ROYAL PHARMACEUTICAL SOCIETY

**Equity in medical devices: independent review call for evidence October 2022**

**RPS Submitted response**

**Which topic does your submission relate to? (Select all that apply)**

- data and evidence related to ethnic and other unfair biases in the design or development of medical devices
- data and evidence related to ethnic and other unfair biases in the use of medical devices
- examples of evidence-based or successful approaches currently in use to limit ethnic and other unfair biases in the design or development of medical devices
- examples of evidence-based or successful approaches currently in use to limit ethnic and other unfair biases in the use of medical devices
- suggestions and ideas (but not evidenced yet) for potential future approaches to improving equity in the development or use of medical devices.

**Question**

**Which type of medical device does your submission relate to? (Select all that apply)**

- medical devices not enabled by artificial intelligence (AI), (for example, pulse oximeters, sensors, software as a medical device)
- AI-enabled devices (for example, devices that use algorithms and software for diagnosis or healthcare decision-making)

**Question**

**Which component of medical device or which aspect of a medical device's life cycle does your submission relate to? (Select all that apply)**

- research and innovation preceding development and manufacturing
- product design
- clinical validation and testing
- pre-deployment testing, research, evaluation
- post-deployment testing, research, evaluation, monitoring
- training on the use of the devices or other relevant training for healthcare professionals
- use of the devices in the healthcare setting (with assistance from healthcare professionals)
- regulation or standards
- datasets
- diagnosis

- algorithms
- Potential issues in the design and development of medical devices

**Question**

**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?**

no

**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

**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.**

Ethnic biases in the design and development of medical devices may have occurred due to:

- Advances in medical devices mainly emerged in the last 50 years or so, particularly with the advent of lasers effect proven experimentally 70 years ago, but applications started to emerge about 20 years later).
- Inherent bias of the technology e.g. infrared light may be reflected to a greater extent on fairer skin as compare to daker skin.
- Calibration studies and clinical trials related to medical devices may have been unintentionally biased at source given the era when the invention was made and the geographical location (i.e. the Western world) where the invention was designed, implemented and invested.
- The limited knowledge we had, and we continued to develop to date on interpretation of results from these devices, and the implications of these results in practice.
- The quality of these devices and the resulting noise in the data, which may impact the quality of the data.

**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?**

no

**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

**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.**

- More research is needed to explore and identify new technologies that are not biased by patient factors such as skin tone and skin types (unpredictable effects can be imparted by physiology in some cases), motion artefacts and signal crossover.
- Understand how biases originate and mitigate their harms through robust calibration studies that ensures equal performance and reduced health disparities.
- Mitigate harms through robust regulatory scrutiny of the physical aspects of the device, representative data, that should also be assessed against racial and ethnic factors.
- Develop an in-depth knowledge of how to pre-process data without manipulating the results. This means develop algorithms that can clean the data and discriminate between the signal and the noise that can be present in the raw data generated from the device. For example, noise sources can originate from individual patient variations (e.g., skin tone, obesity, age, and gender), physiology (e.g., respiration, venous pulsation, body site of measurement, and body temperature), and external perturbations of the device itself (e.g., motion artifact, ambient light, and applied pressure to the skin), which can impact on the functionality and final outcomes of measurements undertaken using certain techniques such as photoplethysmography (Fine et al., 2021).
- Miniaturisation of devices tend to reduce their resolution, the quality of the signal, and increase the risks of false negatives. Quality of the equipment and the resulting signal should be assessed as design level.
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**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?**

no

**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

**If you answered yes, please provide suggestions for the use 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. Be as specific as possible but do not include any personal or identifiable information.**

- Training on the use of the device. Variation in results may result not only from unconscious human bias, but also from human errors when taking measurements and understanding of the technology. Ensuring appropriate intimacy between the device and the skin, for example, may induce variation in the results, which may impact the final outcome, ensuring how to avoid noise such as ambient light which may sometimes induce increased noise in the final signal.
- Develop knowledge of how to enhance a signal e.g. signal from a laser source on a dark sample may be enhanced by changing the laser characteristics (e.g. changing the laser power, the exposure time, etc). This of course depends on the specifications of the equipment. This must also be implemented whilst understanding the adverse effects of such interventions e.g. causing skin burns which can highly affect a darker skin tone as compared to fairer skin tone.
- Sometimes taking multiple measurements, at different sites can help in identify the extent of variability in the results, and help in improving accuracy of the final outcome.
- It is important to use professional judgement and not focus a clinical decision on equipment results.
- Large variation is found between various equipment performing the same task. Hence regulatory standards must be set to specify minimum accepted standards from these devices particularly those which are used by the patients at home without the intervention of a healthcare professional.

**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

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.

- Not all devices are producing racial and ethnic bias, and hence, more robust testing of these devices is required prior to their marketing.
- AI is highly dependent on the quality of data generated from a device. Hence, if a device is producing data that contains too much noise, and this data is not processed with validated algorithms, hence the final outcome will highly be biased.
- For further information on our response, please contact amira.guirguis@swansea.ac.uk or heidi.wright@rpharms.com