



Bringing inclusivity into biomechanics-based technologies

BioMedEng24

Michael Crichton, Ankush Aggarwal and Marlène Mengoni
m.crichton@hw.ac.uk

Equity and Inclusion in Medical Devices?

Medical devices approved for use in the NHS should:

- *Be available to everyone in proportion to need*
- *Support the selection of patients for treatment based on need and risk*
- *Function to the same high standard and quality for all relevant population groups. If there are unavoidable differences in performance in relation to some groups, these need to be understood and mitigated, such as in how the device is calibrated*

Equity in medical devices: independent review, DHSC, 2024

Inclusion in digital medicine means (1) being cognizant of characteristics of different populations, and (2) tailoring solutions to ensure that digital health products meet the needs of and benefit, all individuals and communities.

Sharma, Saha and Goldsack, JMIR Public Health Surveill, 2024



Equity in medical devices: independent review, DHSC, 2024

Where are we?

Optical devices:

“some evidence - so far only from the US healthcare system - of adverse clinical impact of this racial bias in pulse oximeters on the healthcare received by Black patients compared with White patients”

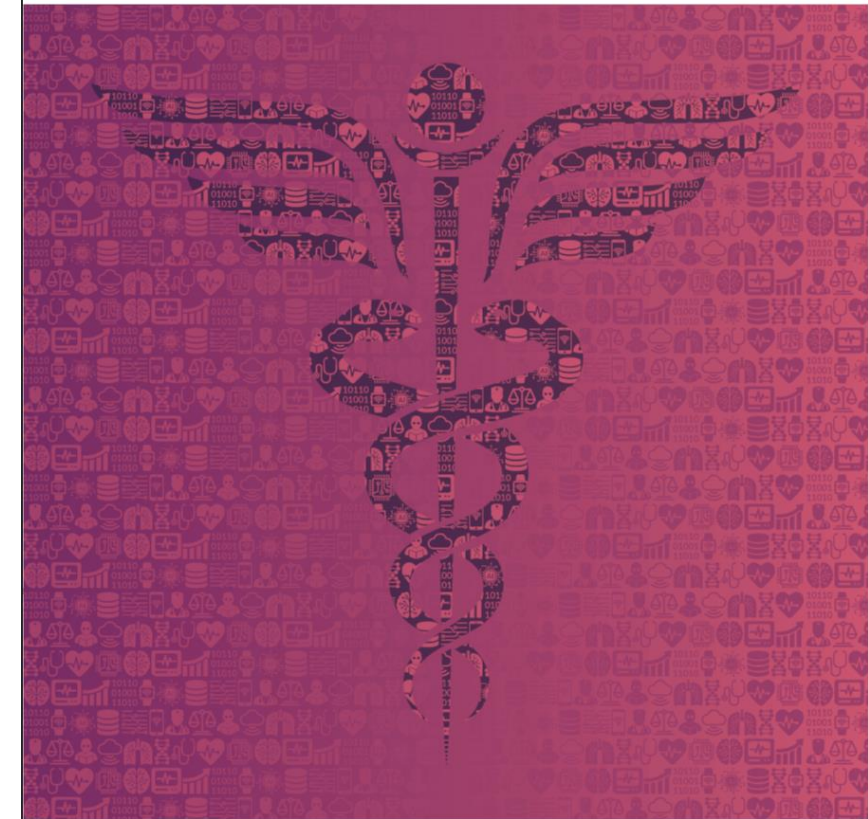
Artificial Intelligence:

“inherent bias against certain groups in the population, notably women, ethnic minority and disadvantaged socio-economic groups”

Polygenic risk Scores:

“data sources upon which PRS draw have a well-established bias against groups with non-European genetic ancestry”

