



## Response of The Royal College of Physicians of Edinburgh to the UK Department of Health's consultation on Equity in medical devices.

Do you have any data or evidence related to ethnic and other unfair biases in the design or development of medical devices, which could affect their effectiveness or safety for different populations?

- yes
- no

If you answered yes, please be as specific as possible in your answer and explain the evidence you are submitting on how and why the design or development may not be equally effective or safe for all the intended patient groups. If relevant, provide:

- the device type, name and brand or manufacturer, in as much detail as possible
- the intended use of this device
- the patient population on which it is used or intended for
- detailed explanation of the evidence you are submitting on how and why it may not be equally effective or safe for all the intended patient groups

If you answered no, do you have any insights or views about the design or development of medical devices that might make them not equitable (that is, not equally effective or safe) for all persons in the population, especially if it's based on their ethnicity or other social or demographic characteristics?

- **yes**
- no

If you answered yes, please be as specific as possible when sharing your insights or views about potential issues in the design or development of medical devices, but do not include any personal or identifiable information.

The Royal College of Physicians of Edinburgh (RCPE) is pleased to be able to respond to this important consultation. In order to ensure our response to this consultation was as holistic as possible we sought the views of members of the College's Lay Advisory Committee (LAC) as well as Fellows.

The RCPE is aware that there are a broad range of potential biases in device design, all of which may potentially reduce the effectiveness of the device for different populations. It considers that all of these should be examined in the most comprehensive way possible with a view to reducing and eliminating them. These biases include physical bias, computational bias and interpretation bias.

One of those giving their views to help us respond to this consultation is involved, at a senior level, in an NHS research ethics committee and indicated that they had experience of clinical studies being submitted for ethical



review or as some kind of post-market surveillance study. They expressed concern that some such study groups often excluded participants who do not speak English, excluding potentially valuable participant cohorts. While translation services do exist in the NHS to support clinical research, there are sometimes cost implications for researchers. In addition, they expressed concern at the studies for medical devices which do not include children because researchers fear that getting ethical approval for paediatric studies may be too difficult and time consuming. While not all devices are intended for paediatric use, they believe some could be trialled in children where valuable data could be obtained as well as helping to ensure that children have equal access to the best in new medical technology.

In terms of computational bias relating to the software or data sets used to develop a device, we consider it extremely important that data sets genuinely reflect population diversity and all potential users of a device. We are aware that there is evidence that adding more variety to the data can improve performance, for example artificial intelligence systems for analysing X-ray images were found to produce more accurate results overall when based on gender balanced data, without losing accuracy for either gender specifically.

Finally it is clear that racial disparities exist in disease prevalence. For example, CKD is more prevalent in black people and devices should be adequately tested and consulted by this population.

### **Potential issues in the use of medical devices**

#### Question

Do you have any data or evidence related to ethnic and other unfair biases in the use of medical devices, which could affect their effectiveness or safety for different populations?

- yes
- no

If you answered yes, please be as specific as possible in your answer and explain the evidence you are submitting on how and why it may not be equally effective or safe for all the intended patient groups. If relevant, provide:

- the device type, name and brand or manufacturer, in as much detail as possible
- the intended use of this device
- the patient population on which it is used or intended for
- detailed explanation of the evidence you are submitting on how and why it may not be equally effective or safe for all the intended patient groups

If you answered no, do you have any insights or views about the use of medical devices that might make them not equitable (that is, not equally effective or safe) for all persons in the population, especially if it's based on their ethnicity or other social or demographic characteristics?

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- no



If you answered yes, please be as specific as possible when sharing your insights or views about potential issues in the use of medical devices, but do not include any personal or identifiable information.

The RCPE shared the widespread concerns over reports, identified due to the Covid pandemic, about the pulse oximeter and its failure to measure accurately in people with darker skins; it has been estimated that it was three times more likely to miss low oxygen levels in black patients than in white ones, something with incredibly serious health consequences for the affected patients.

In addition, we are aware that some devices employing infrared light or imaging, such as remote plethysmography devices, may not perform as well with patients with darker skin pigmentation. It appears that there have been incidences where only patients with a limited range of lighter skin tones may have been recruited as part of the testing and development process with adverse consequences for people with darker skin tones. Therefore the requirement for device developers to demonstrate their products have been tested on as diverse a range of individuals as possible, reflecting real populations, must be reviewed as a matter of urgency and new guidelines considered.

