Title

Unequal Innovation: The Hidden Harms of Medical Devices on Marginalized Communities

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Publication Date

2025-03-17

Unequal Innovation: The Hidden Harms of Medical Devices on Marginalized Communities

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Abstract: While evolving medical devices may improve healthcare for some, a standpoint theory critique of medical device development reveals the potential of wearable biosensors to harm minorities.

INTRODUCTION

The invention of medical devices has improved healthcare by increasing efficiency, reducing invasiveness, and increasing diagnostic accuracy. For example, before the invention of the pulse oximeter, the only way to determine an individual's blood oxygen saturation levels was through sampling the patient's arterial blood [1]. While sampling arterial blood is still the most accurate way to measure blood oxygen saturation levels, it is invasive, time-consuming, and only provides the oxygen saturation level at a single point in time [2]. In contrast, the pulse oximeter is non-invasive, quick, and provides continuous monitoring of blood oxygenation levels [2].

Advancements in self-powered nanogenerators, such as magnetoelastic generators (MEGs) and triboelectric nanogenerators (TENGs), have paved the way for the development of self-sustaining biosensors and energy sources for wearable bioelectronics [3, 4]. At the same time, progress in artificial intelligence (AI) has enhanced pattern recognition and early disease detection capabilities [5]. These technological innovations hold significant potential to transform the healthcare system into a more patient-centered model, enabling continuous remote data collection and reducing healthcare costs through early disease detection.

However, while these developments in medical devices have the potential to improve healthcare for all, care must be taken in their development to ensure that the scientific roots in colonialism do not cause these innovations to become technologies of oppression.

This work is in partial fulfillment of the ENGR184 course using the blueprint curriculum in Ref. [6,7] and captured in a collection [8].

METHODS

The key question analyzed in this paper was, "Is there a connection between the effectiveness of wearable biosensors and current medical device development?" To analyze this question, Sandra Harding's standpoint theory was used [9].

Harding's standpoint theory argues that scientific knowledge is not the only valuable form; knowledge from personal lived experiences, especially those of marginalized groups, is equally important [9]. This is because knowledge is shaped by social positions and power dynamics. When knowledge is restricted to scientific frameworks, it often excludes perspectives from groups historically barred from academia [9]. To apply standpoint theory to a scenario, one must first identify the social context and existing power structures. Once these are identified, an analysis must be conducted on the privileges and penalties resulting from these power

structures. Through this analysis, groups disproportionately affected by penalties can be identified as marginalized groups.

Between 2010 and 2020, the median percentage of clinical trial participants involved in medical drug and device development who identified as white was 80% [10]. This reflects an overrepresentation of white individuals and an underrepresentation of other demographic groups. To better understand why this norm occurs in current medical device development, standpoint theory can be applied to highlight factors that either discourage minority participation or disproportionately encourage white participation in medical research as well as identify who is most impacted by this disparity.

In the social context of medical device testing and development, two major power structures influence medical device testing: the economic power structure and the device regulation power structure. The economic power structure can be simplified to the idea that medical device developers are incentivized to prioritize cost efficiency, regulatory approval, and investor profits due to capitalism.

As for the regulatory power structure, in the U.S., medical devices must receive FDA approval before they can be marketed to the public [11]. The FDA has previously issued guidance documents encouraging researchers to include diverse demographics in their study samples [10]. FDA guidance documents show the agency's interpretation of existing laws related to drug and device development but are not legally binding [12]. Despite this, they are generally followed, as they represent the most reliable pathway to obtaining drug or device approval [12].

However, due to the 2025 Trump administration, all FDA guidance documents related to diversity have been removed from the FDA website, making them inaccessible [13]. As a result, it is currently unknown whether these guidance documents included any recommendations for diversity quotas such as quotas based on county demographics (requiring study participants to reflect the demographics of the county where the research facility is located) or disease demographics (requiring study participants to reflect the demographic distribution of the disease the drug or device is intended to treat).

Regardless, these power structures combine to contribute to a lack of diversity in device testing demographics, resulting in a participant pool primarily composed of white individuals. This analysis reveals how current legislation and economic systems incentivized researchers to use mainly white demographics for medical device testing. Further analysis using standpoint theory, not explored in this paper, could potentially reveal additional reasons for this norm's existence by analyzing the social contexts of work and colonialism within the power structures of heteropatriarchy, population control, and economics.