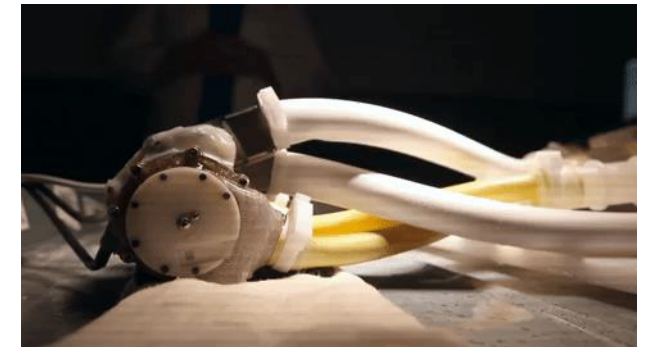
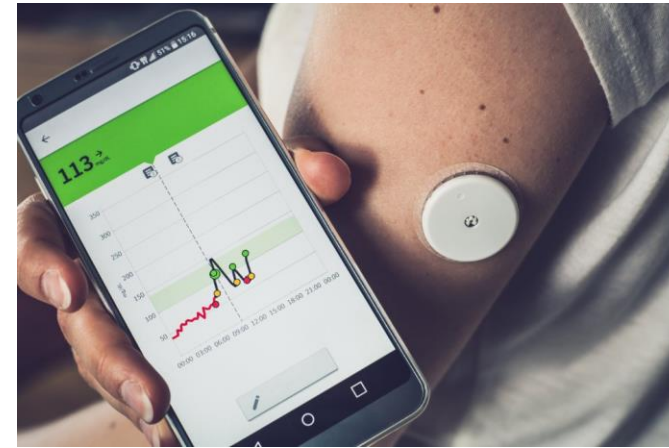
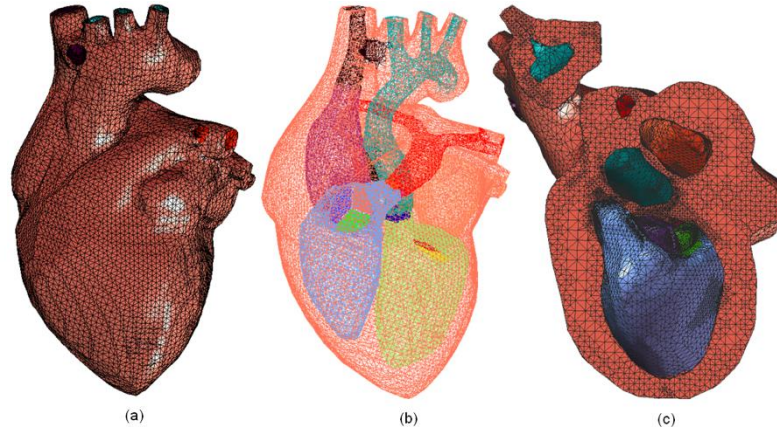
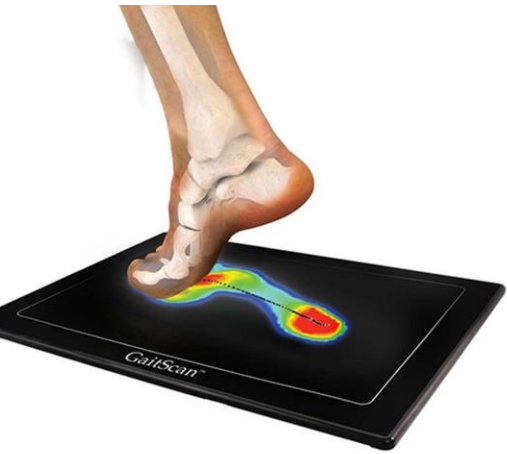
Equity in Medical Devices: Independent Review



Report 2023

Equity in medical devices: independent
review, DHSC, 2024

Looking to technologies underpinned by biomechanics



Royal Society of Edinburgh funded Workshop

- 2-day workshop to discuss approaches to inclusion in biomechanics technologies
- 25 academics including:
 - 12/25 female
 - 3 clinicians
 - Varied fields (soft and hard tissue biomechanics, ethics, behavioural psychology, design theory, biomedical science)
 - No patient representation
 - UK-centric (UK, Ireland, Netherlands)



“Process embeds a value system”

Chris Musei-Sequeira, 2024

Challenges in scope

Table 1. A newly expanded lexicon of dimensions in diversity suitable for the digital era of medicine.

