

# **Independent report Equity in medical devices: independent review – quick read**

## **Scope**

This independent review was tasked by the Secretary of State for Health and Social Care with:

- establishing the extent and impact of potential racial, ethnic and other factors leading to unfair biases in the design and use of medical devices
- making recommendations for improvements

We focussed on 3 types of medical device that may be particularly prone to unfair biases:

- ‘optical’ medical devices, such as pulse oximeters
- those assisted by artificial intelligence (AI)
- polygenic risk scores (PRS) in genomics

For each type, we assessed the extent of the problem, the causes and possible solutions.

## **What we found**

### **Pulse oximeters and other optical devices**

The initial stimulus for this review was growing concern about the pulse oximeter, which estimates the level of oxygen in the blood and is in common use throughout the NHS. The COVID-19 pandemic highlighted that the pulse oximeter may not be as accurate for patients with darker skin tones as for those with light skin tones.

This mattered because an inaccurate reading could lead to harm if there was a delay in identifying dangerously low oxygen levels in patients with darker skin tones, which normally would have triggered referral for more intensive care.

### **Key points**

We found extensive evidence of poorer performance of pulse oximeters for patients with darker skin tones. These devices over-estimate true oxygen levels in people with darker skin tones to a greater extent than with lighter skin.

Evidence of harm stemming from this poorer performance has been found in the US healthcare system, where there is a strong association between racial bias in the performance of the pulse oximeters and delayed recognition of disease, denied or delayed treatment, worse organ function and death in Black compared with White patients. We did not find any evidence from studies in the NHS of this differential performance affecting care, but the potential for harm is clearly present.

Our recommendations start with immediate mitigation measures in the NHS to ensure existing pulse oximeters can perform to a high standard for all patient groups to avoid inequities in health outcomes. We go on to recommend actions to prevent potential bias in further optical devices in the longer term.

## **AI-enabled medical devices**

The advance of AI in medical devices brings with it not only great potential benefits to medicine but also possible harm through inherent bias against certain groups in the population – notably women, ethnic minority and disadvantaged socio-economic groups.

### **Key points**

AI has become incorporated into every aspect of healthcare, from prevention and screening through to diagnostics and clinical decision-making, such as when to step up intensity of care.

Existing biases and injustices in society can unwittingly be incorporated at every stage of the lifecycle of AI-enabled medical devices, and then magnified in algorithm development and machine learning.

Every day brings new calls for action on AI by prominent bodies, but nowhere is the problem more pressing than in the medical field, as the use of AI-enabled medical devices is now widespread and built-in bias may lead to poorer healthcare for the affected population groups. Seven of our recommendations are focused on actions to enable the development of bias-free AI devices, with the voices of the public and patients incorporated throughout.

The advent of large language and foundation models (such as ChatGPT) bring heightened concerns about the potential for these latest developments in AI to disrupt our clinical and public health practice in unpredictable ways.

In recommendation 15, therefore, we call for government action to initiate the thinking and planning that will be needed to face this inevitable disruption and potential unintended consequences arising from the AI revolution in healthcare.

## **PRS in genomics**

PRS are already available commercially through direct-to-consumer tests but have not yet been adopted by the NHS. PRS are used to assess risk of diseases that have multiple social, environmental and genetic causes.

### **Key points**

The data sources upon which PRS draw have a well-established bias against groups with non-European genetic ancestry, but, in addition, we were concerned by the potential for misinterpretation of results by the public and health professionals alike, especially in relation to genetic determinism, which may carry wider risks to society at large.

Our 3 recommendations on PRS therefore focus on addressing these wider challenges to society that these devices pose.

## **Next steps**

Our findings all point to the need to take a system-wide approach to make improvements. Potential bias can be introduced at every stage of the medical device lifecycle – from the original concept for the device, through design and development, to testing and eventual deployment in the NHS – all set in the real-world context in which these devices operate.

The improvements recommended in this report therefore call for concerted action by many stakeholders, and now need to be implemented as a matter of priority with full government support and dedicated funding.