BRITISH ASSOCIATION OF DERMATOLOGISTS
HEALTHY SKIN FOR ALL

# British Association of Dermatologists Position Statement on Artificial Intelligence (AI) Interventions

Artificial Intelligence (AI) collectively describes computer algorithms that perform tasks which normally require human intelligence. There is immense potential to improve the diagnosis and precision management of skin diseases through AI interventions (any health intervention which relies upon AI to serve its purpose). The BAD welcomes adoption of appropriately regulated and governed uses of AI interventions to enhance safe clinical practice and improve patient outcomes. We believe that AI has the potential to improve clinical care, optimise processes and allow greater use of clinical data to inform research, best practice and outcomes. AI technologies should be developed in areas which clearly address an unmet clinical need; by improving disease management and quality of care and by enhancing patient experience without compromising safety.

The BAD aims to support dermatology departments to ensure that safe, ethical, and effective AI interventions are adopted through a robust regulatory framework.

## The evidence base for AI in dermatology

AI is a rapidly advancing field, and the COVID-19 pandemic has accelerated the commercial drive to adopt digital technologies and integrate AI algorithms into clinical practice. However, currently the evidence base for effectiveness of AI interventions in dermatology is limited[1,2,3,4] due to studies being undertaken in artificial conditions which do not adequately reflect real-life clinical settings. Several AI interventions in dermatology focus on differentiating between benign and malignant skin lesions with a particular emphasis on melanoma diagnosis[5]. Other potential applications exist, including monitoring of inflammatory skin disorders e.g., psoriasis, atopic dermatitis, acne vulgaris, leg ulcer assessment, and nail disease[5] but are earlier in their phase of development. The accuracy of AI algorithms intended to support skin cancer diagnoses may be overestimated where studies are conducted in settings which do not reflect clinical practice. For example, a study using a retrospective image database without supplementary clinical information, excluding atypical presentations (e.g., body sites such as palms/soles), using highly selected patient groups (e.g., excluding skin of colour), or limiting study cases to those already selected for excision introduces significant bias, risks missing serious but rare diagnoses which can lead to patient harm and is unlikely to provide strong evidence for widespread use[2].

Furthermore, some producers of skin smartphone apps claim that they can classify (diagnose), monitor and treat a range of skin disorders. Many of these are not designed with the correct intended use in mind or developed properly due to the lack of availability of clinical images representing the full breadth and depth of skin disorders on which these algorithms are developed. This leads to many apps focusing on diagnosis of a limited number of skin cancers and neglecting potentially more serious and rare diseases. Additionally, it is not always clear that these apps have been appropriately investigated in the clinical study setting in which the app will be deployed. A systematic review of algorithm-based smartphone apps used for skin cancer diagnosis identified serious flaws[6] which can lead to overestimating accuracy [7]. Moreover, evaluation of diagnostics is not confined to accuracy and the full scope of harms and benefits from implementing a new technology must also be assessed[8].

The cost-effectiveness of AI apps (like all medical devices) should be considered before adoption in the NHS. This generally requires a cost-effectiveness or cost-minimisation analysis. This analysis should compare the AI intervention to the current standard of care and measure any additional costs and benefits associated with the AI intervention. The NHS runs on a constrained budget and any new spending on medical devices

needs to be considered good value for money before adoption. We encourage product developers to use NICE Advice services to help determine the type of evidence required to demonstrate the value of their product to the NHS. The service operates on a cost-recovery basis and so there are fees associated.

A NICE Early Value Assessment (EVA) looking at evidence for artificial intelligence (AI) technologies for assessing and triaging skin lesions referred via the urgent suspected skin cancer pathway was published on 1 May 2025[9]. NICE has recommended that Deep Ensemble for Recognition of Malignancy (DERM) may be conditionally used within NHS teledermatology services for a defined 3-year evidence generation period. An evidence generation plan has been developed to identify current evidence gaps and outline the real-world data that must be collected. These data will support a follow-up NICE evaluation in which will determine whether the technology should be routinely adopted across the NHS.

We believe it is essential for AI app developers to develop algorithms within a tightly integrated ecosystem bringing together computer scientists, clinicians and patient organisations and to be aware of the relevant regulatory[10,12] and ethics[11] governance frameworks for the usage of their products. These principal areas are summarised under the following headings

## Regulation of medical devices that apply to AI interventions

The Medicines & Healthcare products Regulatory Agency (MHRA) classes the following types of software as medical devices[12]:

- software (including artificial intelligence) and apps (either incorporated into an existing device or supplied separately) that are used for contributing to diagnostic processes;
- software and apps for helping patients to manage their health conditions;
- software and apps for monitoring patients (including remotely);
- software and apps to support clinical decision making.

