NICE advice

Digital technologies for the detection of melanoma

Medtech innovation briefing
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Overview

NICE has developed a medtech innovation briefing (MIB) on digital technologies for the detection of melanoma.

The information provided includes a description of the technology, how it's used and its potential role in the treatment pathway. A MIB also includes a review of relevant published evidence and the likely costs of using the technologies, but it is not NICE guidance and does not make any recommendations on the value of using the technologies.

Summary

- The **technologies** described in this briefing are used for triaging, reporting and identifying possible melanoma in skin lesion images and include nomela, DERM, Moleanalyzer pro and SkinVision.

- The **innovative aspects** are the signal processing and artificial intelligence (AI) capabilities that these technologies report to offer, resulting in improved accuracy in detecting melanoma compared with standard care.
- The intended **place in therapy** can vary across technologies but is predominantly proposed to be in primary care to assist GPs in triaging suspected melanoma for referral to secondary care.
- The **main points from the evidence** summarised in this briefing are from 13 full-text studies and 1 poster abstract (2 UK studies, 7 German studies, 3 studies from the Netherlands, 1 international study and 1 Canadian study). The 14 studies include over 2,598 people and 570 images from datasets. Most of the studies were done in the secondary care setting. Several studies show that the signal processing and AI in these digital technologies outperformed or were equivalent to standard dermatoscope examination in identifying melanoma.
- **Key uncertainties** around the evidence or technologies are that there is a lack of randomised controlled trials and prospective cohort studies to assess any of the tools in the intended use, clinical setting and population. There are no studies identifying the impact of these tools on clinical decision making by GPs. Only 2 companies (nomela and DERM) have UK-based studies. Out of the 14 studies, 12 were not based in the UK, which may limit their generalisability to the NHS setting.
- **Experts agreed** that these are innovative technologies but highlighted significant gaps in the evidence base and uncertainties on the potential system benefits and impact on the clinical pathway. Experts noted that these technologies have potential resource consequences but highlighted that this could vary depending on where the technologies are used in the clinical pathway.
- There are general **safety considerations** around the use of these technologies, which include the risk of false positives leading to anxiety for the person and potentially unnecessary procedures. False negatives could potentially delay diagnosis. The technologies have not been tested on rare skin cancers and there may be uncertainty with using these technologies on people with black or brown skin.

- The unit **costs** of the technologies in this briefing vary in their payment plans from £0.60 per eligible user, £30 to £50 per test use (excluding VAT) and up to £53,574 (excluding VAT) for a single technology. These values are not comparable across technologies without considering the place in the clinical pathway, implementation and staffing costs, as well as additional maintenance costs. All technologies may have the potential to reduce some secondary care consultation appointments, which cost £121 per attendance (excluding VAT).

  The British Association of Dermatologists, a professional membership body for UK dermatologists, has produced a position statement on AI interventions highlighting that AI technologies have the potential to improve clinical care and optimise processes through using clinical data to inform best practice and outcomes.

The technology

The technologies included in this briefing are standalone software platforms that use varying degrees of system processing and adaptive artificial intelligence (AI) to review and inform the detection of possible melanoma. Version updates and periodic maintenance activities are needed for these technologies and can be done remotely. All technologies reported on are for people aged 18 or older. Other similar technologies may be available but are not included in this briefing, for example because of the lack of a current publicly available evidence base.

nomela (Moletest Scotland)

nomela is an advanced image analysis technology for melanoma screening. It is designed for use by healthcare professionals when reviewing suspicious pigmented skin lesions as a 'rule out' test. Hardware needed to use this technology includes an iOS tablet with the nomela software loaded (with all other functions disabled except image capture and analysis) and it can be used offline. However, an internet connection via Wi-Fi or 4G technology is needed to intermittently upload results and reports. The tablet scans a skin lesion using the camera, and the nomela application then identifies the perimeter of the suspicious lesion before analysis. This analysis is made using 5 signal processing algorithms to identify texture, asymmetry, colour, average gradient and edge irregularity. The values of these measurements are compared with reference ranges and if 1 measurement is found to fall outside, then the test provides a binary result within 1 minute, which is shown on screen as either 'no evidence of melanoma' or 'melanoma not

excluded' (McKenna et al. 2020).

DERM (Skin Analytics)

DERM (Deep Ensemble for the Recognition of Malignancy) is an AI-based skin lesion analysis device intended for use in the screening, triage and assessment of skin lesions suspected as being skin cancer, including melanoma, in adults in any body location except where specific exclusions apply. DERM can be used within a pre-primary care model in a community diagnostic hub in addition to a primary care setting to assist GPs in referring people with suspected melanoma. It can also be used in secondary care to triage cases on the 2-week wait referral pathway. DERM needs a dermatoscope, a smartphone and connection kit, internet connection to submit images and receive results, and a computer screen to view the results. If a lesion exhibits features of more than 1 lesion type, DERM uses a risk hierarchy in its final analysis. The algorithm was trained on a proportion of historical and prospectively collected images from a UK population. DERM does not update itself automatically but the algorithm needs retraining with additional images. DERM has been granted a phase 4 AI in Health and Care Award by the NHS AI Lab (formerly known as NHSX).

Moleanalyzer pro (FotoFinder Systems)

Moleanalyzer pro is intended to be used by a medical professional for non-invasive visual documentation of primary skin lesions and aims to help the recognition of melanoma lesions. Moleanalyzer pro is predominantly intended for use by dermatologists in a secondary care setting. Lesions can be between 2 mm to 20 mm and should be intact without additional psoriasis, eczema, acute sunburn or on hair-covered parts of the body (see FotoFinder's information of performance and safety). Moleanalyzer pro needs a video dermatoscope (such as medicam 1000) with FotoFinder universe software. It uses a deep-learning algorithm and complex machine learning to continuously update the algorithm with the goal of increasing sensitivity and specificity.

Lesions are assigned a score from 0 to 1, according to structural characteristics (with 0 indicating no suspicion of melanoma and 1 indicating a high suspicion of melanoma), but a threshold value is not provided to guide excision or biopsy.