Some privileges that arise from this include the following: medical devices are more likely to work effectively for white individuals since they are mainly tested and optimized for them; study participants are easier to recruit in countries like the U.S., where white individuals make up a larger portion of the population; and devices can be developed and approved more quickly when only one demographic's needs are considered. Conversely, a penalty that occurs due to the lack of diversity is that groups not represented in the study participant demographic have no assurance that the device will work for them.

Through this analysis, it is clear that in device development, marginalized groups include underrepresented populations such as black individuals. One famous example of a medical

device that performs more accurately for white people is the pulse oximeter. Pulse oximeters were found to overestimate the blood oxygenation levels in individuals with darker skin tones, like black people, leading to delayed treatment and a higher likelihood of hospital readmission during the COVID-19 pandemic compared to white individuals [14]. Furthermore, recent studies hint that devices like smartwatches may not accurately measure heart rates for non-white individuals [15]. Overall, when medical devices fail to function properly for underrepresented groups, they can create false senses of security that end up harming minorities.

RESULTS AND INTERPRETATION

A standpoint theory analysis of medical device development shows that economic and regulatory power structures incentivize researchers to use study demographics that consist mainly of white people. This results in devices that do not function properly for non-white populations and thus cause harm by delaying diagnoses and treatments. This issue is particularly relevant today, as wearable biosensors are becoming increasingly common for healthcare data collection [16].

Not only are biosensors becoming more common, but combining AI with biosensors for remote healthcare monitoring is a widely anticipated technology [17]. The use of Internet of Things (IoT)-connected biosensors and AI in remote healthcare monitoring is rapidly growing and becoming popularized due to its potential to improve healthcare system efficiency, reduce cost, and shift the system to be patient-centered rather than physician-centered [17].

However, integrating AI with our current healthcare data, which is predominantly based on white populations, raises many concerns. Studies have found that AI models trained on datasets composed of mainly white individuals do not generalize well to other populations [5]. For example, computer-vision algorithms trained on chest X-rays for disease diagnosis, and algorithms for detecting skin cancer were both less effective for black individuals [5].

Additionally, a study on AI in medical imaging has found that AI could successfully determine a patient's self-reported race through X-ray and CT scans by detecting inherent race-specific patterns undetectable by humans [18]. While medical imaging is not yet feasible for remote monitoring through wearable biosensors, this finding raises concern that there are also similar inherent patterns, undetectable by humans, in the data that wearable biosensors can collect like pulse rate monitoring. If AI models are trained on datasets that define "healthy" and "unhealthy" based on mainly white populations, they may fail to recognize important health patterns in minority groups, potentially leading to misdiagnosis and overlooked conditions.

CONCLUSIONS

There is a clear link between modern medical device development and the effectiveness of wearable biosensors: current medical device development results in biosensors that are highly effective for white populations but less effective for other demographic groups due to the predominant use of white individuals in device testing and data collection.

This analysis does not suggest that integrating wearable biosensors and AI into healthcare is inherently problematic. It is true that these technologies have the potential to offer significant benefits, including early disease detection, improved preventative care, and increased overall healthcare efficiency [16]. However, before further research is dedicated to device development and integration, it is important to first challenge the norms and power structures that have led to data collection practices that primarily focus on white populations. Shifting data collection to be

more inclusive will help medical devices provide these benefits equitably, rather than benefiting some populations while harming others.

A potential methodological solution to address this issue is to first fund advocacy groups that promote the inclusion of minorities in research, empowering them to raise awareness and mobilize communities. As these advocacy groups expand, they can begin promoting research participation at the local level by pushing for local-level policies that encourage research participation, such as integrating awareness events into school district programs and providing funding for mailing information about research studies in the area. Over time, they can escalate their efforts to the federal level, advocating for FDA policy changes that mandate diverse clinical trial representation. However, mandating diversity without incentivizing participation isn't enough. Thus, another proposed policy change is the implementation of a federally supported paid time-off program, allowing individuals to take a few paid days off per year to participate in research studies. Unlike jury duty, participation would remain voluntary to respect personal choices and circumstances.

