HIGHLY CONFIDENTIAL

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Advisory Committee – Wednesday 17 July 2024

Artificial intelligence (AI) technologies for assessing and triaging skin lesions within the urgent suspected skin cancer pathway

The following documents are made available to the Committee:

1. **Presentation slides**

2. **Organisation submission from:**
   Psoriasis and Psoriatic Arthritis Alliance's (PAPAA)

DAP76:
Artificial Intelligence technologies for assessing skin lesions: early value assessment

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17 July 2024

NICE National Institute for Health and Care Excellence

For stakeholders – contains noACIC information

EVA decision making at committee

Based on the available evidence and expert opinion what is the likely impact of using the technology in the NHS on:

- Patients/carers
- System

If multiple technologies are being considered, each should be assessed independently unless specified differently in the scope.

Risks | Benefits

Risk of harm

Some benefits and risks

Does the assessment show sufficient promise to conditionally recommend for use with data collection?

Yes

This outcome is likely for a technology which has

- some acceptance by healthcare professionals & patients
- acceptable risks for use in a data collection context
- acceptable evidence of potential benefit

Conditionally recommend for use while further evidence is generated

Highlight any risks which could be mitigated in evidence generation

Identify key evidence gaps to be addressed by evidence generation

No

Is more research needed to better understand the potential risks and benefits of this technology?

Yes

Recommend only in a research context

Describe key uncertainties for future research

This outcome is likely for a technology which has

- significant uncertainty about how the technology fits into NHS pathways
- significant uncertainty about the risks or benefits of the technology that needs exploration in a research context.

Recommend not used

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Early value assessment considerations

Unmet need and risk of harm?

- Do all the technologies have the potential to address the unmet need?
- Is there any potential risk of harm to patients with any of the technologies?

Suitable for use with data collection?

- Is the evidence of potential benefit sufficient to support use with data collection?
- Are the risks acceptable? Can any of the risks be mitigated?
- Can the technology be integrated into the NHS and is it likely to be acceptable to healthcare professionals and patients?

Suitable for research only?

- Is there significant uncertainty about the potential risks and/or benefits of using the technology?
- Are there concerns about integration of the technology or its acceptance in the NHS?

Possible recommendations

Conditionally recommended for use while further evidence is generated

- Likely that the technology will solve the unmet need and it is acceptable for the technology to be used in practice while further evidence is generated

Recommended only in a research context

- Uncertain if the technology has the potential to solve the unmet need, or it is not acceptable to be widely used in practice while further evidence is generated

Not recommended for use

- Unlikely that a technology has the potential to meet the unmet need, or where there are concerns about the potential harms associated with using the technology even in a research context

Background

Topic background

NICE took the decision to pause development of its guidance on '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: EVA' in January 2024 to allow for further discussions prior to consultation.

Further information has now been received and the EAG has provided commentary on this new information.

These slides have been produced by the NICE team and include:

- Further information and data from NHSE and other stakeholders
- New publications

Capacity in dermatology

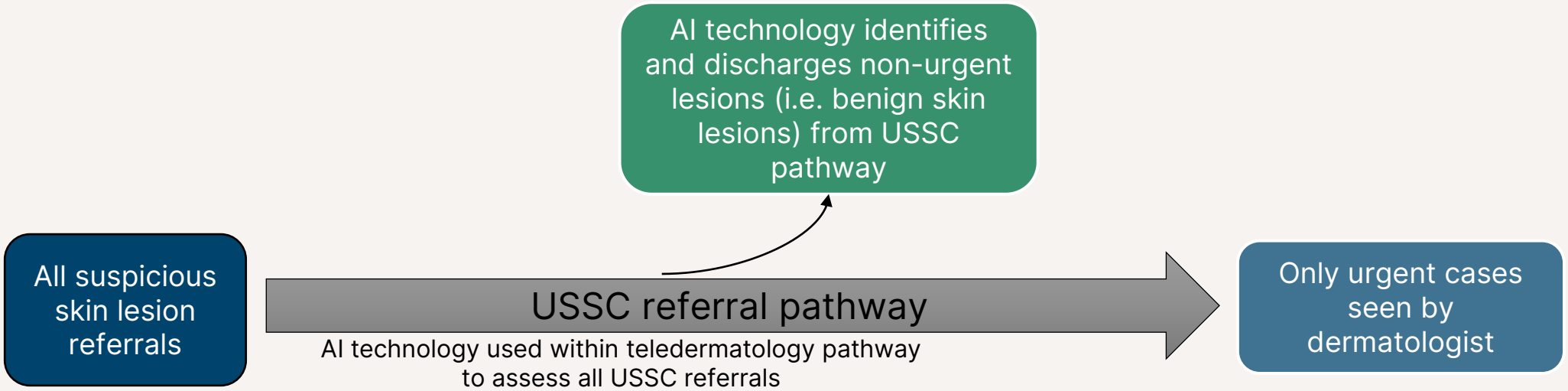
Need for appropriate referrals of skin lesions

- In the UK, dermatology services receive 1.2 million referrals a year. About 60% of these are suspected skin cancer pathway referrals, but only 6% are converted to a confirmed case of skin cancer.
- The high numbers of urgent referrals combined with shortages in the workforce have resulted in a reduced clinical capacity for inflammatory skin conditions that are classified as non-urgent but often need face-to-face assessment. People face long delays to diagnosis and specialist treatment that can impact on health outcomes and quality of life.
- Depending on the local set-up, urgent suspected skin cancer lesions are seen either in a face-to-face dermatology appointment or through teledermatology. NHS England's (NHSE) teledermatology roadmap intends to support local systems to accelerate the roll out of teledermatology to help manage demand and reduce face-to-face appointments.