SkinVision

SkinVision is a smartphone app intended to provide immediate risk indication for the most common types of skin cancer of a specific lesion on the skin. SkinVision is a patient-facing technology and is designed for people to self-examine suspicious skin lesions; its place in the pathway is before formal interaction with a healthcare professional in a primary care setting. SkinVision needs a smartphone, internet connection and a subscription, as well as the mHealth app (which SkinVision's algorithm is integrated into). SkinVision's AI algorithm assesses an image of the suspicious skin lesion to provide a recommendation on whether there is a need to visit a healthcare professional for further review. There are 3 risk indications for skin lesions: low risk, low risk (plus symptoms) and high risk. SkinVision's algorithm rates images as high risk when there is some similarity between the image and the skin cancer images in its database. The algorithm is trained and validated on SkinVision's large clinical database of skin lesion images. It quantifies variations in texture, the lesion's borders, the ratio in intensity between the skin and skin lesion and the number of distinct regions with different intensity values (Maier et al. 2015). If the skin lesion is high risk or the person has concerns, they share the high-quality image and the risk assessment directly with their healthcare professional through the app. The healthcare professional decides after viewing the image and risk assessment whether to book the person for follow-up treatment or not. SkinVision reports to allow people to self-check and monitor their condition using an interactive body map and reminders in their smartphone app to monitor their skin health over time.

Innovations

Digital technologies, with or without AI capabilities, that analyse skin images for melanoma may help increase diagnostic accuracy and reduce waiting times for onward referral by improving triaging for specialist care from both primary and secondary care.

Current care pathway

Most skin lesions will first be examined in a primary care setting. Experts report variation in practice across the country and significant variability in staff and set up in primary care. NICE's guideline on the recognition and referral of suspected cancer includes a weighted 7-point checklist, where suspicious pigmented skin lesions with a weighted score of 3 or more should be urgently referred under the 2-week rule. GPs may or may not use a dermatoscope (a handheld, specialised magnifying device) to support their assessment of

the lesion. Any lesions that cannot be considered definitively or unequivocally non-cancerous should be referred to a skin specialist.

As outlined in the British Association of Dermatologists' UK guidelines (Marsden et al. 2010), when a suspicious skin lesion presents and there is a need to exclude melanoma, the lesion will be examined using a dermatoscope (carried out by healthcare professionals trained in this technique) and, when indicated, a biopsy carried out for histopathological review.

The following publications have been identified as being relevant to this care pathway:

- NICE's guideline on the assessment and management of melanoma
- NICE's guideline on suspected cancer recognition and referral
- NICE's diagnostics guidance on VivaScope 1500 and 3000 imaging systems for detecting skin cancer lesions
- NICE's quality standard on skin cancer.

Population, setting and intended user

There are reportedly around 16,700 new melanoma skin cancer cases in the UK every year (see Cancer Research UK's melanoma skin cancer statistics). These technologies are intended to be used in addition to current methods of assessing, detecting and characterising adults with suspected melanoma.

There are different options for using these technologies in the NHS care pathway for melanoma:

- Pre-primary care. Patient-facing technologies such as SkinVision are positioned to allow people to proactively monitor their skin over time. DERM is currently being piloted in a community diagnostic hub. Both of these technologies provide an immediate risk assessment and indication on whether to visit their GP and with what urgency.
- Primary care. These technologies can be used as a tool to help GPs make a more informed diagnosis of skin malignancies such as melanomas to improve the appropriateness of onward referrals.

- Secondary care. These technologies can be used to support remote triage of cases that have already been referred on the 2-week wait referral pathway, thus streamlining workflow and reducing backlog. If the technologies can correctly identify people without malignancies, then theoretically this will reduce the number of unnecessary biopsies. These technologies, particularly DERM, can be used for triaging people in both primary and secondary care settings. They have the ability to reduce inter-clinician and department variability and improve patient outcomes (sensitivity or negative predictive value) compared with standard care.

Using these technologies in any of these settings has the potential to reduce the high number of people in specialist clinics by reducing the number of inappropriate referrals:

- nomela's place in the care pathway may be in primary care, a diagnostic centre or a specialist GP community service setting.
- DERM can be effectively used in the pre-primary (pre-GP) setting on a self-referred population, in a primary care setting as a decision support for GPs or in a secondary care setting as part of a community hub (when a dermatologist forms part of the care team).
- Moleanalyzer pro may be used in the secondary care setting.
- SkinVision is a patient-facing technology, placed as a pre-GP tool. It is a smartphone-only technology, allowing people to proactively monitor their skin for signs of skin cancer and providing indication for referral to the GP when needed.

Costs

Technology costs

nomela

The company has not yet listed any price for nomela, but they plan to supply and maintain the iOS devices for free, together with the use of their infrastructure, which can deliver eConsents and reports securely to NHS systems as needed. They are currently working on 2 provisional pricing models: a per-test fee in the range of £30 to £50 (excluding VAT) or a yearly one-off licensing fee calculated on the estimated annual trust patient volume.

DERM

The price of the technology includes basic hardware, software, service and support. The hardware includes an iPhone, a dermatoscope and a connection kit. This technology does not replace the use of a dermatoscope but is used alongside. DERM can be used either as a standalone web-based service or with a cloud-based platform called Ov2. This cloud-based teledermatology platform allows secure collection of consent, medical and lesion history, and contextual clinical and dermoscopic images of lesions and produces a final report. There are multiple possible options for the image capture hardware kit based on client preference, with prices starting from around £350 (excluding VAT). One kit is shared across several clinical users within the same trust (typically 3 to 5 kits per site). A secondary care model reviewing up to 10,000 people per year would need around 5 to 6 kits. Third-party client software is included within the price of the technology. The company report the current pricing model is either a pay per use or a block contract model and is around £40 per use (excluding VAT). Use is estimated on previous years' activity levels or estimated referral volume.

Moleanalyzer pro

The price of the technology is £53,574 (excluding VAT) for a total body mapping system. The price includes the master tower, medical components, raw imaging kits, dermatoscope components, software and licence. The machine comes with 2 years' free maintenance, which covers both software and hardware. Depending on the system purchased, there is an annual maintenance cost at the end of the 2-year warranty. The lifespan of the technology is around 7 to 8 years. The technology can also be purchased separately from the total body mapping system, in which case a monthly cost of £200 or £1.50 per suspected mole analysed is charged per trust. Any dermatoscope connected to an iOS or android device can be used for this.

SkinVision

The technology costs £0.60 to £2.50 (excluding VAT) per eligible user, based on population size, or £10 to £30 (excluding VAT) per activated annual plan, based on volume of activated users. There are no other set-up costs or licensing fees reported.

