Review launched into the health impact of potential bias in medical devices

- Independent review will look at potential bias in items like oxygen measuring devices and the impact on patients from different ethnic groups

- UK-led review aims to drive forward new international standards to improve healthcare and tackle disparities

- Rapid review to launch shortly with initial findings expected in late January 2022

A far-reaching review is being launched into the impact of potential bias in the design and use of medical devices.

There are concerns that the way medical devices and technologies are designed and used could mean a patient's diagnosis and treatment is affected by their gender or ethnic background, exacerbating existing inequalities in healthcare.

The coronavirus (COVID-19) pandemic has exposed health disparities across the country as the virus had a greater impact on those whose underlying health was poorer and death rates have been higher among people from ethnic minority communities.

While current UK regulations set out clear expectations, they do not currently include provisions to ensure that medical devices are equally effective regardless of demographic factors, such as ethnicity.

The independent review will look at devices such as oximeters – used to measure oxygen levels – to identify potential discrepancies in how they work for different ethnic groups. As part of this, the review will consider whether existing regulations mean there is a systemic bias inherent in medical devices.

For example, some research has concluded darker skinned patients who might need to be hospitalised are at greater risk of inaccurate results from oximeters due to a tendency for this group to present higher levels of oxygen in their blood.

Existing research on this has highlighted the need for this issue to be further examined, as these devices are critical for monitoring and deciding if treatment is needed for diseases such as COVID-19, where every minute counts and accurate data is vital.

All devices will be covered by the review. Another specific example includes

MRI scanners, which are today still not recommended for use for pregnant or breastfeeding women, and further research is needed on how to expand the scope of the equipment’s use, which this review seeks to do.

Patients can be reassured that the NHS are experts in providing the best possible care with the devices currently available, and the review is intended to accelerate the process of improving the quality and availability of devices to diverse communities.

Details of who will be leading the review will be set out in due course.

Current UK regulations offer a clear set of expectations, although there is a growing risk of inequalities as devices are developed at pace and focus on large patient groups.

Not being confined to EU regulations allows the UK to strengthen the focus on ensuring that devices are appropriately designed and tested so that they can support the full range of our diverse communities.

The review will examine medical devices currently on the market to identify areas of concerns in these products, and aims to:

- take forward work on identifying where systematic bias and risk exist with existing approved devices

- make recommendations on how these issues should be tackled in the creation of a medical device from design to use, including potentially via regulation, and

- be future-focused and consider the enhanced risk of bias in the emerging range of algorithmic based data / artificial intelligence tools

It is hoped initial findings can be completed and presented by the end of January 2022.