Equity in medical devices independent review: terms of reference

April 2022

Purpose

The purpose of the review is to establish the extent and impact of potential ethnic and other unfair biases in the design and use of medical devices and to make recommendations for more equitable solutions.

Context

A core responsibility of the National Health Service (NHS) is to maintain the highest standards of safety and effectiveness of medical devices currently available for all patients within its care. Evidence is emerging about the potential for ethnic bias in the design and use of some medical devices commonly used in the NHS, and that the treatment of patients from some ethnic groups may be less effective as a result.

An illustrative example relates to devices employing infrared light or imaging which may perform differently depending on the skin pigmentation of the patient. Some studies of pulse oximeters, for example, have found that inaccurate readings are more common in Black patients than in White patients and that some devices consistently overestimate blood oxygen levels in darker-skinned patients. Potentially, this means that dangerously low oxygen levels could be missed in these patients, with adverse health consequences. Some devices were originally developed in populations that were predominantly white and the calibration of the devices was carried out against these lighter skin tones, potentially resulting in unintended ethnic bias.

Another substantial line of enquiry for the review concerns artificial intelligence (AI) tools, used in healthcare, and whether their algorithms have in-built biases. It has been demonstrated, for example, that advanced clinical prediction models underperform on women, ethnic minorities and poorer groups, partly because these population groups are

under-represented in the data sources for the models. This issue is of growing importance because such predictive algorithms are increasingly used to support crucial decision-making tasks in healthcare – from prevention to diagnostics to therapeutics. The risk of biases that lead to differentially harmful decisions for patients in certain population groups is increasing.

It is important that this review establishes the extent and impact of such potential ethnic and other unfair biases in the design and use of medical devices used in the NHS and what can be done to remedy it.

Scope

The review will focus on those products classified as medical devices under current GB and EU regulations and in use across the UK. The definition of 'medical devices' includes not only physical instruments and machines, but also artificial intelligence tools and software increasingly used to assist crucial diagnostic or therapeutic decision making, as well as AI derived predictive analytics including those based on genomics data. The Review will also be future-focused and consider the enhanced risk of bias in the emerging range of such tools.

It will review the current regulatory framework for approving medical devices and consider any proposed changes by the Medicine and Healthcare products Regulatory Agency (MHRA) following its recent consultation on this framework and form a view on whether additional actions should be taken to mitigate risks. Recommendations on relevant training for health professionals will also be made.

The Review Chair will issue the panel's report to the Secretary of State for Health and Social Care setting out clear options for consideration. The government will publish the report of the Review and the government's response.

Questions to be addressed

The review panel will be asked to make an assessment in relation to the following questions:

- How far reaching is the problem?

- Where medical devices do not function equally well for all ethnic groups, is the scale of this difference of clinical significance, and could it cause adverse health outcomes for some ethnic groups?

- What could be done to mitigate such adverse outcomes?

- How effective are any such mitigations?

- What further action should be taken to address these issues?

In addition, the review will make recommendations in relation to preventing potential ethnic and other inequalities related to the design and use of medical devices, including unintended or implicit bias. These recommendations will cover the following:

- How to address potential ethnic and other unfair biases, including through a whole system approach – from design to use?

- What role could and should regulation play in removing identified bias?

- What systems needs to be in place to ensure emerging technologies, including software, artificial intelligence and genomics-based tools as medical devices are developed without inbuilt ethnic and other unfair biases?

- How can the UK drive forward international standards to improve healthcare and promote equity in medical devices?