Cost of standard care

The current practice is for GPs to refer a suspected melanoma case to a dermatology clinic

for further testing. GPs with a particular interest in the disease area may perform dermoscopy. In primary care, GPs do a basic screening, and this may or may not include use of a dermatoscope (ranging in price from £700 to £1,000 excluding VAT, with an expected lifespan of 5 to 10 years).

In secondary care, a specialist uses a dermatoscope for examination and then refers on to biopsy if needed. The cost of screening for melanoma per person in a secondary care setting would be a standard outpatient consultation (dermatology), costing £121 excluding VAT (National Cost Collection 2019/20).

Resource consequences

There is no publicly available information on the resource consequences (economic studies reporting the cost effectiveness) of the technologies. However, Skin Analytics (DERM) states that a study done to assess the resource consequences of deploying the technology (DERM Health Economics Study, 2020/21) was presented at the American Academy of Dermatology conference in 2022 and will be published as a full-text article. If these technologies are adopted in a primary care setting, this could result in a reduction of inappropriate referrals to specialist dermatologists. Resource consequences of adopting the technology will be contingent on use or volume settings, and further data on the effectiveness and cost effectiveness of these technologies across the NHS are needed.

For all technologies, there is a necessary set-up and training period that will require additional resources. For example, users will get training on how to capture good-quality clinical images for optimal performance of the AI algorithm, and there will be IT costs associated with establishing cloud connectivity through the NHS firewall and limited options for connection to external sites. For each local installation, this may take some time to be negotiated because there are currently no national guidelines for using cloud-based technology solutions in the NHS.

The DERM company website states that the technology is hosted on a cloud-based service. DERM is intended to be used under the supervision of a healthcare professional as part of a predetermined or agreed clinical pathway only. It is also intended to be used when users responsible for capturing images and interpreting the results have been appropriately trained to perform these tasks. nomela is designed for use solely by trained medical professionals, with a training and certification system that has been used for clinical trials. For Moleanalyzer pro, the installation and training will be done by FotoFinder UK and is included in the price. SkinVision users need a smartphone device with a camera

to download and use the SkinVision app.

Regulatory information

- DERM (version number 3.0) obtained UK Conformity Assessment (UKCA) certification as a Class IIa device (March 2022) under UK Medical Device Regulations (MDR) 2002.
- Moleanalyzer pro (version number 3.4) is CE marked as Class I (Annex VIII MDR) under the Annex IX (EU), 2017/745 regulation.
- nomela (version number 4.0) is CE marked Class I under Medical Device Directive, 93/43/EEC, with plans to transition to MDR by 2024.
- SkinVision (version number 6.0) is CE marked Class I under Medical Device Directive, 93/42/EEC, with plans to transition to MDR by 2024.

The Medicines and Healthcare products Regulatory Agency (MHRA) has not reported any safety issues. However, it mentioned that CE markings for SkinVision, nomela and Moleanalyzer pro may not be sufficient for these technologies, and they should be reclassed as Class IIa diagnostic medical devices since a missed diagnosis poses a moderate risk to the person.

Safety considerations

The risk of such assistive technologies is 2-fold. Too many false positives could lead to referring people inappropriately to secondary care, causing unnecessary anxiety to the person and exposing them to potentially unnecessary procedures. Too many false negatives pose a potentially greater safety concern; they could lead to a delay in diagnosis and worse patient outcomes. Moreover, the technologies have not been tested on all skin cancers and, as such, there is a possibility that less common diagnoses, particularly rare skin cancers, could be missed. Experts advised there is also a lack of training and testing of these technologies in people with black and brown skin.

The British Association of Dermatologists, a professional membership body for UK dermatologists, has produced a position statement on AI interventions highlighting that AI technologies have the potential to improve clinical care and optimise processes through using clinical data to inform best practice and outcomes. However, it reports that a robust regulatory framework is needed and notes the following considerations:

- The technologies should have a clinical evaluation, and evidence presented should adequately support the intended use of the technology; studies should be done in the same clinical setting and in the same population as their intended use.
- All technologies must be accompanied by information needed to use them safely and properly, considering training and knowledge of intended users. Manufacturers' statements on labelling should be consistent with any promotional material.
- The technologies should be classified as Class IIa if they are intended for diagnosis or indicative diagnosis in the context of use by patients.

Equality considerations

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

Melanoma is more common in older people, with incidence highest in people aged 85 to 89. It is increasing in younger people and is the second most common cancer in adults aged 25 to 49. In younger people, melanoma is more common in women, but it becomes more common in men over 55.

Melanoma is more common in people with white skin because they have less of the protective pigment melanin. People with black or brown skin are more likely to be diagnosed with advanced melanoma. Late diagnosis of melanoma is associated with worse outcomes and a higher risk of death. There are considerations needed with artificial intelligence (AI) technologies for detecting melanoma in terms of transparency of reporting the training data used to inform the system. The evidence base reports on skin types using the Fitzpatrick scale, which has 6 main skin types (type 1: always burns, never tans; type 2: usually burns, tans minimally; type 3: sometimes burns mildly, tans uniformly; type 4: burns minimally, tans easily; type 5: very rarely burns, tans very easily; type 6: never burns, tans very easily). The training data must reflect the diversity of the population in which it will be used and therefore must demonstrate evidence of accurate performance across all skin types (Food and Drug Administration's AI and machine learning in medical devices, 2020; British Association of Dermatologists' position statement 2022). This will ensure that this technology will not contribute to inequitable access to healthcare. Age and race are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

This briefing includes the most relevant or best available published evidence relating to the diagnostic accuracy of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

This briefing summarises 1 poster abstract for nomela, 2 published full-text studies on DERM, 4 published full-text studies on SkinVision and 7 published full-text studies on Moleanalyzer pro. There are further studies published for DERM and Moleanalyzer pro but only the most relevant studies are reported here.

In the 14 studies summarised in this briefing, over 2,598 people were included. Thirteen of the 14 studies included in this briefing assessed diagnostic test accuracy of the different technologies using sensitivity, specificity and receiver operating characteristic (ROC) area under the curve (AUC) compared with a dermatologist's diagnostic accuracy.

