign by the second read dermatologist, the patient is discharged and advised to monitor the lesion and return to their GP if they notice any changes. If the second read dermatologist is uncertain about the diagnosis or if the AI suggests possible malignancy (whether the AI is used autonomously or not), the images are reviewed by the Trust dermatologist and triaged appropriately with communication to the patient. Experts noted that the use of AI technologies with second read is already deployed in several centres across the UK.

### 4.3.2 Post-referral setting used autonomously

If AI technologies are used autonomously, a lesion classified as benign can be discharged from the AI pathway without a second read by a dermatologist. The person is advised to monitor the lesion and return to their GP if they notice any changes. If the lesion changes overtime, the GP may re-refer to the urgent suspected skin cancer pathway. Experts noted that there is interest in the autonomous use of AI technologies.

### 4.3.3 Pre-referral setting

An alternative setting suggested for positioning of AI technologies is the pre-referral setting. Experts noted there are many potential models for how AI technologies could be positioned in the pre-referral pathway. One model proposed for use with DERM involves people being triaged by a GP receptionist or an online question form and invited to attend an appointment for image capture (settings may include a GP surgery, CDC photography hub, or a teledermatology clinic) for an assessment to determine the most appropriate referral pathway. If the assessment returns suspected melanoma or SCC, this results in an urgent suspected skin cancer referral. A lesion identified as a suspected BCC or pre-malignant results in a routine referral, community dermatology or a GP review to confirm the next steps. A benign lesion results in the person being discharged. This setting is outside the scope of this assessment.

## 4.4 Treatment

### 4.4.1 Treatment of melanoma

NICE guideline (NG14) for assessment and management of Melanoma describes the different recommendations for treatment of melanoma by staging of disease.

### 4.4.2 Treatment of squamous cell carcinoma

The British Association of Dermatologists guideline for the management of people with squamous cell carcinoma describes the treatment of SCC. Surgery is usually the recommended first-line treatment option for people with SCC in most cases. This involves removing the SCC with a margin of normal skin around it, using local anaesthetic.

In some cases, surgery is not possible or not chosen by the patient, and other treatment methods are considered, such as curettage and cautery, Mohs micrographic surgery or radiotherapy. For advanced SCC, a combination of treatments may be used, including surgery, radiotherapy and/or chemotherapy.

### 4.4.3 Treatment of basal cell carcinoma

NICE guidelines for the management of low-risk basal cell carcinomas in the community (CSG8) describe the management of BCCs depending on whether it is classified as a high- or low-risk BCC. This classification depends on criteria that consider: risk of incomplete excision; the skill and experience required by the healthcare professional to achieve good cosmetic result; risk caused by underlying anatomical structures (for example, major blood vessels or nerves); and other management risks (for example, children and young people, recurrent BCC, Gorlin syndrome, immunosuppression).

The British Association of Dermatologists guidelines for the management of adults with basal cell carcinoma describes the management of BCC in adults with low- and high-risk BCC. The management depends on a number factors including the size, site and histological subtype of the tumour, patient comorbidities, previous treatment history and patient preference. The most common treatment for BCC is surgery. Usually, this means cutting away the BCC under local anaesthetic, along with some of the healthy skin around it. Other types of treatment can also be used such as: Mohs micrographic surgery, radiotherapy, chemotherapy, curettage and cautery, cryotherapy, topic creams, and photodynamic therapy.

NICE guidelines for the management of low-risk basal cell carcinomas in the community (CSG8) describes the management of BCCs depending on whether it is classified as a high- or low-risk BCC. This classification depends on criteria that consider: risk of incomplete excision; the skill and experience required by the healthcare professional to achieve good cosmetic result; risk caused by underlying anatomical structures (for example, major blood vessels or nerves); and other management risks (for example, children and young people, recurrent BCC, Gorlin syndrome, immunosuppression). Section 1.7.6 of NICE guidelines NG12 indicates that if there is particular concern that a delay in treatment may have significant impact, a referral to the urgent suspected skin cancer pathway is recommended. NICE's quality statement 2 in QS130 indicates that low-risk BCCs can be managed by GPs in the community.