Technology purpose

Triage of suspicious skin lesions post referral

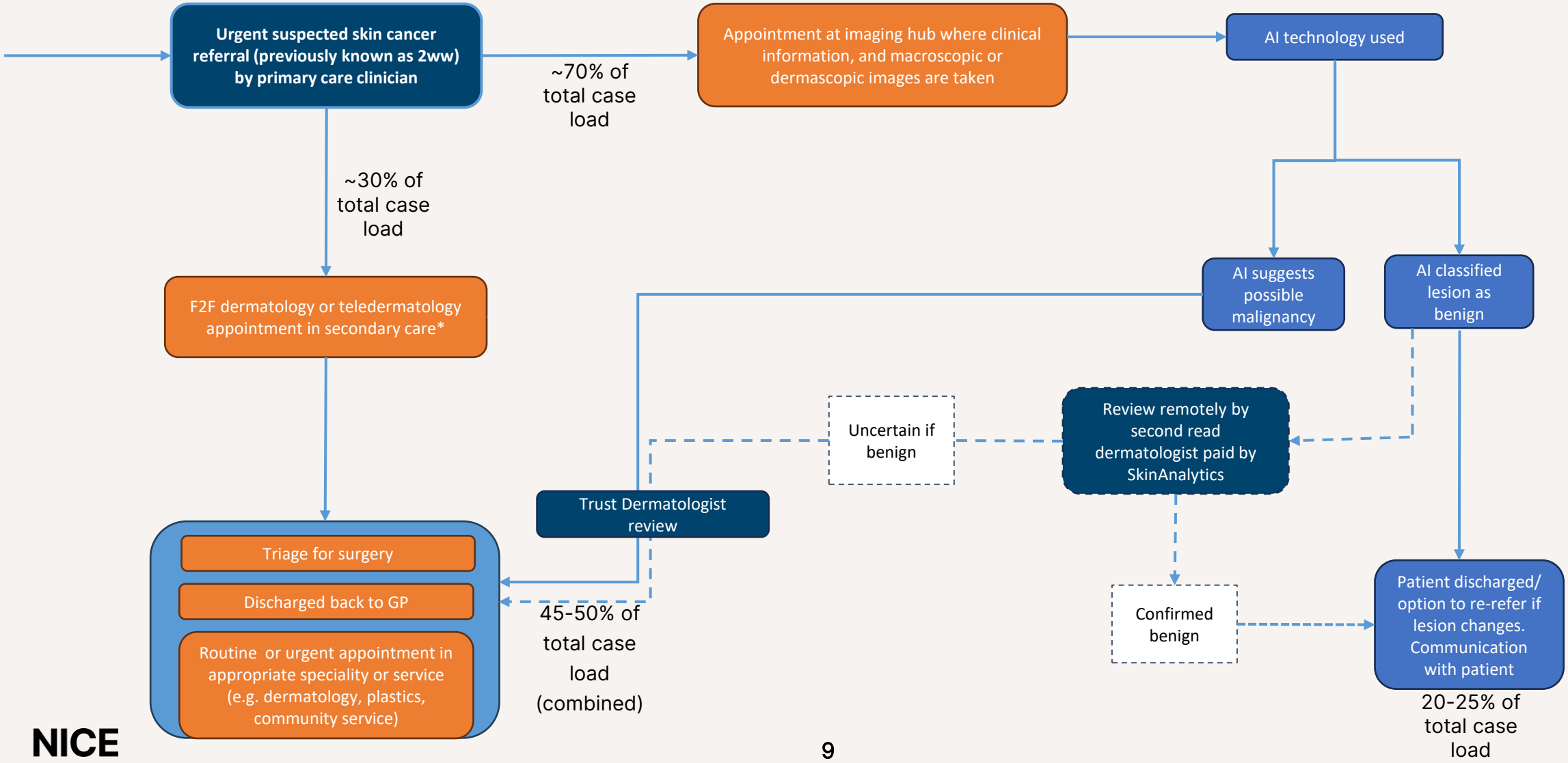
- Purpose of this assessment is to investigate the use of AI technologies for identifying benign lesions that can be discharged from the urgent skin cancer pathway.
- Artificial intelligence (AI) technologies used within the teledermatology pathway could have capacity-releasing benefits to help address the unmet need.



Potential capacity-releasing benefits:

- Fewer non-urgent referrals sent for dermatologist review
- Increasing capacity for clinicians to focus on diagnosing and treating higher risk cases and inflammatory skin conditions

Proposed positioning of AI technologies (with second read)