The clinical evidence and its strengths and limitations are summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The 1 study for nomela is a prospective study with a large sample size of 1,200 people done in a secondary care setting in 2 phases. The 2 studies for DERM include an algorithm development study compared with current diagnostic practices based on a meta-analysis of 82 published studies and a prospective, multicentre, single-arm clinical validation study of 514 people. The studies for SkinVision are a mix of prospective and retrospective single and multicentre accuracy studies with a total of 628 people included. Five of the 7 studies for Moleanalyzer pro are cross-sectional diagnostic test accuracy studies with a total of 570 images analysed, 1 is a non-randomised comparative study with 72 people, and 1 is a prospective diagnostic accuracy study with 184 people.

The primary outcome in most of the studies was diagnostic accuracy of the technologies against dermatologist clinical examination as a reference standard (measured using ROC AUC, sensitivity and specificity). Thirteen of the 14 studies included in this briefing are full-text papers with different population sizes, of which the smallest is 72 people and the

largest is 514 people. The poster abstract for nomela referred to 1,200 people.

All people included in these studies were aged 18 and above. Only 2 studies were done in the UK (McKenna et al. 2020; Phillip et al. 2019), 7 studies were in Germany (Fink et al. 2019; Haenssle et al. 2020; Maier et al. 2015, Winkler et al. 2019, 2020, 2021a, 2021b), 1 study was in Canada (McLellan et al. 2021), 1 was international (Phillips et al. 2020) and 3 studies were in the Netherlands (Sangers et al. 2022; Thissen et al. 2017; Udrea et al. 2020).

Studies done outside the UK may have limited generalisability to the NHS. None of the included studies have any patient-relevant outcomes reported and are not done in all the intended clinical settings (pre-primary care, primary care and secondary care) or with the population of interest. However, Skin Analytics states that there has been a recent study (DERM Health Economics Study 2020/21) on lesions referred from primary care, which included a patient feedback survey and is expected to be published soon. Most of the studies were done in secondary care settings, therefore limiting their generalisability to primary care settings. Further population-based prospective studies in the NHS done in the intended clinical setting, focusing on the impact of accuracy, clinical management and outcomes (both patient and system) would be beneficial in providing further evidence to support clinical adoption and use of these technologies in the NHS.

McKenna et al. (2020)

Study size, design and location

A phase 1 and 2 performance evaluation study of 1,200 adults from a secondary care UK setting. Phase 1: an open prospective study of non-randomised evaluation from primary care referrals (1,200 people). Phase 2: a retrospective evaluation of historical images using nomela of malignant melanomas, as diagnosed by a pathology department.

Intervention and comparator(s)

nomela software for the detection of melanoma compared with the clinical (and, when possible, histological) diagnosis at primary care.

Key outcomes

The sensitivity of nomela is set at 100%, and its specificity is 53%.

Strengths and limitations

Strengths: the study used a large sample size, which increases its power and reduces bias. The study was done in a UK setting.

Limitations: the secondary care single-centre study design with a wide range of exclusion criteria, although in the UK, may make these results less generalisable to other locations. The poster abstract provides only minimal information to critique but does state that the study design had prospective and retrospective components, which could have led to bias. The exclusion criteria for this study were extensive, which limits its utility as a referral tool in a primary care setting. No people from African or African Caribbean skin type were included in the study but it does state that the mix of Fitzpatrick skin types included type 4 (35.1%), type 5 (8.9%) and type 6 (0.1%).

Phillips et al. (2019)

Study size, design and location

A prospective, multicentre, single-arm masked diagnostic trial with 514 participants in a secondary care setting at 7 UK hospitals.

Interventions and comparator

DERM AI technology compared with dermatologist clinical assessment of likelihood of melanoma with a dermatoscope.

Key outcomes

The algorithm achieved a ROC AUC of 90.1% (95% confidence interval [CI] 86.3% to 94.0%) for biopsied lesions and 95.8% (95% CI 94.1% to 97.6%) for all lesions. When set at 100% sensitivity, the algorithm achieved a specificity of 64.8% with iPhone 6s, while dermatologists achieved ROC AUC of 77.8% (95% CI 72.5% to 81.9%) and a specificity of 69.9%. However, at 95% sensitivity, the specificity of biopsied and all lesions for each camera were as follows: iPhone 6s, 50.6% and 78.1% respectively; Galaxy S6, 46.9% and 75.6% respectively; and for digital single-lens reflex (DSLR) cameras, 27.6% and 45.5% respectively. This compares with a specificity of 69.9% on all lesions by clinicians.

The number of biopsies needed to identify 1 case of melanoma at 95% sensitivity was 3.04

for biopsied lesions and 4.00 for images taken with iPhone 6s; 3.22 and 4.39, respectively, for images taken with Galaxy S6; and 4.32 and 9.02, respectively, for images taken with DSLR. This compares with the number needed by clinicians of 4.92. At 100% negative predictive value, the positive predictive value was 20.3% for clinicians' assessment, 17.9% for images taken with iPhone 6s, 13.4% for Galaxy S6 and 9.5% for DSLR.

Strengths and limitations

Strengths: the study included a large sample size of 514 people and was done in 7 UK hospitals. Gender distribution is almost balanced, and the mean age allows generalisability of the study. The study used 3 different cameras and included both biopsied lesions and lesions that were clearly benign.

Limitations: 96.8% of the people in the study were white, which may introduce bias in the accuracy of detecting melanoma in white, black and brown skin. A total of 849 images were excluded because of poor quality. The secondary care settings limit the generalisability of these results to a primary care setting.

Phillips et al. (2020)

Study size, design and location

An algorithm development study compared with current diagnostic practices based on a meta-analysis of 82 published studies.

Intervention and comparators

DERM technology accuracy compared with clinical assessment performance, assessed by meta-analysis of studies examining the accuracy of naked-eye examination, with or without dermoscopy, by specialist and general physicians whose clinical diagnosis was compared with histopathology.

Key outcomes

DERM achieved a ROC AUC of 93% (95% CI 92% to 94%). The statistically determined optimum sensitivity and specificity were 85.0% and 85.3%, respectively, though these are not DERM settings proposed for use in clinical practice. When DERM was set to achieve 95% sensitivity, it achieved a specificity of 64.1%. When DERM was set to achieve 95%

specificity, it achieved a sensitivity of 66.9%. In comparison, a meta-analysis of more than 10 studies showed that primary care physicians achieve an AUC of 83% (95% CI 79% to 86%), with sensitivity and specificity of 79.9% and 70.9%. Dermatologists (92 studies) achieved an AUC of 91% (95% CI 88% to 93%) and sensitivity and specificity of 87.5% and 81.4%, respectively.

