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

This is a version of the BAD Position Statement on Artificial Intelligence (AI) interventions which has been developed to be accessible for non-experts and members of the public. It reflects our position on AI in dermatology and provides guidance for AI developers, users, and healthcare professionals.

Artificial intelligence (AI) is used to describe a wide range of technologies. Essentially it involves computers being able to perform complex tasks that would normally require human intelligence. AI is present in many aspects of everyday life, from face recognition in smartphones, speech recognition in home assistants like Alexa or SIRI, and targeted advertisements on commercial websites.

Dermatology is a field with great potential for AI and the British Association of Dermatologists (BAD) is keen to encourage the use of effective and safe AI technologies to improve patient care. AI can be trained to spot the signs of skin diseases such as skin cancer; in simple terms, the AI is provided with a large number of confirmed images skin diseases so that the computer can 'learn' how to recognise cases.

While AI has a great deal of potential to improve patient care, it is important that AI is rolled out in a manner that is safe for patients and cost-effective for the NHS.

The evidence behind AI in dermatology

Advances in AI technology mean that patients are increasingly likely to come across AI in healthcare, often in the form of smartphone apps. In particular this statement is relating to AI being used to classify images of skin lesions or rashes. However, the evidence to support AI in dermatology is weak. This means that when it is used in a medical setting, it may not be safe or effective and it is possible that AI is putting patients at risk.

The risk here is misdiagnosis. One aspect of this is telling people that they have a condition when they don't, causing stress, unnecessary treatment, and potentially wasting NHS resources. The other risk is telling people that they don't have a skin condition when they do, leading to no treatment. The consequences can be disastrous for patients, particularly in the case of skin cancers.

One of the main reasons why the evidence for using AI in dermatology is weak, is that studies aimed at testing smartphone apps for diagnosing skin conditions rarely reflect the real world. Examples of limitations which make AI apps appear more accurate than they really are, include:

- Limiting the number of skin diseases included in testing, when there are more than 2000 skin diseases
- Ignoring certain body sites like the soles of the feet

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

The BAD encourages AI technology developers to work closely with healthcare professionals and patients to ensure patient safety is at the heart of every development and that they are aware of the regulations and ethical issues relevant for the products they create.

AI apps used for diagnosis as medical devices

All apps that use AI for medical diagnosis or treatment are classified as 'medical devices' by regulatory bodies such as the Medicines and Healthcare products Regulatory Agency (MHRA). This means that they must undergo an approval process to make sure that they are safe and perform with the accuracy that they claim to achieve.

All medical devices sold in the UK must be certified by one of three marks: the CE (Conformité Européene), UKCA (UK Conformity Assessed) or UKNI (UK Northern Ireland). These marks confirm that they have undergone an official approval process run by national or international health authorities.

From July 2023, Great Britain will transition to UKCA marking only, but devices on the Northern Ireland market can continue to be CE or UKNI marked.

Most apps for dermatology will have a CE mark. CE class 1 is a self-reported mark normally submitted by the app developer. Any app with a **CE class I** mark is not safe for making a diagnosis of a skin lesion. It is not enough for these types of apps to avoid the word 'diagnosis' by 'classifying' skin lesions as benign or malignant. Any AI app which is intended to make a diagnosis of a skin lesion should have a **CE class IIa.**

The CE mark directly relates to the intended purpose of the app and software (in this case AI) used as a medical device must have the correct regulatory approval to ensure that it is safe to use.

Advice to NHS commissioners and clinicians

For approval, all medical device developers must submit a *clinical evaluation report* which summarises all studies that have been carried out with the device. The main purpose of the report is to confirm that the device (here an AI app) performs as specified by the manufacturer when used according to manufacturer's instructions. For example, if an app is intended to be used by patients, it must have been previously tested with the general public. It would not be appropriate to only include patients who have been referred to the hospital, as they represent a very specific part of the general population.

We recommend that commissioners within the NHS, who are considering purchasing a device, should request a copy of the clinical evaluation report. This should include a) clear description of the data used to show it is effective and b) a clear statement outlining limitations of the app according to their research. The BAD AI WPG can be contacted to help assess the evidence presented.

It is also important to carefully consider the manufacturer's statement about what the intended purpose of the AI app is. We recommend comparing this with app user instructions to check that they match. These should match promotional material including information provided on app stores or on product websites.

Before agreeing to use AI apps, clinicians should ensure that the apps have the correct regulatory classification and the appropriate evidence supporting this (i.e., well designed studies carried out in the right clinical setting).

Strong regulation to ensure patient safety

The NHS is under pressure to promote and explore innovative ways to improve healthcare and make it more efficient. AI has the potential to deliver in both of these areas. However, no shortcuts can be taken. AI apps must be shown to be safe and effective. Crucially, they must show that they are solving a problem in dermatology.

Where there are concerns about whether an AI app is being used appropriately, a query can be raised with the MHRA (https://yellowcard.mhra.gov.uk/). Where concerns are justified, the Health Research Authority (HRA) recommends further research studies are undertaken to ensure that patients are not put at risk. The HRA can help both app developers and clinicians to understand and follow the legal and ethical processes that apply to AI and other data-driven innovations in these circumstances.

The BAD can provide guidance and can be contacted to assist in local evaluations. Please contact our dedicated AI team using the email address: ai.dermatology@bad.org.uk for further information.