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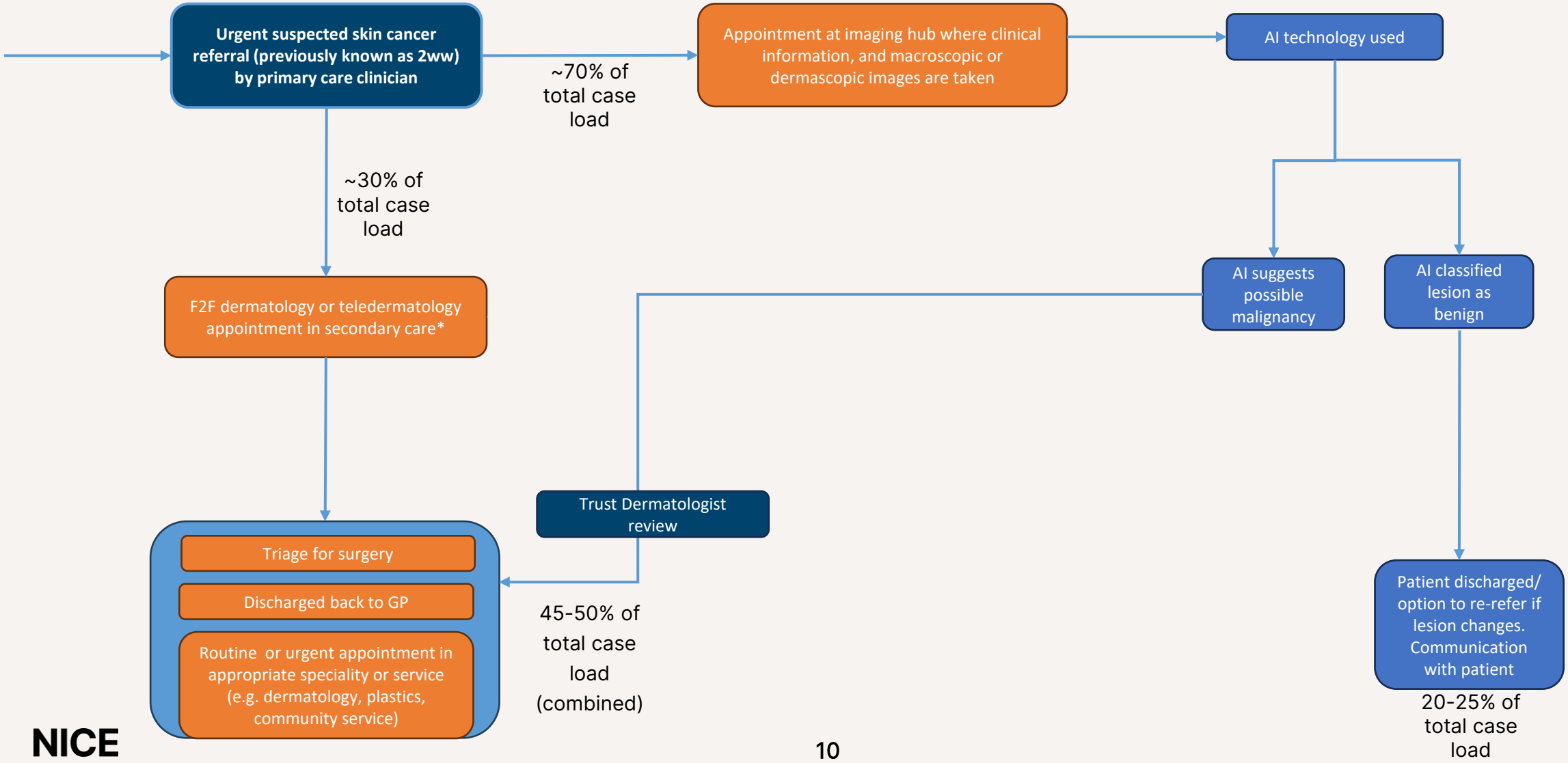
Dotted lines and boxes represent the “second read” element which would not be necessary in an automated AI pathway

Proposed positioning of AI technologies (automated)



Technology under assessment

AI technologies in the NHS

DERM

- DERM has Class IIa UKCA certification for the following intended use cases:
  - Use of DERM by healthcare professionals as a **decision support tool** in the screening, triage and assessment of skin lesions suspicious for skin cancer
  - Use of DERM as an **automated clinical management tool** to screen or triage skin lesions suspicious for skin cancer
- Uses a fixed algorithm

MoleAnalyzer Pro

- MoleAnalyzer pro is intended to be used by a medical professional of skin lesions and aims to help the recognition of melanoma lesions
- A risk score-based approach is used to indicate a statistical estimate of the similarity of the lesion to malignant lesion images.
- MoleAnalyzer pro is a Class IIa CE-marked AI product according to EU MDR

Diagnostic accuracy

Recap: Overview of included studies

DERM

Study	N patients (lesions)	Intervention	Comparator	Setting	Study design
DERM-003 Marsden et al. 2023	N=544 (585)	Automated DERM (with 3 smartphone cameras)	Dermatologists	Hospital (UK) Multi-centre	Prospective cohort
DERM-005 Now published as Marsden et. al 2024	N=617 (782)	Automated DERM	Teledermatology	Hospital (UK) Chelsea & Westminster	Prospective cohort
Thomas et al. 2023	N=NR (8,571)	Automated DERM (version A and version B), then used second read to assess outcomes	-	TD hub (UK) Birmingham & West Suffolk	Prospective cohort
Edge Health report	N=4,403 (5,186)		Dermatologists	TD hub (UK)	Before-and-after study

MoleAnalyzer pro

Study	N patients (lesions)	Comparator	Setting	Study design
MacLellan 2021	N=184 (209)	F2F assessment, teledermatology	Secondary care (Canada)	prospective study design
Winkler 2023	N=188 (228)	F2F assessment	Secondary care (Germany)	

All studies of MoleAnalyzer pro assessed diagnostic accuracy for melanoma only (excluded all non-melanocytic lesions)

Recap: Accuracy of DERM for detecting benign lesions

Study	Index test	Outcome	Sensitivity	Specificity
DERM-003	Automated DERM [redacted] (iPhone 11)	Benign	**43.9%** (95% CI 37.4–50.6)	93.3% (95% CI 90.0–95.6)
	F2F dermatologist assessment	Benign	**73.9%** (95% CI 67.6–79.4)	93.7% (95% CI 90.5-95.9)

Study	Index test	Outcome	Sensitivity	Specificity
DERM-005 Manuscript (Chelsea & Westminster)	Automated DERM [redacted]	Benign	**82.3%** (95% CI 78.8-85.4)	-
	Teledermatologist	Benign	**72.1%** (95% CI 68.1-75.8)	-

Study	Index test	Outcome	Sensitivity	% of overturned cases by second reviewer out of all cases eligible for discharge by DERM	% of skin cancers found by hospital dermatologist among overturned cases
Thomas et al (2023) (Birmingham & West Suffolk Trusts)	Automated DERM-vB (UHB site)	Benign	**73.4%** (95% CI 71.4-75.4%)	39.6%	0%
	Automated DERM-vB (WSFT site)	Benign	**70.1%** (95% CI 65.4–74.4%)	49.2%	0%

Recap: Accuracy of DERM for detecting any malignancy

Diagnostic accuracy data extracted to know technology maintains high sensitivity for malignant lesions and is not misclassifying as benign and consequently missing malignant lesions.