### **Potential solutions in the design and development of medical devices**

#### Question

Do you have examples of evidence-based or successful approaches currently in use during the design or development of medical devices to mitigate potential or actual risks and unfair biases that may affect their effectiveness and safety for different patient groups?

- yes
- no

If you answered yes, please provide information about the existing solutions in the design or development of medical devices to make them more equitable. Be as specific as possible and include information about the medical device type or specific name and manufacturer, what the potential or known risk of bias is, and how it is being addressed now.

If you answered no, do you have any suggestions for designing or developing medical devices that might make them more equitable (that is, equally effective or safe) for all persons in the population, especially if it's based on their ethnicity or other social or demographic characteristics?

- yes
- no

If you answered yes, please provide suggestions for the design or development of medical devices that could make them more equitable (that is, equally effective or safe) for all persons in the population, especially if it's based on their ethnicity or other social or demographic characteristics.

The individual involved in an NHS research ethics Committee notes that when conducting clinical research it is increasingly common to use PPI (public-patient involvement) groups in the design of the research, particularly where the research is aimed at a particular disease or patient group. This helps to ensure that participant-facing



material has been proof read by individuals who fit the inclusion criteria for the study and that the design of the study and participant burden is acceptable to potential participants. In a similar way, design and development of medical devices could possibly employ user groups at various design stages to ensure fairness and equity of design and ensure that users- both clinicians and patients- can highlight any possible risks associated with equity of use.

The RCPE would also be supportive of efforts within device development companies to make research teams themselves more diverse and inclusive.

One Fellow also indicated they were aware of the concept of “fairness statements” that give an indication of how a medical device may perform across different populations and are published alongside other evidence relating to a design’s effectiveness. It may be that the greater use of such statements is a positive step.

The NEJM asks for a synopsis of how a trial is generalisable to the whole population given their mix of participants.

### **Potential solutions in the use of medical devices**

#### Question

Do you have examples of evidence-based or successful approaches currently in use during the use of medical devices to mitigate potential or actual risks and unfair biases that may affect their effectiveness and safety for different patient groups?

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If you answered yes, please provide information about the existing solutions in the use of medical devices to make them more equitable. Be as specific as possible and include information about the medical device type or specific name and manufacturer, what the potential or known risk of bias is, and how it is being addressed now.

If you answered no, do you have any suggestions for the use of medical devices that might make them more equitable (that is, equally effective or safe) for all persons in the population, especially if it’s based on their ethnicity or other social or demographic characteristics?

- yes
- no

The RCPE considers that raising awareness around the issues of equity of device use among NHS staff members is important, as is focused training on the impact of racial and other biases on health treatment and outcomes.

### **Final comments**

#### Question

Do you have any other comments, suggestions or ideas for potential future approaches to improving equity in the development or use of medical devices?

- yes

- no

If you answered yes, please provide any comments, other suggestions or ideas for potential future approaches to improving equity during the design, development or use of medical devices.

The RCPE is committed to working with all relevant stakeholders to tackle health inequalities at every level. Addressing the potential lack of equity in relation to the development and use of medical devices is an important element of this and therefore we welcome the increased focus on and profile of this subject as a result of this consultation.

The College recognises that the development and use of new medical devices has in many ways transformed the lives of many patients and significantly improved health outcomes and will continue to do so. We believe that all sections of the community should be able to benefit from the availability of new devices, based on clinical need, and we look to the UK Government to work closely and constructively with academia and industry to take forward measures that ensure that biases in their development or use based on ethnicity or other social or demographic characteristics are eliminated.

One of our Fellows, who is particularly concerned with equity related to gender, race and BMI, noted that opaque algorithms transferred across social contexts without clear definitions or nuance could be problematic. Algorithms of course depend on human knowledge and data and unintended bias may be transferred or amplified. While some algorithms are not used in the UK, globally shared algorithms could also transfer bias. This Fellow wished to highlight this article from the New England Journal of Medicine as a useful piece on algorithm biases: <https://www.nejm.org/doi/pdf/10.1056/NEJMms2004740?articleTools=true>