Healthcare Providers, Federal Agencies, and the Media Change in Trust Due to Bias Found in Pulse Oximeters

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

Advisor
Kent Wayland, Department of Engineering and Society

Introduction

Healthcare providers closely monitor the oxygen level in a patient's blood, known as blood oxygen saturation, as it provides vital information about the patient's respiratory function. Healthcare providers carry out this monitoring during various medical procedures such as surgery, critical care, and sleep studies. Pulse oximeters are widely utilized in both clinical and non-clinical settings due to their affordability, ease of use, and quick results (Bousfield et al., 2021; Jubran, 2015). Blood oxygen saturation levels serve as valuable indicators of patient health, aiding in the decision-making process to end respiratory treatment and determining insurance reimbursement thresholds (Jubran & Tobin, 1990). Additionally, pulse oximeters played a crucial role during the COVID-19 pandemic by assisting in the identification of patients who required life-saving ventilator treatment. As low blood oxygen saturation is a symptom of viral infection, pulse oximeters were promoted as a safe and convenient means of monitoring respiratory health at home.

Furthermore, recent research has revealed a significant limitation of optical measurement devices like pulse oximeters, particularly when used on individuals with darker skin tones. Pigments such as melanin, which determine skin tone and are potent light absorbers, can affect the accuracy of these devices. As a result, the presence of these pigments reduces the ability of optical imagers to penetrate the skin, requiring the use of less light to measure the intended value (Mantri & Jokerst, 2022). In the case of pulse oximeters, this bias leads to significantly higher reported blood oxygen saturation levels in the dark-skinned population. This disparity results in a 3.2-fold increased likelihood of undiagnosed hypoxia and potentially inadequate supplemental oxygen for dark-skinned individuals, which can result in worse disease outcomes (Sjoding et al.,

2020). The bias became widely known to the public during the 2019 COVID outbreak when several articles highlighted bias in pulse oximeters.

Now that healthcare providers, patients, and society know that the blood oxygen saturation readings from the pulse oximeter now are less trustworthy it motivates my research question. How did healthcare providers, federal agencies, and the media respond to the new knowledge about biases of the pulse oximeter during and after the COVID-19 pandemic? This research will provide critical insight into the motivations of these groups in addressing this care disparity and facilitate effective and comprehensive solutions for future issues.

Background and Relevant Literature

Pulse oximeters operate by measuring the absorption of light at two wavelengths through a person's finger, enabling the estimation of blood saturation levels using a calibration curve provided by the manufacturer. However, these absorption values are affected by the relative concentration of other skin pigments such as melanin. Since the 1990s researchers have observed an overestimation of blood oxygen saturation in darker-skinned patients, but this bias has remained largely unaddressed due to small sample sizes (Jubran & Tobin, 1990). In 2020, Sjoding et al used over 10,000 measurements to find that Black patients had an 11.4% chance of having unknown low oxygen saturation compared to 3.6% in White patients (Sjoding et al., 2020). More recent research from Patwari et al. (2022) concluded that new race-adjusted calibration curves would not remove the bias because the variance of readings from dark-skinned populations is much greater than from fair-skinned populations (Patwari et al., 2022). Therefore, the bias from the pulse oximeter must be corrected by adjusting procedures in the patient care settings or the development of new equitable medical devices.

Political responses were catalyzed by the expanded use of pulse oximeters in the home due to the COVID-19 pandemic and the news articles covering Sjoding et al.'s 2020 study. Articles by Moran-Thomas (2020) in Boston Review and Rabin (2020) in The New York Times discussing the racial bias encoded in pulse oximeters drew further attention to the issue (Moran-Thomas, 2020; Rabin, 2020). These research findings and media coverage prompted responses from US Senators, the FDA, physicians, researchers, manufacturers, patients, and other stakeholders.

Political responses to address the bias in pulse oximeters have garnered attention from key stakeholders. In response to a letter from Senators Warren, Wyden, and Booker in January 2021 urging a review of the accuracy of pulse oximeter devices, the FDA released a statement in February 2021 (Food and Drug Administration, 2021). The FDA's statement included recommendations for patients and caregivers, emphasizing the importance of being aware of factors such as skin pigmentation. It also highlighted the FDA's policy that every pulse oximeter clinical study should include at least two darkly pigmented participants or 15% of the participant pool, whichever is larger. These political responses, influenced by research findings and media coverage, reflect the importance of discussing the accuracy and trustworthiness of pulse oximeters on multiple social groups.