Diversity dimensions	Characteristics
Age ^a	Pediatric and adolescent populations and adults older than 65
Annual household income ^a	Individuals with annual incomes equal to or below 200% of the Federal poverty level
Digital technology access	Communities with limited access to high-speed internet, such as broadband, or access to digital technologies, such as computers and tablets
Digital technology literacy	Individuals or communities not well versed in the use of digital technology (eg, connecting to the internet and Bluetooth pairing)
Disability ^a	Individuals with either a physical or cognitive disability, including visual, auditory, and mobility
Educational attainment ^a	Individuals with less than a high school degree or equivalent and individuals with limited health literacy
Gender identity ^a	Individuals who identify as a gender variant, nonbinary, transgender, or something else
Geography ^a	Individuals who reside in rural or nonmetropolitan areas, individuals residing in areas with limited internet access, and individuals who are homeless
Language	Individuals with limited English proficiency (written or spoken)
Race and ethnicity ^a	Individuals who identify as other than White and non-Hispanic based on their ancestry (eg, African Americans/Black, Asian, Hispanic/Latinx, Native Hawaiian or Pacific Islander, and Middle Eastern or North African)
Cultural practices	Individuals or communities that may abstain from accessing and using digital technologies (eg, some religions discourage the use of technology on certain days)
Sex identified at birth ^a	Individuals who are neither male nor female (eg, intersex)
Sexual orientation ^a	Individuals who identify as asexual, bisexual, gay or lesbian, or something else

^aDefinitions adopted from Mapes et al [12]. The other definitions were developed by members of the Digital Health Measurement Collaborative Community [28].

Identifying key starting questions

1. Who is the appropriately representative population for a study, and how do we collect their data?
2. Is there a process or methodological bias or could there be a future bias?
3. How do we account for the costs of wider inclusion ?Globally distributed differences
4. What is the existing evidence of need for a more inclusive/diverse research?
5. What stakeholders need to be engaged - from research funders to academics, to clinicians and to patients.