Strengths and limitations

Strengths: the algorithm wasn't developed using a single dataset of images. The study reports a range of data from the development of an early version of DERM, providing transparency to the underlying drivers of the performance of the algorithm. The use of a meta-analysis to derive performance of standard care was novel at the time.

Limitations: the study does not define the ethnic diversity included and there is limited information about the demographic data of images used. Since this was not a systematic literature review, there may be some bias about determining the included papers for the comparison. In addition, and linked to this, the number of studies pooled in each group for the comparison of primary and secondary care is not equivalent to give a comparable effect size.

Udrea et al. (2020)

Study size, design and location

A retrospective diagnostic accuracy study of 285 images sourced from 2 previous clinical studies (Maier et al. 2015 and Thissen et al. 2017) and a smartphone application user database in the Netherlands.

Intervention and comparator

Smartphone application machine learning algorithms.

Key outcomes

Overall, the algorithm has a sensitivity of 95.1% (95% CI 91.9% to 97.3%) to detect skin cancer. In particular, the sensitivity to detect melanoma is 92.8% (95% CI 87.8% to 96.5%) and the sensitivity in detecting keratinocyte carcinoma and their precursors is 97.3% (95% CI 93.2% to 99.3%). The specificity of the algorithm is 78.3% (95% CI 77.24% to 79.34%).

Strengths and limitations

Strengths: the study used data from different sources, including 2 previous studies and a smartphone application user database. Combining data from different sources provides a larger dataset.

Limitations: the study is retrospective, drawing on data from 2 previously published studies and a smartphone application user database. Because of the inclusion of mainly high-risk lesions in the clinical studies, it may mean the dataset is inadequate in the evaluation of specificity. It was not possible to have complete follow up for all smartphone application users, so it was not possible to calculate positive and negative predictive values. Dermatologist assessment for risk rating was based on images taken by users without further investigation, and the cases were clinically validated as benign without histopathological report. The main risk associated with the use of smartphone applications by lay users is that malignant melanoma and keratinocyte carcinoma are incorrectly classified as low risk (that is, a false negative) and their diagnosis and treatment is delayed.

Fink et al. (2019)

Study size, design and location

Non-randomised comparative study of 72 patients in Germany.

Intervention and comparator

Moleanalyzer pro compared with 11 dermatologists who were presented with dermoscopic images on screen.

Key outcomes

For the classification of the 72 dermoscopic images, dermatologists showed a sensitivity, specificity and diagnostic odds ratio (DOR) of 90.6%, 71.0% and 24, respectively. With the same set of images, the Moleanalyzer pro revealed a diagnostic performance of sensitivity of 97.1%, specificity of 78.8% and DOR of 34. However, there was no statistically significant meaningful difference between dermatologists and a convolutional neural network.

Strengths and limitations

Strengths: the study comparator included 11 dermatologists ranging in experience and practice.

Limitations: non-randomisation of the study might introduce bias. There is no reference to a sample size calculation. The study included only 2 types of lesions, which is not representative of clinical practice. Also, dermatologists were not given additional information for decision making that would be present in a real-life clinical setting and therefore may underestimate the diagnostic performance of dermatologists in real-life practice. The study does not define the ethnic diversity included or provide data on skin types.

Haenssle et al. (2020)

Study size, design and location

A cross-sectional study in Germany of 100 cases of pigmented and non-pigmentated skin cancers in a 2-level reader study including 96 dermatologists.

Intervention and comparator

Moleanalyzer pro analysing dermoscopic images was compared with dermatologist image assessment using a web-based platform at 2 levels; at level 1, dermoscopic images were assessed alone, and at level 2, images included clinical close-ups, dermoscopy and textual information.

Key outcomes

Moleanalyzer pro achieved a sensitivity, specificity and ROC AUC of 95.0% (95% CI 83.5% to 98.6%), 76.7% (95% CI 64.6% to 85.6%) and 91.8% (95% CI 86.6% to 97.0%), respectively. At level 1, for management decisions based on 1 dermoscopic image per case, the dermatologists' sensitivity and specificity was significantly lower than Moleanalyzer pro at 89.0% (95% CI 87.4% to 90.6%) compared with 95.0% (95% CI 83.5% to 98.6%), $p<0.001$.

With level 2 information, the sensitivity for dermatologists significantly improved to 94.1% (95% CI 93.1% to 95.1%; $p<0.001$), while the specificity remained unchanged at 80.4% (95%

CI 78.4% to 82.4%; p=0.97). When fixing the Moleanalyzer pro's specificity at 80.4% (the mean specificity of the dermatologists' management decision in level 2), the sensitivity was 95.0% (95% CI 83.5% to 98.6%), almost equivalent to the sensitivity of the dermatologists, which was 94.1% (95% CI 93.1% to 95.1%), p=0.1. The Moleanalyzer pro demonstrated accuracy of 84.0% (95% CI 75.6% to 89.9%) compared with mean dermatologists' accuracy of 85.9% (95% CI 84.7% to 87.1%), p=0.003.

Strengths and limitations

Strengths: the study included a comparison at level 2, where dermatologists have additional information to base their decision and is more reflective of clinical practice.

Limitations: the study was done in a single centre and is based on selected cases without clear reporting of inclusion and exclusion criteria. The dataset had a small proportion of melanoma cases per test set. This limited number of melanoma cases means it cannot be generalised to a primary care setting. The study does not report the sample's ethnic diversity or demographic data, including Fitzpatrick skin type.

MacLellan et al. (2021)

Study size, design and location

A prospective diagnostic accuracy study in 184 adults in a secondary care setting in Canada.

Intervention and comparator

Non-invasive imaging techniques (Moleanalyzer pro compared with MelaFind and Verisante Aura) and teledermatology (teledermoscopist) compared with dermatologist naked-eye examination (clinical examination) with a dermatoscope.

Key outcomes

Sensitivity and specificity were 88.1% (95% CI 79.4% to 96.9%) and 78.8% (95% CI 71.5% to 86.2%), respectively, for Moleanalyzer pro and 96.6% (95% CI 91.91% to 101.31%) and 32.2% (95% CI 18.4% to 46.0%), respectively, for dermatologist examination.

