



Abstract N°: 95

Multi-centre prospective clinical performance analysis of an Artificial Intelligence as a Medical Device deployed within UK NHS urgent suspected skin cancer pathways

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Introduction & Objectives:

Over 25% of patients with suspected skin cancer in England waited over four weeks from urgent referral to diagnosis in October 2023 [1]. Implementation of AI can augment this pathway to improve timely diagnosis.

Materials & Methods:

A prospective, post-deployment, multi-centre clinical performance review of AIaMD - a UKCA Class IIa-approved, AI-based, skin lesion analysis medical device - was performed. AIaMD is intended for use in the screening, triage and assessment of skin lesions suspicious for skin cancer, and is currently deployed as a decision support tool at 11 NHS sites. Patients assessed by the three most recent versions of AIaMD from April 2022 to November 2023 were eligible for inclusion. Outcomes were confirmed from histology reports for cancerous lesions and histology reports or Consultant teledermatology assessment for non-cancerous lesions.

Results:

AIaMD assessed 29,453 lesions with outcomes confirmed, including 686 melanoma, 1,014 SCCs, 2,123 BCCs and 1,200 pre-malignant lesions. AIaMD referral sensitivity for histologically-confirmed melanoma, malignancy and pre-malignancy was 95.2% (653/686), 97.1% (3754/3866) and 96.4% (1,135/1,200) respectively. Across all benign lesions confirmed by teledermatology Consultant review or histopathology, AIaMD specificity was 71.2% (13,409/18,824) and for those confirmed by biopsy it was 28.5% (993/3481). The negative predictive value - how often AIaMD labelled cases as eligible for discharge and correctly ruled out cancer - was 99% or 100% in all 11 sites. Across 7 Secondary Care sites, the conversion rate of referrals to skin cancer diagnosis of the AIaMD pathway was 31-73% greater than the Primary Care referrals that had come in. One site reported reduced average wait time to first appointment by 11 days, 10% reduction in biopsies and 13% reduction in routine follow-up appointments.

Conclusion:

This post-market service evaluation reported the clinical outcomes of AIaMD - an AI device used for assessment of skin lesions. The pathway was sensitive, identifying 3,754 out of 3,866 skin cancers, and specific, correctly identifying seven out of every ten benign lesions assessed and confirmed clinically or histologically. Moreover, AIaMD implementation was linked to a number of pathway benefits. The integration of AIaMD into skin cancer diagnostic pathways could significantly improve the accuracy of urgent suspected skin cancer referrals, removing unnecessary specialist review of benign lesions.

[1] Statistics | Cancer Waiting Times. NHS; [cited 2023Dec29]. Available from:

<https://www.england.nhs.uk/statistics/statistical-work-areas/cancer-waiting-times/monthly-data-and-summaries/2023-24-monthly-cancer-waiting-times-statistics/cancer-waiting-times-for-october-2023-24-provisional/>

Declarations: Authors are employed by or contractors with the AI provider

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