Study	Index test	Outcome	Sensitivity	Specificity
DERM-003	Automated DERM [redacted] (iPhone 11)	Malignant	**96.0%** (95% CI 92.6–98.0)	**45.0%** (95% CI 39.5–50.6)
	Dermatologists	Malignant	**93.8%** (95% CI 90–96.3)	**77.4%** (95% CI 72.4-81.8)

Study	Index test	Outcome	Sensitivity	Specificity
DERM-005 Manuscript (Chelsea & Westminster)	Automated DERM [redacted]	Malignant	**92.5%** (95% CI 82.7-97.2)	**80.4%** (95% CI 77.3-83.2)
	Teledermatologist	Malignant	**97.0%** (95% CI 88.7-99.5)	**72.4%** (95% CI 69.0-75.7)

Study	Index test	Outcome	Sensitivity	Specificity
Thomas et al (2023) (Birmingham & West Suffolk Trusts)	Automated DERM-vB (UHB site)	Malignant	**98.9%** (95% CI 96–99.7)	**64.8%** (95% CI 62.9–66.7)
	Automated DERM-vB (WSFT site)	Malignant	**100.0%** (95% CI 94.7–100)	**60.6%** 95% CI 56.6–64.5)

Recap: EAG's analysis of pooled results

Meta-analysis of DERM diagnostic accuracy from DERM publications				
Studies	**Index test**	**Outcome**	**Sensitivity**	**Specificity**
DERM 003, DERM 005, Thomas et al. 2023	Automated DERM	Any malignant lesion	**97.8%** (95% CI 93.1–99.3)	**63.8%** (95% CI 48.0–77.1)
DERM 003, DERM 005, Thomas et al. 2023	Automated DERM	Melanoma	**98.4%** (95% CI 92.5–99.7)	**81.1%** (95% CI 74.8–86.1)
DERM 003 & 005	Dermatologists	Any malignant lesion	**90.6%** (95% CI 78.7–96.1)	**85.7%** (95% CI 66.7–94.7)

These data overlap with data from publications, but appear more up-to-date/detailed

Pooled data of DERM diagnostic accuracy from unpublished data				
Sites	**Index test**	**Outcome**	**Sensitivity**	**Specificity**
UHB and C&W study centres	Automated DERM	Any malignant lesion	**96.1%** (95% CI 95.4–96.8)	**65.4%** (95% CI 64.7–66.1)
	Automated DERM	Benign	**71.5%** (95% CI 70.7–72.3)	**86.2%** (95% CI 85.4–87.0)
	DERM with second read	-	Diagnostic accuracy could not be assessed	

Cochrane review comparison				
Study	**Index test**	**Detection of**	**Sensitivity**	**Specificity**
Chuchu et al. 2018	Teledermatology	Any malignant lesion	**94.9%**	**84.3%**

New data: DERM-005 published March 2024

DERM had a significantly higher rate of identifying pre-malignant and benign lesions that did not need biopsy or urgent referral compared to teledermatology (p-value<0.0246), with comparable sensitivity to detect malignant lesions.

Sensitivity for detecting pre-malignant or benign lesions (phase 2)			
Study	**Test**	**# of lesions**	**Sensitivity % (95% CI)**
DERM-005 (Chelsea & Westminster)	DERM version A	590	85.1% (81.8–87.9%)
	DERM version B	590	81.6% (78.8–84.7%)
	Teledermatologist	590	71.3% (67.3–75.1%)

Accuracy for detecting malignant lesions					
Test	**Sensitivity (95% CI)**	**Specificity (95% CI)**	**PPV**	**NPV**	**NNR**
DERM	91.0 (80.9-96.3)	83.2 (80.3-85.9)	33.5 (26.8-40.9)	99.0 (97.7-99.6)	4.5 (3.6-5.8)
DERM – real world setting	94.0 (84.7-98.1)	73.3 (69.9-76.4)	24.6 (19.6-30.4)	99.2 (98.0-99.8)	5.2 (4.1-6.6)
Teledermatologist	97.0 (88.7-99.5)	71.9 (68.4-75.1)	24.2 (19.3-29.9)	99.6 (98.5-99.9)	8.6 (6.2-12.3)

All Fitzpatrick skin types represented: (25/622 (4.0%)) type IV-VI skin.

NNR: Number needed to refer to confirm a diagnosis of intraepidermal carcinoma (Bowen's disease) or actinic keratosis.

New data: Company data on DERM (1)

Data on DERM from 20 April 2020 to 3 November 2023	# sites	# cases	# lesions	# lesions with final diagnosis
Post Deployment Real World Evidence (RWE)	17	72,390	85,955	
> Secondary Care	12	61,974	71,552	49,638
>> Not assessed by DERM		15,616	18,510	11,207
>> Assessed by DERM		46,358	53,042	38,431
>>> v3.0.1+ with final outcomes	9	33,809	38,788	**27,747**

Cochrane Teledermatology meta-analysis	22		5,506	

~25% of cases not assessed by DERM but went on to have teledermatologist review

- Exclusion criteria for DERM
- Technical/network issues
- Failed image quality check

Data incomplete when:

a) Outcome data not yet received from partner site
b) Patients undergo F2F assessment but not a biopsy (unlikely to include skin cancer)

New data: Company data on DERM (2)