Moleanalyzer pro achieved the highest results in specificity. Sensitivity and specificity for

other comparators were reported and can be found in the study results.

Strengths and limitations

Strengths: different non-invasive imaging techniques were compared, ensuring accurate comparability of the result. All lesions were excised regardless of the clinical diagnosis, which enabled gold standard review by 2 dermatopathologists. The study uses pathology as the comparison of sensitivity and specificity.

Limitations: the study is a non-UK study, which may limit its generalisability to the NHS setting. The study does not define the ethnic diversity included and excluded Fitzpatrick skin type 2 and above. The sample size of melanoma is small (only 32), and 2 out of 3 individuals with melanoma were males. The study lacked statistical comparison between the intervention and comparator.

Winkler et al. (2019)

Study size, design and location

A diagnostic test accuracy study across 130 melanocytic lesions in Germany.

Intervention and comparator

Moleanalyzer pro accuracy in detecting melanoma in skin, both marked and not marked with gentian violet surgical marker.

Key outcomes

In unmarked skin lesions, Moleanalyzer pro achieved a sensitivity of 95.7% (95% CI 79% to 99.2%), specificity of 84.1% (95% CI 76.0% to 89.8%) and ROC AUC of 96.9% (95% CI 93.5% to 100%). In marked skin lesions, Moleanalyzer pro achieved a sensitivity of 100% (95% CI 85.7% to 100%), specificity of 45.8% (95% CI 36.7% to 55.2%) and ROC AUC of 92.2% (95% CI 87.1% to 100%), $p<0.001$, demonstrating that skin markings increased the false-positive rate of Moleanalyzer pro.

Strengths and limitations

Strengths: the study used a large sample size of 130 melanocytic lesions, which gives good power and reduces bias. The study also considered the practical impact of artefacts, in this case a purple marker used when lesions were listed for excision or reviewed by a clinician and image cropping, on the accuracy of Moleanalyzer pro.

Limitations: the study included a highly selected population, as only benign naevi or melanoma were included in this cohort, and as such is not applicable to current clinical practice. As skin markings were electronically duplicated from digital images and superimposed on a melanoma background, this may introduce bias in results. Fitzpatrick skin type and ethnicity, age and gender of included cases were not reported.

Winkler et al. (2020)

Study size, design and location

A diagnostic test accuracy study using 180 images of melanoma in Germany.

Intervention and comparator

Moleanalyzer pro accuracy in different subtypes of melanoma (for example, superficial spreading melanoma [SSM], lentigo maligna melanoma [LMM], nodular melanoma [NM], mucosal melanoma [MM], acrolentiginous melanoma [AMskin] and acral melanoma [AMnail]) compared with recorded ground truth of all melanoma cases (n=180) and benign lesions (n=600) based on histopathological diagnosis.

Key outcomes

Moleanalyzer pro achieved a high-level performance in set SSM, NM and LMM with sensitivity of more than 93.3%, specificity of more than 65% and ROC AUC of more than 92.6%. In set AMskin, sensitivity was lower at 83.0%, with a specificity of 91.0% and ROC AUC of 92.8%, while set-AMnail sensitivity was 53.3%, with a specificity of 68.0% and ROC AUC of 62.1%.

Strengths and limitations

Strengths: the study addresses that there are different subtypes of melanoma, which have

different clinical presentations and differing outcomes, demonstrating that accuracy is affected by subtype. Ground truth for melanoma was histological diagnosis. The study used a large sample of images, which reduces bias.

Limitations: selecting dermoscopic images from local libraries of different institutions (Lyon and Munich) does not guarantee a representative sample of the population and further limits its generalisability to the NHS. A small cohort of melanoma was included in each dataset (n=25) and there was variable gender distribution. The study does not define the ethnic diversity included.

Winkler et al. (2021a)

Study size, design and location

A cross-sectional study in Germany of 130 dermoscopic images.

Intervention and comparator

In this diagnostic test accuracy study, Moleanalyzer pro performance was compared on images with and without a digitally superimposed scale bar.

Key outcomes

In images without a scale bar, Moleanalyzer pro achieved a sensitivity of 87% (95% CI 67.9% to 95.5%), specificity of 87.9% (95% CI 80.3% to 92.8%) and ROC AUC of 95.3% (95% CI 91.4% to 99.2%). In images with a scale bar, no significant change was seen in the sensitivity range (87% to 95%, all p=1.0). However, specificity was reduced by 4 scale bars (range 0% to 43.9%, all p<0.001). ROC AUC was also reduced by 2 scale bars (range 52.0% to 84.8%, both $p \leq 0.042$).

Strengths and limitations

Strengths: the study demonstrates that clinically relevant artefacts impact on accuracy, in this case a digitally superimposed scale bar (scale bars are used when imaging lesions are subsequently listed for excision or reviewed by a clinician). The study used a large sample size, which reduces bias.

Limitations: the image sets used were limited in diagnosis (melanomas and naevi) and

numbers (130 images per set). This may impact its overall generalisability. The image library comes from a single centre and is therefore less applicable to the UK. Fitzpatrick skin type and skin colour are not reported. Benign naevi did not have histological ground truth.

Winkler et al. (2021b)

Study size, design and location

A cross-sectional reader study of 30 adults in Germany.

Intervention and comparator

Moleanalyzer pro compared with images of lesions presented for review to a collective human intelligence (CHI) of 120 dermatologists who were offered a choice of 6 different diagnoses.

Key outcomes

CHI achieved a significantly higher accuracy of 80% (95% CI 62.1% to 90.5%) compared with Moleanalyzer pro at 70% (95% CI 52.1% to 83.3%), p<0.001.

CHI achieved a higher sensitivity of 82.4% (95% CI 59.0% to 93.8%) and specificity of 76.9% (95% CI 49.7% to 91.8%) than Moleanalyzer pro's sensitivity of 70.6% (95% CI 46.9% to 86.7%) and specificity of 69.2% (95% CI 42.4% to 87.3%).

The diagnostic accuracy of CHI was superior to that of individual dermatologists (p<0.001) in multiclass evaluation, while the accuracy of the latter was comparable to multiclass Moleanalyzer pro.

Strengths and limitations

Strengths: the technology is compared with individual or collective dermatologists, which gives a good indication of its accuracy.