## 4.5 Patient issues and preferences

The following issues may be of concern to people with suspicious skin lesions:

- Some patients may have concerns about the use of an AI technology to diagnose lesions and would prefer a face-to-face interaction with a dermatologist. They may feel more confident seeing an expert who is able to examine the entire skin and can provide guidance on self-surveillance which would not be provided by an AI technology as it only provides information about a single lesion.
- There is a need to provide information that is appropriate for the person in terms of language, ability, and culture, recognizing the potential for different cultural meanings associated with the possibility of cancer.
- Not all patients or lesions are suitable for teledermatology because some lesions may be more challenging to assess and diagnose; for example, those in body creases such as the groin area.
- There are specific exclusions for which the AI technologies cannot be used, for example on tattooed skin. This may limit the number of people that can potentially benefit from the technology.

- People referred through the teledermatology pathway need to be able to get to a place to have their medical photography taken. This may be disadvantageous to those who do not live close to any hospitals or community diagnostic centres, or to those who find it difficult to travel. If a face-to-face follow-up appointment is needed a second visit would be needed.
- Some people may not want their photos being stored on a commercial platform.
- There are potential legal issues around who is legally responsible for a missed cancer diagnosis when AI technology has been used.
- There are potential ethical issues around excluding people from a pathway who could benefit from a new technology.

# 5 Comparator

The comparator is the assessment of suspicious skin lesions referred on the urgent suspected skin cancer pathway via teledermatology services or face-to-face secondary care appointments without the use of AI technology (see section 4.3).

# 6 Scope of the assessment

**Table 1: Scope of the assessment**

| | |
|---|---|
| **Decision questions** | • Does the use of AI technology for the analysis of suspicious skin lesions referred on the urgent suspected skin cancer pathway have the potential to be clinically and cost-effective to the NHS?<br>• What evidence is available to support the value proposition outlined in the scope and where are the evidence gaps? |

| | |
|---|---|
| **Populations** | People with suspicious skin lesions eligible for assessment using AI technology who are referred on the urgent suspected skin cancer pathway.<br>Where data permits, subgroups based on skin colour and socioeconomic status should be considered. |
| **Intervention** | • Deep Ensemble for Recognition of Malignancy (DERM) (Skin Analytics)<br>• MoleAnalyzer Pro (FotoFinder systems)<br>Used either with a second-read dermatologist or autonomously |
| **Comparator** | The comparator is the assessment of suspicious skin lesions through:<br>• Urgent virtual teledermatology services or<br>• Urgent face-to-face secondary care appointments |
| **Healthcare setting** | Community settings<br>Secondary care |
| **Outcomes: intermediate measures** | Intermediate measures for consideration may include:<br>• Diagnostic accuracy for the detection of melanoma, basal cell carcinoma (BCC), squamous cell carcinoma (SCC), rare skin cancers and benign skin lesions<br>• Proportion of cancers missed/detected<br>• Proportion of benign lesions diagnosed<br>• Proportion of referrals confirmed to be skin cancer<br>• Proportion of urgent cancer referrals:<br>  ○ needing a face-to-face hospital appointment with a specialist for review of lesion |

| | |
|---|---|
| | ○ converted to routine referral pathway<br>○ resulting in a diagnostic biopsy<br>○ booked for a surgical procedure<br>○ discharged back to GP<br>• Time to: diagnosis; discharge; face-to-face consultant appointment; treatment (surgery)<br>• Ease of use/acceptability of AI technology to healthcare professionals<br>• Number of people consenting to use the technology<br>• Technical failure rates (i.e., proportion of cases that cannot be processed due to image capture issues)<br>• Proportion of patients excluded for any reason (for example, due to tattoos or scars) and reasons for exclusion |
| **Outcomes: clinical** | Clinical outcomes for consideration may include:<br>• Morbidity (including, adverse outcomes of treatment and cancer outcomes such as distant metastases)<br>• Mortality |
| **Outcomes: patient-reported** | Patient-reported outcomes for consideration may include:<br>• Health related quality of life (i.e. anxiety-related)<br>• Acceptability of AI technology to patients |
| **Outcomes: costs** | Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include:<br>• Cost of annual subscription for AI software<br>• Cost of training healthcare professionals to take images and to interpret AI software results |

| | |
|---|---|
| | • Costs associated with setting up a teledermatology pathway<br>• Costs associated with image capture, uploading images and teledermatology<br>• Cost of consultant dermatologist to interpret the AI technology results<br>• Cost of consultant dermatologist face-to-face appointments<br>• Costs related to missed cancers |

# 7 Other issues for consideration

The British Association of Dermatologists (BAD) published a position statement on AI interventions which highlights that the evidence to support AI use in dermatology is weak and comes with risks of misdiagnosis. A false positive could cause stress, unnecessary treatment, and potentially waste NHS resources. A false negative could result in telling people that they don't have skin cancer when they do, leading to no treatment and potentially worse outcomes. BAD advises that before agreeing to use AI apps, healthcare professionals should ensure the apps have the correct regulatory classification and the appropriate supporting evidence (well designed studies carried out in the right clinical setting).