Data on DERM from 20 April 2020 to 3 November 2023	DERM discharge		DERM Urgent	
	Cases	Lesions	Cases	Lesions
Assessed by DERM v3.0.1+, with final diagnosis	**11,372**	**12,856**	**13,166**	**14,891**
Melanoma	33	33	624	631
Malignant 'other'	5	5	36	38
SCC	16	16	947	960
BCC	47	46	1,892	1,979
Bowen's disease (IEC)	83	85	1,089	1,172
Actinic Keratosis	441	453	2,581	2,943
Atypical Naevus	637	679	950	1,039
Refer 'other'	21	21	53	54
Benign	10,089	11,518	4,994	6,075

NPV

- MM, MO & SCC = 99.5%
- Including BCC = 99.1%

Sensitivity

- MM = 95%
- SCC = 98%
- BCC = 98%
- All Cancer = 97%

NICE

NPV: discharges correctly ruling out cancer

New data: Data on darker skin tones (1)

- 1,474 lesions from skin types V-VI were assessed by DERM. No malignancies were missed in this group; DERM correctly identified specific malignancies in all 26 instances.
- Acral lesions on palms of hands and soles of feet, more common sites for cancers in patients with darker skin tones, are not suitable for DERM assessment and are therefore routed to dermatologist assessment.
- **EAG:** This suggests that the diagnostic accuracy of DERM should be maintained in people with darker skin tones. As numbers remain small, continued monitoring of people with darker skin tones may be of value.

Number of lesions assessed by DERM, with confirmed diagnoses, in secondary care, by Fitzpatrick skin type from 20 April 2020 to 26 January 2024			
Fitzpatrick skin type	I-IV	V	VI
# lesions through services	56,496	2,054	411
# assessed by DERM	44,761	1,276	198
# with ground truth diagnosis	32,237	899	127
# melanoma/SCC/BCC (caught by DERM)	4,921 (4,783)	24 (24)	2 (2)
# melanoma (caught by DERM)	865 (825)	3 (3)	0
# SCC (caught by DERM)	1,283 (1,261)	2 (2)	1 (1)
# BCC (caught by DERM)	2,773 (2,697)	19 (19)	1 (1)

New data: Data on darker skin tones (2)

AI in Health and Care: Skin Analytics evaluation report (published 18 June 2024)

The report shows the distribution of Fitzpatrick skin type in 3,494 cases (4,023 lesions) assessed by DERM at 4 evaluation sites (CW, UHBW, ASPH, UHB).

All confirmed cancers were correctly classified in the groups representing skin types 5 to 6.

Whilst there remains a low number of cases with types 5 to 6 in the evaluation dataset (only 145 cases and 157 lesions), there was no indication of performance of DERM varying with respect to skin type.

Fitzpatrick skin type	# of lesions (%) (total = 4,023 lesions)
Missing Fitzpatrick skin type	26 (0.6%)
Type 1 to 3	3,410 (84.6%)
Type 4	456 (11.3%)
Type 5 to 6	**157 (4.2%)**

CW: Chelsea & Westminster NHS Foundation Trust

UHBW: University Hospitals Bristol and Weston Foundation Trust

ASPH: Ashford and St Peter's Foundation Trust

UHB: Birmingham University Foundation Trust

Question for committee:

Does DERM have the potential to accurately rule-out skin cancer without missing more malignant lesions than current standard of care?

What are the key data gaps in the accuracy data?

Patient and clinician considerations

NICE National Institute for Health and Care Excellence

Recap: Acceptability to healthcare professionals and patients

Edge Health report - survey of staff responses (n=6)

- Considered second read requirement to be important for full service (vast majority agreed with need for second read dermatologist reviewing benign lesions)
- Mixed responses on their confidence of AI reliably differentiating between benign and malignant lesion
- Clinicians and Hub staff expressed lack of confidence in different steps of the pathway such as capturing of high-quality images, skills of the Skin Analytics dermatologists responsible for the ‘second read’ of AI decisions
- Mixed responses pertaining to perceived benefits of time saving for clinicians and reducing backlog

Edge Health report - survey of patient perception (n=115):

- Patients had a positive response with AI being used to help doctors as a decision aid tool, but were more cautious when considering the use of AI to replace dermatologists.
- Mixed responses on preference for hub service than wait for F2F

DERM-005 - patient survey responses:

- Participants generally responded positively when considering AI as a tool to help doctors, but more cautiously when considering the use of AI to replace a dermatologist
- most would rather have their lesion assessed by a computer than waiting weeks to see an in-person dermatologist
- patients generally indicated they felt comfortable with the use of AI and the dermoscopic images required, but there was a mixed response to a statement on preference for a face-to-face dermatologist appointment.

The use of Moleanalyzer pro was generally supported by both clinicians and patients, and its results were trusted, however, most patients indicated that they would like the opinion of an expert physician besides an AI-assisted diagnosis.

AI in health care award report (Unity Insights and University of Surrey): Patient surveys

AI in Health and Care: Skin Analytics evaluation report (published 18 June 2024)

- **Broad acceptance of DERM**
  - 67% acknowledged value of AI to speed up getting an appointment rather than waiting to be seen by a doctor
  - 85% rated AI-enabled teledermatology services as good or very good
- **Patients did express concerns over using AI as a diagnostic tool**
  - 17.6% were “not confident”
  - 13.1% were “uncomfortable” about the AI being used to help in their diagnosis
- **Some preferred a F2F assessment with a dermatologist**

New submission: Non-cancer skin conditions

Psoriasis and Psoriatic Arthritis Alliance (PAPAA) submitted a response to a series of questions. Key takeaways are noted:

- Given the chronic nature of psoriasis and its ability to flare quickly, which can make self-care difficult, immediate and urgent access to care, appropriate referral is essential to reduce the impact.
- At its worst, it has huge psychological impact and can impede daily life, take time away from employment and education, and also affects other family members.
- Patients typically face reluctance for primary care to refer, coupled with delay in diagnosis, leads to an initial delay to specialist care. When referred, patients report they are not seen within the 18-week appointment window. Some report more than 30 weeks. With the addition of primary care delays people have expressed delays of 50+ weeks.
- Delayed diagnosis and care may require greater intervention which creates fear of not being able to return to work or retaining work.