Limitations: the study used a relatively small sample size of 30 'difficult to diagnose' lesions, which may reduce its power and introduce bias. The results are applicable to a secondary care population only. Because of the limited test cases, a statistically significant

difference could not be found for a number of assessments. The study does not define the sample's ethnic diversity.

Maier et al. (2015)

Study size, design and location

A prospective single arm study in Germany of 195 lesions in secondary care.

Intervention and comparator

SkinVision application's accuracy in detecting melanoma compared with clinical diagnosis and histological results as gold standard.

Key outcomes

Compared with histological results, the sensitivity of SkinVision was 73% (95% CI 52% to 88%), the specificity was 83% (95% CI 75% to 89%) and the accuracy was 81% (95% CI 74% to 87%). The positive predictive value for recognising melanoma was 49% (95% CI 32% to 65%) and the negative predictive value was 93% (95% CI 87% to 97%).

Strengths and limitations

Strengths: the study used a large sample size of images, which reduces bias.

Limitations: this is a single-centre study based outside of the UK, which could reduce its generalisability to the NHS. The study was limited to pigmented lesions only; this is not applicable to NHS clinical practice as standard practice does not have isolated clinics for pigmented lesions only. The study includes only 3 lesion types (there are actually more than 2,000 skin conditions) and although prospective, this is a selected population and therefore not generalisable to primary care. Also, 26% of lesions were excluded from analysis because of poor images.

As per the company's feedback, the study was done on an older version of the SkinVision service and may not be representative of its current performance.

Thissen et al. (2017)

Study size, design and location

A prospective study of 256 adults (with 341 lesions) in a secondary care setting in the Netherlands. The study was done in a secondary care setting with 1 dermatologist and 1 trainee dermatologist. Images of patients were acquired by the dermatologist.

Intervention and comparator

SkinVision application's sensitivity and specificity in the diagnosis of melanoma and non-melanoma skin cancer along with actinic keratosis and Bowen's disease compared with the histopathology and clinical diagnosis of clearly benign lesions.

Key outcomes

Images of 233 of the 341 lesions were used to train the algorithms, and the remaining 108 lesions were used as test data.

High-risk lesions (n=44): sensitivity was 80% (95% CI 62% to 90%) and positive predictive value was 63% (95% CI 47% to 77%).

Low- to medium-risk lesions (n=64): specificity was 78% (95% CI 66% to 86%) and the negative predictive value was 89% (95% CI 78% to 95%).

Strengths and limitations

Strengths: the study used a large sample size, which reduces bias.

Limitations: the study is not based in the UK and includes premalignant skin lesions, which is not applicable to NHS practice. SkinVision technology is designed as a patient-facing technology, although it can also be used in secondary care. This study does not provide information about its intended use. Although a large sample of 341 images was used, most of these were for training the algorithm and only 108 were used for testing, which might reduce the study power. There was no reference to a power calculation. Additionally, only 4 melanomas were used to train or calibrate the algorithm and only 2 melanomas were used for the test set. This study, therefore, cannot be used to infer any data about diagnostic accuracy for melanoma. Furthermore, the high-risk category included

premalignant skin lesions, which are not considered high risk in the UK and would not be referred on a 2-week wait pathway to secondary care. This further limits generalisability to a UK NHS population. The study does not define skin type or include an ethnically diverse population. The images were acquired by the doctor but the company propose this technology as a patient-facing app, so it is not demonstrating its proposed use in practice. In routine clinical practice in the NHS, GPs and patients frequently take images which are out of focus and therefore would impact sensitivity.

The company reports that the study was done on an older version of the SkinVision service algorithm and may not be representative of its current performance.

Sangers et al. (2022)

Study size, design and location

A prospective cross-sectional multicentre diagnostic accuracy study of 372 adults (with 785 lesions) in a secondary care setting in the Netherlands.

Intervention and comparator

SkinVision application's accuracy in detecting premalignancy and malignancy in skin lesions compared with histopathology and clinical diagnosis of clearly benign lesions.

Key outcomes

Overall sensitivity and specificity for the app were 86.9% (95% CI 82.3% to 90.7%) and 70.4% (95% CI 66.2% to 74.3%), respectively. The subgroup analysis sensitivity was significantly higher for iOS-operated devices compared with Android-operated devices (91% compared with 83%; $p<0.001$). The specificity calculated on benign control lesions was significantly higher than suspicious skin lesions (80.1% compared with 45.5%; $p<0.001$).

Strengths and limitations

Strengths: this was a prospective multicentre study using a large sample size, which reduces bias.

Limitations: its cross-sectional design and the fact it was done outside of the UK might

limit its generalisability to NHS settings. There was a small number of melanoma cases in the dataset. The study does not define the sample's ethnic diversity. Only 4 people with Fitzpatrick skin type 4 were included and there were no people included with types 5 or 6. There were only 6 malignant melanomas and 6 in situ melanomas in this dataset, rendering this data insufficient to reliably report melanoma detection accuracy.

Sustainability

These digital technologies have the potential to reduce carbon emissions from travelling to and from appointments because of the projected number of reduced onward referrals to secondary care. However, none of the 4 companies have provided any information about sustainability and there is no published evidence to support the theory that the technology can reduce footfall or the impact that a reduced footfall would make on the volume of carbon emissions.

Recent and ongoing studies

- A hospital-based study: Testing nomela on suspicious pigmented naevi (moles). ISRCTN registry: ISRCTN99987356. Status: No longer recruiting. Device: nomela. Country: UK. Expected completion date: September 2022.
- A prospective health economic study: Assessing the effectiveness of artificial intelligence (AI) algorithm to Deep Ensemble for Recognition of Malignancy (DERM) in primary care. ANZCTR: ACTRN12619000398101. Status: Ongoing, recruiting. Device: DERM. Country: Australia. Expected completion date: December 2022.
- A prospective cohort study: A clinical validation study to demonstrate the effectiveness of an artificial intelligence algorithm (DERM) to identify skin cancer in patients undergoing a skin biopsy. Clinicaltrials.gov identifier: NCT05126173. Status: Active, not recruiting. Device: DERM. Country: US and Italy. Expected completion date: September 2022.
- A prospective cohort study: Effectiveness of an image analysing algorithm (DERM) to diagnose non-melanoma skin cancers and benign skin lesions compared to gold standard clinical and histological diagnosis. Clinicaltrials.gov identifier: NCT04116983. Status: complete. Device: DERM. Country: UK. Expected completion date: March 2022.