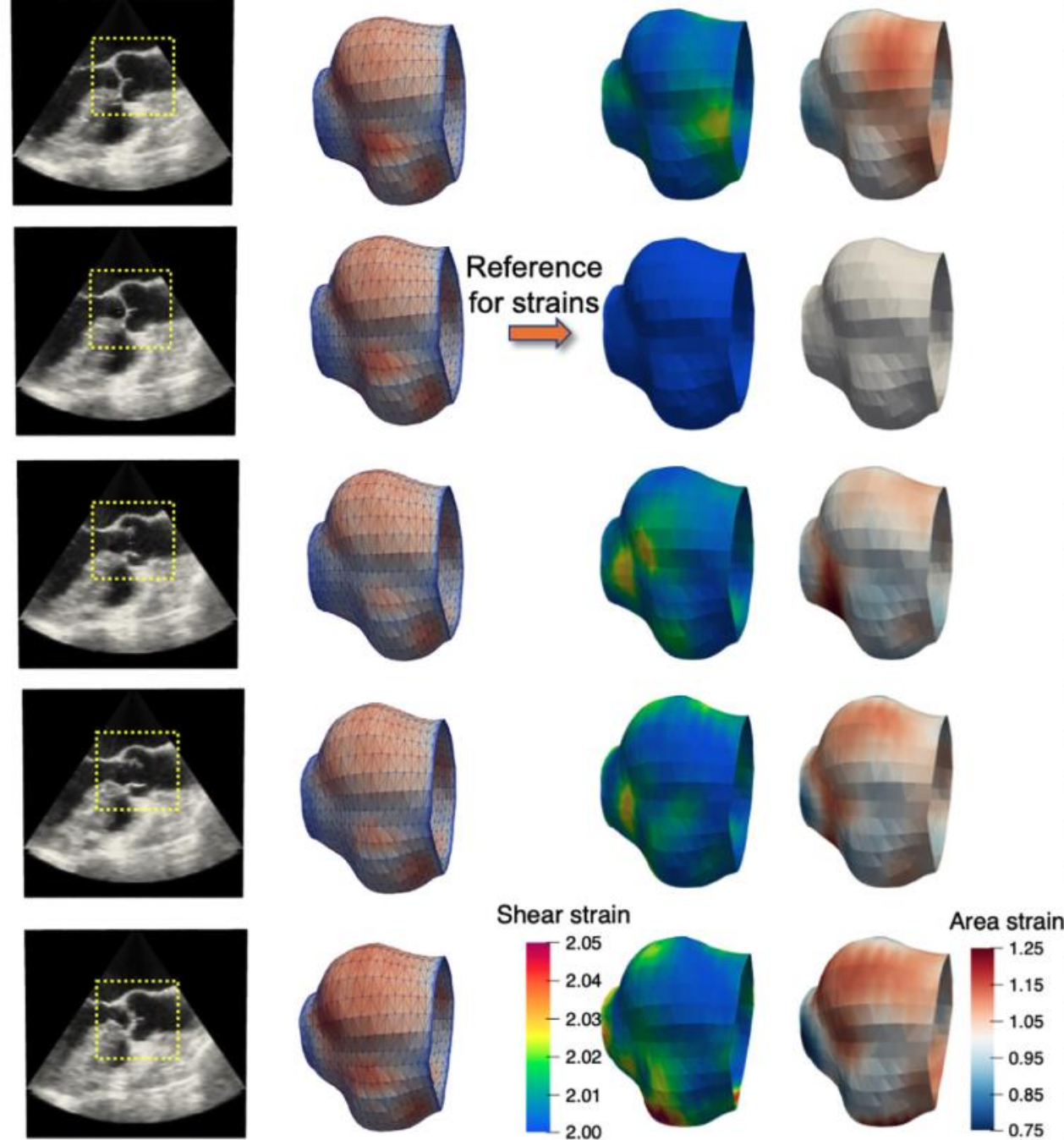
Populations

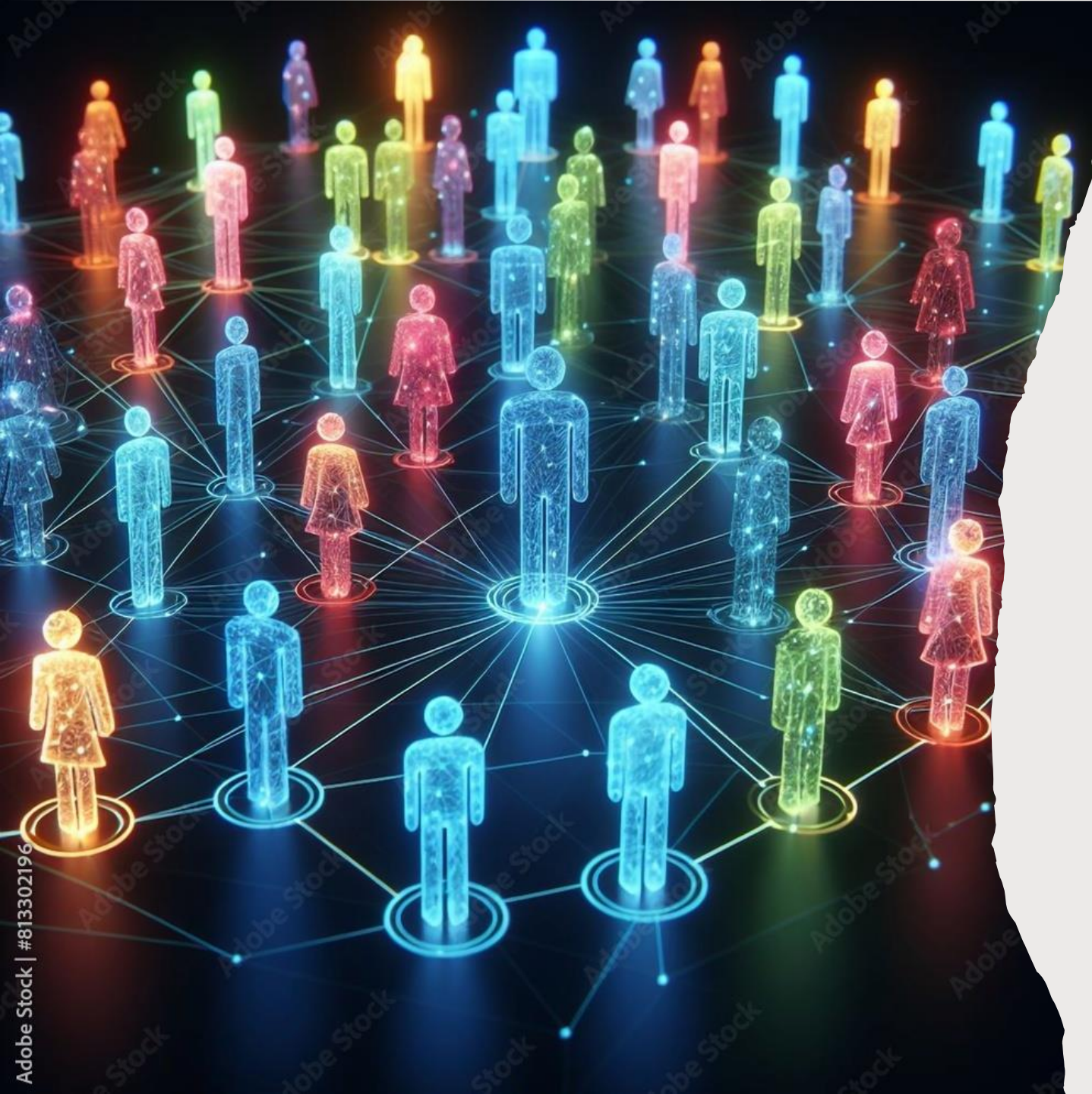
1. Are our volunteers representative of the appropriate population for diseases, or simply those available?
2. Are tissues obtained for testing a good reflection of the widespread population or a subset of particular race, sex, age etc. etc.
3. What parameters should we consider for an individual and how do we record these?
4. Are animal or cadavers appropriate for our research questions?
5. What about individuals with multiple health issues?
6. How do we ensure that those who have religious/ethical reservations about participations, are represented in our data?
7. How do we account for non-visible differences?



Technical challenges

1. How do we balance specificity (e.g. patient specific) vs deployability (e.g. more averaged treatment)?
2. How do we know what diversity features to record/include?
3. Can we use better statistical training to allow inferences to build inclusivity?
4. What structures exist (or are needed) for open reporting?
5. What good models of practice are included elsewhere?
6. How do we build large bodies of shared data when confidentiality is often needed with patient data?
7. How can PPI data be captured in a way to input to diverse technical studies?





Biomechanics as a collaborative field

1. Assessment of methodological bias at project start
2. Reproducibility across centres – Protocols and methods sharing will be critical for experimental and modelling research
3. Explicit statement in papers and grants on what population the work was conducted on, and which it may be applicable to.
4. Considerations of inclusivity and diversity in the development of data sharing protocols.
5. Models (computational) need to be built to be augmented and adapted as new populations are trialled.
6. Are we practicing what we are advocating for?

Summary – Our recommendations so far



Patient voices – Understand who are not catered to, and share their perspectives allowing understanding of need and considerations.



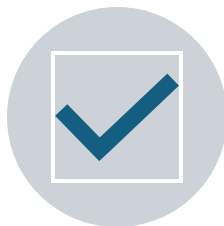
Transparency in biomechanics research – what was the purpose of the research? who was the research performed on? who will it impact?



Team biomechanics



Funders should consider to who research represents, and require inclusivity in MedTech proposals.



Peer review should consider inclusivity impact



Cautious use of animals, excised tissue or cadavers for experiments due to differences from live human populations.

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