The BAD position statement describes the limitations of the AI apps in the points below:

- AI technologies face limitations by only focusing on a limited number of skin cancers which risks missing rare but serious diseases. There are over 2000 skin diseases and technologies have limited number of skin conditions that have been included in their testing.
- Ignoring certain body sites like the soles of the feet

- Testing apps only on some parts of the population, rather than a representative sample of the population that the app will be used on
- Not including all skin types, particularly excluding skin of colour
- Only considering skin images and not taking into account other patient information such as a clinical history.

# 8 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

NICE's guideline on sunlight exposure: risks and benefits (NG34) highlighted that people with light skin colour or fair hair are more likely than others to develop skin cancer. But, people with darker skin are often diagnosed with skin cancer at a more advanced stage compared to people with white or lighter skin (Cancer Research UK, 2016). There are concerns with the ability of AI software in recognising skin cancer in people with darker skin tones because the datasets on which the AI technologies are trained use predominantly fair skinned people, therefore the performance of the algorithms when used for dark skin may be poor.

The British Association of Dermatologists' UK guidelines for the management of cutaneous melanoma (Marsden et al. 2010) highlight that there some people at higher risk of melanoma who should be considered for referral to specialist clinics. Individuals at moderate risk (about 8-10 times that of the general population) include people with either a previous primary melanoma, or large number of moles some of which may be clinically atypical (fair skin more likely to develop more moles), or organ transplant recipients. Individuals at greatly increased risk (more than 10 times that of the general population) include people with giant congenital naevi, strong family history of melanoma or of pancreatic cancer.

People from lower socioeconomic groups may be at greater risk of skin cancer as they may find it difficult to afford sunscreen. However, some experts noted that people from higher socioeconomic groups were at greater risk of skin cancer, but those in lower socioeconomic groups were less likely to be diagnosed.

Outdoor workers may be at higher risk due to longer periods of sun exposure.

Rural populations may be disadvantaged by AI technology as there is a requirement to travel to centres for image capture appointments.

These technologies are aimed at those with fewer than 3 lesions. Experts mentioned that after a certain age it is more likely to find lesions on a total skin examination which you are unable to do in a teledermatology appointment aimed to focus on a specific single lesion.

DERM is not eligible for use in people under 18.

# 9 Authors

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# Appendix A Glossary of terms

### Artificial intelligence

The ability of a computer system to perform human cognitive functions. In the context of this topic, artificial intelligence is used to perform the diagnosis of skin lesions similar to a clinical examination by a specialist.

### Biopsy

Removal of a sample of tissue from the body to assist in diagnosis of disease.

### Breslow thickness

The measurement of the depth of the melanoma lesion from the surface of the skin to the deepest point of the tumour. There are 5 levels of tumour thickness and it is used in the staging system for melanoma.

### Excision

Removal of tissue with surgery; typically done with a margin around the lesion.

### Gorlin syndrome

An inherited condition that can increase an individual's chance of developing basal cell carcinoma. Also called basal cell nevus syndrome.

### Lymph node status

Lymph nodes are small structures in the body that filter foreign substances such as cancer cells. The spread of cancer to nearby lymph nodes indicates a positive lymph node status and the absence of this means a negative lymph node status. Spread of cancer to lymph nodes is typically indicative of poorer prognosis.

### Moles (naevi)

**Atypical moles or naevi** are growths on the surface of the skin that are usually flat and more than 5mm in diameter. They have ill-defined or irregular borders and varying shades of colour. They usually occur in fair-skinned people due to sun exposure and can be solitary or numerous. They can be found anywhere on the body, but most commonly on the trunk, upper limbs, scalp, and buttocks.

**Congenital melanocytic naevi** (birthmarks) are present from birth or develop shortly after birth. They are usually larger than acquired naevi and are dark brown or black in colour, they can be raised, bumpy, or hairy. They usually grow proportionally with the child.