Question for committee:

Is there some acceptance of DERM by healthcare professionals and patients?

Are there any data gaps in terms of professional and patient opinions on AI technologies and their impact?

Resource impact

Recap: Resource impact of using automated DERM

EAG's analysis from unpublished data

DERM

The EAG's analysis from unpublished data estimated that automated use of DERM could approximately halve (47.7%) all referrals (urgent and routine combined) to a dermatologist (of lesions that can be assessed by DERM).

However, a small number (0.9%) would be both malignant and incorrectly discharged (false negatives).

- Most of these incorrect discharges would be BCC cases and only 0.2% would be melanoma or SCCs.

Most referrals would be false positives, with around 64% of all referrals being benign.

- Among urgent referrals, the substantial majority (~85%) would be false positives.
- Routine referrals would be uncommon (~9%).

Estimated AI-teledermatology pathway service could potentially reduce time burden on dermatologists by 22% compared to F2F assessment.

Edge Health report

An evaluation of AI Powered Tele Dermatology for Skin Cancer 2WW Pathway (published October 2023)

1. DERM used in the teledermatology pathway led to a reduction in USSC referrals, freeing up 1450 appointments, which were made available to non-cancer patients
2. DERM-TD required 3.2 mins/lesion, compared to 15mins/lesions with F2F dermatologist assessment. Overall clinical time saving of 263 mins/100 patients
3. Increase in time patients spend on the AI-teledermatology pathway (21 day wait for potential melanoma and 25 day wait for potential non-melanoma) compared to standard of care (13 day wait)
    - Linked to administrative delays in appointment scheduling, and not an issue with the technology
4. Insignificant cost savings (benefit cost-ratio 1.05) observed with DERM second read
    - However benefits including a reduction in biopsies, a reduction in longer-term care costs, and a reduction in WLI clinics, could not be quantified in this calculation
    - In scenario modelling, removing or reducing second read delivered improved cost savings (BCR 1.88)
5. 29% of lesions flagged as benign were overturned by second read and sent for Trust dermatologist review, however 76% of the overturned lesions were confirmed as benign by Trust dermatologists.
6. Histology-confirmed sensitivity of DERM was 95% for melanoma and 98% for non-melanomas.
7. 22.4% of all cases were not eligible for the AI-teledermatology pathway

AI in health care award report (Unity Insights and University of Surrey): Resource impacts

AI in Health and Care: Skin Analytics evaluation report (published 18 June 2024)

Reduction in unnecessary referrals: Of the 4,639 cases assessed by DERM, 45.5% of cases were recommended for discharge. However 35.7% of DERM recommended discharges were overturned by after second read, of which 40.7% are subsequently discharged by Trust dermatologists review.

Conversion rates: Increased to an average of 12.6% following DERM assessment, compared to the overall conversion rate of 8.2% observed from GP referrals.

This has positive effects in releasing dermatologist time compared to teledermatology; a prudent estimate brought out from the cost-benefit analysis is that DERM saves between 9 and 17% more consultant time than traditional teledermatology (based on the value of virtual review time and appointments saved).

During interviews, dermatologists across three of the four sites individually estimated that DERM reduced unnecessary referrals by 20%. Further interview estimates suggest the DERM platform reduced virtual review time from seven minutes per case to one minute per case; this was due to ease of use of the DERM platform compared to existing software. Clinicians felt this provided more review time to spend on patients with complex conditions who require specialist attention.

Conversion rate: The proportion of referrals which result in a confirmed cancer diagnosis.

Questions for committee:

Does DERM have the potential to increase dermatologist capacity (e.g. freeing-up appointments and reducing waiting lists)?

Could any increased capacity have an impact on health outcomes and quality of life for people with skin cancer and/or for people with non-cancer skin conditions?

What are the key data gaps in the resource impact data?

Cost considerations

NICE National Institute for Health and Care Excellence

Recap: Company cost-utility model results (1)

Company model finds that automated DERM generates cost savings

	DERM without second read	DERM with second read	Teledermatology	Comments
Eligibility for assessment	81%	81%	90%	• DERM has higher cost than teledermatology. • Fewer lesions are eligible for DERM than for teledermatology.
First line assessment cost per patient (avg.)	£72	£72	£57	
Specificity	42%	Lower than DERM without second read	35% (Cochrane review reported 84.3%)	• Assumed specificity of teledermatology appears low compared with published sources
Effective discharge rate	36.9%	15.7%	30.9%	• Higher discharge rates lead to fewer F2F appointments and biopsies. • Second read dermatologists appear very cautious and overturn many lesions marked as benign by DERM. These would have otherwise been discharged by DERM without second read.
Total avg. cost of pathway	£118	£172	£146	• The higher discharge rate for DERM without a second read offsets first line assessment costs, which generates cost savings compared with teledermatology. • DERM with a second read is the costliest approach.

Recap: Company cost-utility model results (2)

Company model finds that DERM dominates teledermatology and usual care

			Incremental (vs usual care)		Incremental (vs teledermatology)		
Strategy	Cost (£)	QALY	Cost (£)	QALY	Cost (£)	QALY	ICER
DERM + second read	£466	11.1925	-£31	+0.0077	-£6	+0.0039	£24,655
DERM (automated)	£445	11.1917	-£52	+0.0069	-£27	+0.0031	-
Teledermatology	£472	11.1886	-£25	+0.0038	-	-	Strictly dominated
Usual care	£497	11.1848				N/A	Strictly dominated

EAG: It remains highly uncertain whether currently available diagnostic accuracy evidence is sufficient to reliably populate a cost-utility model, particularly with regards to the specificity of AI technologies compared with the specificity of an effectively implemented teledermatology service.