- A prospective cohort study: Clinical performance of the new artificial intelligence powered 3D total body photography system VECTRA in early melanoma detection and its impact on patients' burden of disease. Clinicaltrials.gov identifier: NCT04605822. Status: Ongoing, recruiting. Device: VECTRA (MELVEC). Country: Switzerland. Expected completion date: December 2023.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

One of the 3 experts was familiar with these technologies but none of the experts had used these technologies in clinical practice. None of the experts felt these technologies have been superseded.

Level of innovation

All 3 experts agreed that DERM, SkinVision, Moleanalyzer pro and nomela are innovative technologies. They noted that these technologies are innovative in providing faster, computer-assisted diagnosis. However, 1 expert noted that published evidence does not represent the current NHS clinical pathways for any of the technologies. Another expert highlighted that the technologies would add to the complexity of care in the clinical settings as both GPs and secondary care clinicians would have to be trained and maintain their skills to use them.

Potential patient impact

All 3 experts agreed that the main potential benefit would be faster diagnosis, appropriate triage of conditions and referral for further management. However, 1 expert noted that there have been no published studies assessing the usability of these technologies, which is a notable issue for patient-facing technologies. One expert stated that computer-generated decisions will always be perceived as using more robust data and providing a more accurate diagnosis than a clinician-generated decision. Another expert commented that patient-facing technologies could be beneficial for people who are comfortable using new technologies. They may feel anxious about their moles or have a large number of moles and are able to afford and access technologies which offer the potential for self-

referral. All 3 experts agreed that it is too early to understand the changes these technologies could have on the current clinical pathway and if they would result in improved outcomes as these technologies are not widely used in the NHS. Two experts were concerned that if clinicians became dependant on these technologies for diagnosis, they may in the long run reduce clinician skills and experience of differential diagnosis of potential melanoma. They also noted that lack of inclusion of diverse skin types and access to digital technologies may widen health inequalities in society.

Potential system impact

Two of the 3 experts agreed that these technologies, through improved accuracy of diagnosis, will lead to system benefits by reducing the number of unnecessary visits to secondary care, and unnecessary biopsies, and ultimately increase system throughput. One of the experts was unclear on the potential system benefits of the technologies. The 3 experts stated that there would be a high initial cost associated with these technologies in terms of purchasing, maintenance of software and training of staff. However, 2 of the experts predicted that cost in the long run could be lower compared with standard care if it results in early detection of melanoma and appropriate referral and treatment. One expert highlighted that a clear health economic assessment of these technologies needs to be done to ascertain the claimed benefits as healthcare costs come from diverse sources. Two of the experts noted that the optimal positioning of these technologies in the care pathway is crucial in reducing healthcare costs and that block pricing would be a better model than price per use. One expert highlighted that the current positioning of these technologies varies, so their potential impact and resource consequences will also vary. One expert noted that for the adoption of these technologies, robust clinical governance considerations need to be in place to address issues such as data protection, interoperability of the technologies within the NHS system, diagnostic coding and patient safety needs.

General comments

One expert stated that dermatology knowledge and experience among GPs is lacking and that these technologies could support GPs in making accurate diagnoses. Another expert stated that these technologies should be used in combination with the person's full clinical history to reduce the number of referrals to secondary care. All 3 experts agree that these technologies act as an addition to the current clinical methods for diagnosis of melanoma. One expert did not think NICE guidance for these technologies would be necessary as the

current published guidance already covers the use of a dermatoscope by GPs and in a secondary care setting. Another expert felt there was insufficient evidence to support NICE guidance, and a third expert thought that there would be value in NICE guidance. In terms of factors that could hinder adoption, 1 expert highlighted that a lack of appropriate regulatory approvals that can be obtained with unpublished data could possibly contribute to the lack of confidence in the efficacy and safety of these technologies in real-world settings. Two other experts noted system compatibility issues; in particular, systems that recommend onward referral to secondary care need full electronic referral system compatibility across institutions.

Patient organisation comments

A representative from the patient organisation Melanoma UK gave the following comments on digital technologies for the detection of melanoma.

They reported to have had experience working with 2 of the 4 technologies (SkinVision and Moleanalyzer pro).

The organisation supports using these technologies in multiple places in the pathway, including patient-facing, primary and secondary care settings to support optimum management. The organisation felt that these technologies could change peoples' experiences because they provide opportunities for melanoma skin lesions to be caught early. The organisation highlighted that the technologies could improve patient outcomes through early detection, noting that patient-facing technologies could have the potential to reduce face-to-face follow-up appointments at GP practices. The organisation also noted the potential for a reduction in the number of unnecessary biopsies if used in secondary care. The organisation reported that the technologies may particularly benefit:

- groups of people with white skin
- those who report always or usually burning and who tan minimally or never
- those that tend to have either a weakened immune system or family history of melanoma and could benefit from more regular skin monitoring (such as that available with SkinVision).

From working with SkinVision during the COVID-19 pandemic, positive feedback was received from people, saying it was user friendly and easily available.

The organisation highlighted that these technologies are innovative and acknowledged that, although it is a change to current practice, the pandemic has been a catalyst to technological change and as a result people are now more comfortable with these types of technologies. But the organisation highlighted the importance of clear instructions and training materials, such as videos and manuals, to assist with adoption and implementation of patient-facing technologies. These include accessibility considerations for people whose first language is not English, and people with hearing and eyesight difficulties.

The organisation raised concerns over the limited evidence available for people with black and brown skin and the negative impact this may have on patient care.

Expert commentators

The following clinicians contributed to this briefing:

- Mrs Jenny L C Geh, consultant plastic surgeon, Guy's and St Thomas' Hospital. Did not declare any interests.
- Dr Rubeta Matin, consultant dermatologist, Oxford University Hospital NHS Foundation Trust. Dr Matin is the chair of the Artificial Intelligence Working Party Group at the British Association of Dermatologists.
- Dr Stephanie Gallard, GP with special interest in dermatology, Wirral and South Liverpool. Did not declare any interests.

Representatives from Melanoma UK contributed to this briefing. In 2021, Melanoma UK formed a partnership with SkinVision, which provided monetary donations to Melanoma UK and discounted app access until March 2022.

Development of this briefing

This briefing was developed for NICE by the King's Technology Evaluation Centre (KiTEC). The interim process and methods statement for medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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