REFERENCES

1) Witt, Chance. “Vital Signs Are Vital: The History of Pulse Oximetry.” Acponline.org, 15 May 2014, acphospitalist.acponline.org/archives/2014/05/free/newman.htm.
2) Torp, Klaus D, and Leslie V Simon. “Pulse Oximetry.” Nih.gov, StatPearls Publishing, 2023, www.ncbi.nlm.nih.gov/books/NBK470348/.
3) Zhang, Songlin, et al. “Leveraging Triboelectric Nanogenerators for Bioengineering.” Matter, vol. 4, no. 3, Mar. 2021, pp. 845–887, https://doi.org/10.1016/j.matt.2021.01.006. Accessed 31 Mar. 2022.
4) Zhou, Yihao, et al. “Giant Magnetoelastic Effect in Soft Systems for Bioelectronics.” Nature Materials, vol. 20, no. 12, 1 Dec. 2021, pp. 1670–1676, www.nature.com/articles/s41563-021-01093-1, https://doi.org/10.1038/s41563-021-01093-1.
5) Weber, Tomas. “Rooting out AI’s Biases | Hopkins Bloomberg Public Health Magazine.” Magazine.publichealth.jhu.edu, 2 Nov. 2023, magazine.publichealth.jhu.edu/2023/rooting-out-ais-biases.
6) Lee, Ethan, et al. "Education for a Future in Crisis: Developing a Humanities-Informed STEM Curriculum." *arXiv preprint arXiv:2311.06674* (2023).
7) Y. Sergio Carbajo, Nurturing Deeper Ways of Knowing in Science, Issues in Science & Technology, 2025, v. 41, n. 2, p. 71, doi. 10.58875/jkrw4525
8) Z. Carbajo, Sergio. "Queered Science & Technology Center: Volume 3." (2025).
9) Harding, Sandra G. Objectivity and Diversity: Another Logic of Scientific Research. Chicago, The University Of Chicago Press, 2015, pp. 26–51.
10) Ndugga, Nambi, et al. “Racial and Ethnic Disparities in Access to Medical Advancements and Technologies.” KFF, 22 Feb. 2024, www.kff.org/racial-equity-and-health-policy/issue-brief/racial-and-ethnic-disparities-in-access-to-medical-advancements-and-technologies/. Accessed 16 Mar. 2025.
11) “Code of Federal Regulations (CFR).” FDA, 3 Nov. 2018, www.fda.gov/medical-devices/overview-device-regulation/code-federal-regulations-cfr. Accessed 16 Mar. 2025.
12) “Guidances.” U.S. Food and Drug Administration, 2024, www.fda.gov/regulatory-information/search-fda-guidance-documents/guidances.
13) Herper, Matthew. “FDA Purges Material on Clinical Trial Diversity from Its Site, Showing Stakes of Trump DEI Ban.” STAT, 23 Jan. 2025, www.statnews.com/2025/01/23/fda-purges-pages-clinical-trial-diversity-after-trump-dei-ban/. Accessed 16 Mar. 2025.
14) Fawzy, Ashraf, et al. “Clinical Outcomes Associated with Overestimation of Oxygen Saturation by Pulse Oximetry in Patients Hospitalized with COVID-19.” JAMA Network Open, vol. 6, no. 8, 24 Aug. 2023, p. e2330856, jamanetwork.com/journals/jamanetworkopen/fullarticle/2808735, https://doi.org/10.1001/jamanetworkopen.2023.30856. Accessed 8 Sept. 2023.
15) Koerber, Daniel, et al. “Accuracy of Heart Rate Measurement with Wrist-Worn Wearable Devices in Various Skin Tones: A Systematic Review.” Journal of Racial and Ethnic Health Disparities, vol. 10, no. 2676–2684 (2023), 14 Nov. 2022, https://doi.org/10.1007/s40615-022-01446-9.
16) Vijayan, Vini, et al. “Review of Wearable Devices and Data Collection Considerations for Connected Health.” Sensors (Basel, Switzerland), vol. 21, no. 16, 19 Aug. 2021, p. 5589, www.ncbi.nlm.nih.gov/pmc/articles/PMC8402237/, https://doi.org/10.3390/s21165589.

17) Alshamrani, Mazin. “IoT and Artificial Intelligence Implementations for Remote Healthcare Monitoring Systems: A Survey.” Journal of King Saud University - Computer and Information Sciences, vol. 34, no. 8, 17 June 2021, www.sciencedirect.com/science/article/pii/S1319157821001385, https://doi.org/10.1016/j.jksuci.2021.06.005.
18) Gichoya, Judy Wawira, et al. “AI Recognition of Patient Race in Medical Imaging: A Modelling Study.” The Lancet Digital Health, vol. 4, no. 6, 11 May 2022, www.thelancet.com/journals/landig/article/PIIS2589-7500(22)00063-2/fulltext, https://doi.org/10.1016/S2589-7500(22)00063-2.
19) Ifty, Syed Mosaddik Hossain, et al. “Advancements, Applications, and Future Directions of Artificial Intelligence in Healthcare.” Journal of Angiotherapy, vol. 8, no. 8, 1 Aug. 2024, pp. 1–8, https://doi.org/10.25163/angiotherapy.889843.