Since January 2021, all medical devices placed on the UK market must bear one of the following conformity markings: CE (Conformité Européene), UKCA (UK Conformity Assessed), or UKNI (UK Northern Ireland). While the UKCA marking was introduced for Great Britain (England, Scotland, and Wales) in January 2021, the CE marking continues to be recognised in Great Britain for medical devices until specific transition deadlines, depending on the type of device and the applicable EU legislation. For example, in vitro diagnostic devices (IVDs) that meet EU rules can be sold in Great Britain until their certificate expires or until 30 June 2030 — whichever comes first [13]. In Northern Ireland, medical devices must continue to meet EU requirements and carry the CE mark. If a UK Notified Body conducts the conformity assessment, both the CE and UKNI markings are required [14]: All devices require a clinical evaluation of the relevant scientific literature of equivalent devices and/or of all the clinical investigations of the product. A clinical investigation is required to verify that, under normal conditions of use, in accordance with the manufacturer's instructions for use, the product performs in the way the manufacturer intends. The clinical evaluation report should be appropriate to the device under evaluation, its specific properties, and its intended purpose. The evidence presented should adequately support its intended use, for example, the study should be undertaken in the same clinical setting (primary versus secondary care) and with the same patient population in which it is intended for deployment.

Whilst there is no requirement that manufacturers provide a copy of the clinical evaluation, we recommend that commissioners request a copy before purchase of a device. The BAD AI WPG can be contacted to assist in critical evaluation of the evidence presented.

All devices must be accompanied by the information needed to use them safely and properly, taking account of the training and knowledge of potential users. This should include (but is not limited to) a clear description of the tests and data used for validation and a clear statement of limitations emerging from validation studies. It is important to distinguish between use within the scope of an existing CE/UKCA legislation marking (1 January 2021)[15] and use in order to evaluate the product for a purpose that is not within that

scope. This requires careful consideration of the manufacturer's statements about the intended use of the product, and careful scrutiny of the instructions for use. Manufacturer's statements on labelling and instructions for use should be consistent with information provided in any promotional material. This can include adverts, information provided in the app stores, information on the product's landing page or in the manufacturer's social media channels. There is a risk of liability for example, for negligence or breach of product safety legislation, if a product is used outside the scope of its CE/UKCA marking.

Manufacturers are required to incorporate Post-Market Surveillance (PMS) data as one of several inputs into their risk management process and use it to update the technical documentation for UKCA-marked devices[16]. In turn, the technical documentation serves as a key input in the development of the PMS plan. The regulation obliges manufacturers to systematically collect and evaluate data on the device's performance and safety throughout the duration of the PMS period and the level of detailed data required will depend on risk class of the device.

Medical device stand-alone software including apps (including in vitro diagnostic medical devices [IVDMDs]) v1.10 specifically states (Page 27 Rule 10): *any device intended to allow for direct diagnosis should be classified as at least Class IIA*. This applies even if the word 'diagnosis' is not used but words to that effect or claims that give that impression or have a demonstrable function is sufficient. 'Indicative diagnosis' in the context of lay usage can be sufficient that the device should be Class IIA classification. 'Allow for direct diagnosis' also applies to devices that 'provide decisive information for making a diagnosis'. It is incumbent upon clinicians to ensuring that AI interventions used for skin disease diagnosis or triage are appropriately classified and have the necessary supporting evidence base prior to adoption.

## A robust regulatory framework is needed

The NHS is currently under pressure to deploy innovative technologies[17], and there is an understandable impetus towards adoption of experimental approaches. However, these must be appropriately verified and clearly address an unmet need in the local population. Where the evidence for safety and efficacy is lacking or the use of the product falls outside the scope of intended use for which it was CE/UKCA marked, the Health Research Authority (HRA) system for the approval of research can enable AI innovations to be trialled with appropriate safeguards. The HRA can help both developers and clinicians to recognise, understand and comply with the legal and ethics governance processes that apply to AI/data-driven innovations.

It is the responsibility of all clinical users to independently evaluate the regulatory case and intended use for current AI skin cancer diagnostic products which are being offered to improve their local /regional patient pathways. There are indications that current pre-market regulatory requirements are not always robust enough and clinicians'/managers/ commissioners may not be aware of the right assessment questions to ask and/or the apparent risk if they adopt insufficiently validated AI tools. The BAD can provide guidance in this regard and can be contacted to assist in these local evaluations (please see accompanying flow chart for further guidance).

## Conclusion

- We are concerned that there may be products on the market which make unsubstantiated or misleading claims about the power of AI in its use for skin cancer triage and implied diagnostics.
- The BAD aim to support our patients and professionals in engaging with AI in its current study phase for dermatology by ensuring that new AI technologies are developed in an ethically acceptable way that promotes engagement, involvement, and transparency.
- We are working closely with the MHRA, NHS Transformation Directorate, the Department of Health and Social Care, NICE, and NHS national bodies to ensure that AI is safely deployed for its intended populations to provide maximum clinical benefit for both patients and clinicians.
- This includes highlighting the risk to local service providers where AI applications are being commissioned outside a study setting or their "approved use" for a specific skin disease population.

- The BAD aims to lead a UK-wide Dermatology AI Skin Consortium to optimise the development of AI across the entire patient pathway for individuals presenting with a skin condition. The work of the UK Dermatology AI Skin Consortium purpose is to align with the UK wider AI strategy and research community to drive AI and government long-term plans to drive AI, Health, and social care.

All enquiries for AI applications for use in dermatology should be sent to our dedicated team using the email address: ai.dermatology@bad.org.uk.

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