EAG: Whilst this analysis predicted that DERM with or without a second read would dominate all other options, this was highly dependent on the relative specificity of teledermatology. If the Cochrane diagnostic accuracy values are applied for teledermatology, DERM strategies become more costly than teledermatology. Teledermatology also becomes cost saving versus the traditional pathway.

Questions for committee:

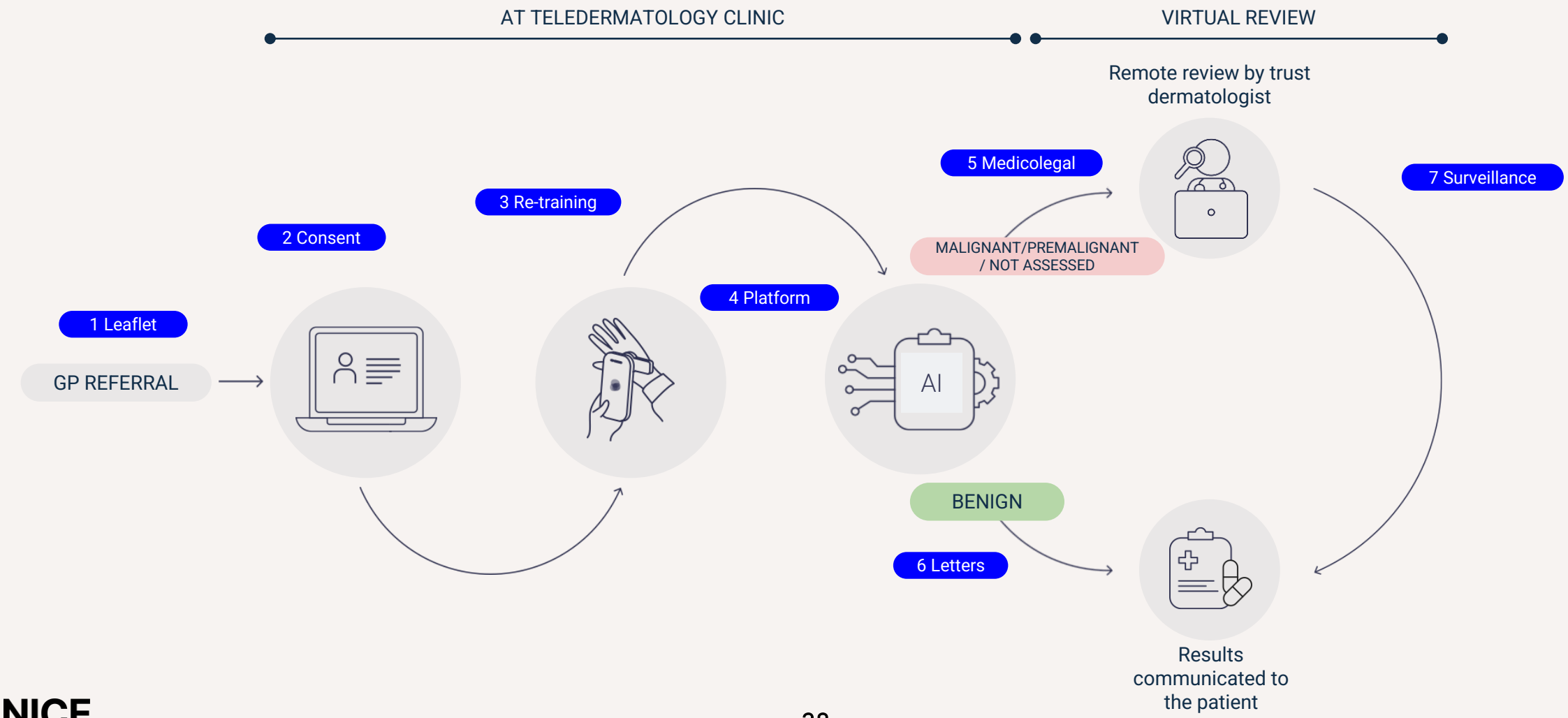
Does DERM have the potential to be a cost-effective use of NHS resources?

What are they key data gaps in the cost analysis data?

Information on automated use

NICE National Institute for Health and Care Excellence

Risk mitigation with automated use



Blue highlights opportunities for risk mitigation

Risk mitigation with automated use

Safety netting

Safety Netting Statement for DERM output of 'Probably Benign':

- Discharge patient, recommend self-monitoring and further GP review if there are any changes or they remain concerned. If you are concerned despite this result, consider referral

Discharge letters would include the wording:

- Although your skin lesion was diagnosed as benign (harmless) it is not certain. It is always worth continuing to monitor your skin. You can find out more about how to keep an eye on your skin and reduce your future risk of skin cancer by reading the information on the following links:

  www.nhs.uk/conditions/moles; www.skinhealthinfo.org.uk/sun-awareness/the-sunscreen-fact-sheet/

Chelsea & Westminster additional steps

- SMS messages to be sent to all patients discharged from AI, Teledermatology, and F2F pathways at 6 and 12 months and called if no response. Asked about further treatment received, any concerns and planned action, and provided with patient education

NHSE

- Proposal that all patients with darker skin tones who are recommended locally for the AI pathway are also scheduled in parallel for face-to-face or traditional teledermatology assessments.

Risk mitigation with automated use

Surveillance by Skin Analytics

- Screening for repeat attenders (already monitored)
- Image quality audit for non-approved hardware
- Regular audits of appropriate application of exclusion criteria
- Users aware of the MHRA Yellow Card Scheme
- Existing complaints, incidents and corrective and preventative action procedures, including trend analysis
- Proactive monitoring of % of lesions labelled as MM/SCC
- A defined % of cases will be routed to trusts and second read to monitor NPV and sensitivity
- False negative root cause analysis includes consideration of whether reinstatement of Second Read is required

Question for committee:

Would the processes described help to mitigate any of the potential risks associated with the use of DERM?

Summary

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Equality considerations

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

- The evidence base included few patients with non-white ethnicity or darker skin tones. Since skin cancer may be harder to detect in these people this is of concern. Data suggests that the diagnostic accuracy of DERM should be maintained in people with darker skin tones. Continued monitoring of people with darker skin tones may be of value
- DERM could not be used for a substantial number of patients, due to lesions being too large to assess; lesions being in areas with tattoos, scarring or hair covering; or lesions being on parts of the body unsuited to assessment with a dermatoscope. This could result in differences in diagnostic pathways and access to diagnostic services for some people.
- Use of AI could improve access to skin cancer diagnosis as it may reduce the need for face-to-face appointments, so reducing patient time commitment and need to travel to appointments.
- Use of AI could free-up capacity for non-cancer skin conditions

What are the potential risks and benefits of introducing AI alongside data collection?

Potential benefits	Potential risks
Automated use of DERM appears to have a high sensitivity for detection of malignant lesions.	A small number of malignant lesions would be missed by DERM (<1%). Most of these would be BCCs.
DERM has a high negative predictive value (99%), so could rule out malignant lesions.	There is less data on the use of DERM in people with darker skin tones because of the lower prevalence of skin cancer in these groups.
DERM appears to reduce the number of GP referred lesions by half that need further assessment.	Potential increases in time to diagnosis possibly due to administrative delays in scheduling community hub appointments for photos to be taken.
DERM may reduce demand on services, freeing-up appointments for specialist consultations for non-cancer dermatology condition and potentially leading to improvements in quality of care and outcomes.	Additional costs associated with establishing new medical photography infrastructure if a teledermatology pathway is not currently in place.
Reasonably high certainty that DERM has the potential to be cost-effective in the post-referral setting, compared with the traditional urgent skin cancer referral pathway.	DERM with a second read is less likely to generate cost-savings.

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Thank you

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Please find below the Psoriasis and Psoriatic Arthritis Alliance's response to the questions asked in relation to the topic:

Assessing the impact of delayed dermatological care for patients with non-cancer conditions

	Questions:	Response:
1.	**What are the most common non-cancer skin conditions your members seek support for?**	As an organisation that supports and represents people with psoriasis, this is the most likely condition they would seek support. With 1.2 million people (1-50) affected in the UK, this is a significant number of individuals. Given the chronic nature of psoriasis and its ability to flare quickly, which can make self-care difficult, immediate and urgent access to care, appropriate referral is essential to reduce the impact.
2.	**Please describe the impact that non-cancer skin conditions have on the people experiencing them and their families.**	With psoriasis at its worst, the impact on those affected and their families is extensive. A visible skin condition that is very flaky in appearance, often red and bleeding, because of constant itching, can cause huge psychological impact and can impede many activities, not least employment and education. Recreational activities, sport, swimming in particular, where exposed skin with widespread lesions can be very traumatic and often avoided. This can affect other family members as it restricts what people do and act. There is also a revulsion from others who do not understand that the condition is not contagious and will direct a prejudice towards them. Treatments also cause issues, particularly the messy topical applications.
3.	**What are the typical waiting times to see a dermatologist reported by patients? Have patients reported any improvements or deteriorations in waiting times over the past few years?**	Those we speak to relate two issues in relation to waiting times. Firstly, a reluctance for primary care to refer, this coupled with delay in diagnosis due to lack of awareness of psoriasis, leads to an initial delay to specialist care. When a decision to refer is made, our members report that they are not being seen within the 18 week appointment window. We've had reports of more than 30-weeks for scheduled appointments, add that to the primary care delay, people have expressed delays of 50+ weeks.
4.	**Have there been instances where delayed diagnosis and treatment has led to worsening of**	I think with a condition such as psoriasis, where a flare can cause a widespread eruption of flaky skin plaques, it's inevitable that a delay in referral will restrict access to more effective secondary care

	conditions or additional complications?	only therapies, although psoriasis patients are not generally admitted as inpatients, it is a feasible possibility that a delay in referral could lead to the need for more intensive care. This in turn could increase the time an individual is away from employment and education, which will have an impact.
5.	**Please describe the psychological or emotional impact of delayed dermatology appointments on people with non-cancer skin conditions and their families.**	Any delay in diagnosis and subsequent treatment of psoriasis, will have a wide-spread psychological effect. The uncertainty of diagnosis carries fear, delayed access to care, will have a profound effect and fear of psoriasis spreading and leading to worse disease which may require greater intervention. This knocks on to peoples' fears around being able to work or retaining work, if they are uncertain about when they are well-enough to return. The latter will of course impact on other family members too, waiting for care and appointments, puts people on 'hold', therefore delaying any ability to plan, such as trips, holidays and family activities.
6.	**Please describe the impact of delayed dermatology care on patients' daily activities, quality of life, and/or any financial impact.**	As described in answers to other questions, there is no doubt that for those with psoriasis, any delay in diagnosis and treatment will potentially affect daily activities, widespread psoriasis at its worst is a constant struggle. The scaly flaky skin needs constant care when flaring, disruptive sleep, fatigue associated to the inflammatory process. Extra costs of laundry and personal care and loss of earnings, are key points that delay can cause.
7.	**Do patients from certain demographics, regions or different NHS trusts experience longer wait times or delays?**	There are variabilities in waiting times across NHS trusts, but as a charity we tend to hear the worst case scenarios, so it would be disingenuous to apply the experiences of those who contact us to the whole NHS dermatology care service, but in our experience, it is widespread, and more than just a few isolated incidences. I'm sure there are many 'silent voices' who will just 'put up' with delays and be resigned to the fact that the NHS is unable to cope with demand.

Responses collated and created by David Chandler. Chief Executive. 28 June 2024.