The balance between trust and distrust in the eyes of patients, researchers, and physicians will determine new FDA policies, new medical devices, and new clinical procedures. This STS research will focus on how patients' trust in the pulse oximeter changes with differing responses to new research about the bias encoded in pulse oximeters from physicians, the FDA, and the media because it has been largely unresearched.

Methods

This research consists of three social groups: healthcare providers, federal agencies, and the media. The data about each group comes from coding and analyzing public statements and documents following the 2020 Sjoding et al study. Some data from before this was included, but the majority is following the onset of the COVID-19 pandemic. The articles were found by online Google searches and filtering out articles that did not discuss research about skin tone or race.

The perspective of healthcare providers comes from public statements and blog posts from professional medical organizations addressing the bias of pulse oximeters. To collect these perspectives, search criteria “medical society”, “medical association” and “anesthesiologist society” followed by “pulse oximeter.” These statements provide insights into how these professional organizations have responded and endeavored to regain their patients' trust.

The perspective of the federal agencies is from statements from government agencies about the pulse oximeter. These were found using the following search criteria “FDA”, “CDC”, “NIH”, “NHS”, and “UK”. Additionally, any correspondence from politicians asking agencies for support will be included.

The media perspective comes from news articles and posts from journalists discussing biases in pulse oximeters, including several discussed above. These were found by searching major news publications like the New York Times, Washington Post, Wall Street Journal, and National Public Radio. Additionally, Medium was searched using “Pulse Oximeter” and the articles were filtered using the same criteria.

These articles and statements were analyzed by identifying common themes about what initiated the statement and their recommendations to address the bias within each group (Rampin

et al., 2021). Then, further analyzed to see how each group responded as a whole. It focused on how they reported the studies and how they encouraged the public to change their trust in the pulse oximeter.

Results

	Publisher	Date
Medical Organizations	PAHO & WHO	2020
	Anesthesia Patient Safety Foundation (APSF)	2021
	American Thoracic Society Patient Education	2021
	American Thoracic Society to the Editor	2021
	Penn Medicine News	2022
	American College of Physicians (ACP) Hospitalist	2022
	Nurse Anesthesiology	2022
	Federation of American Scientists	2022
	American Medical Association (AMA)	2022
	CHEST Physician	2022
	California Society of Anesthesiologists	2023
Media	Medium - Yasmin	2020
	Boston Review	2020
	Medium - Smith	2020
	New York Times	2020
	Wall Street Journal	2022
	National Public Radio (NPR)	2022
	Washington Post	2022
Gov. Reg	Senator Warren Letter	2021
	Food and Drug Administration (FDA)	2021
	United Kingdom (UK) Government	2021
	National Health Service (NHS)	2021

Table 1 An overview of the articles found for each social group, including the publisher and publishing year**.**

Medical Organizations

The articles from the healthcare providers included articles from the California Society of Anesthesiologists, American Association of Nurse Anesthesiology, American Medical Association, Penn Medicine New, CHEST Physician, and the American Thoracic Society. The range of associations is appropriate since there is representation from large medical organizations that include perspectives from physicians, nurses, and hospitals. After completing the content analysis, the majority of the findings were that they responded to the increased use of pulse oximeters during the COVID-19 pandemic and the new research about measurement bias due to skin color, which is expected due to the search criteria and filtering steps. The organizations responded by acknowledging the limitations of pulse oximeters and urging federal agencies to change their regulations.

Federal Agencies

The articles from the federal agencies included statements and reviews from the FDA and NHS along with Senator Warren's Letter to the Commissioner of the FDA. Including perspectives from the United Kingdom in addition to America allows for a diverse perspective and will allow greater generalization of how governments responded to criticism to change policies, new research, and created guidance for citizens and healthcare workers. Their main responses were to acknowledge the limitations of the pulse oximeter but continue to use the device. Additionally, many of the articles said that more research must be completed to better understand the device's current limitations. There were no articles from the NIH because the results from Google generated research studies were excluded since they did not directly come from the NIH.

The Media

The articles from the media included pieces from Medium and the major publishing companies, listed above, which will provide a proxy for the perspective of the public. Although not a perfect replacement, the articles are the most important for the public because they are directed toward the public and have a great impact on public opinion. This can be seen in the New York Times and Boston Review articles catalyzing reactions from Senators, medical organizations, and other news outlets. Additionally, including the Medium articles help widen the scope of the "media" perspective to include smaller writers who are not attached to million to billion-dollar companies. As such, the media had a diverse reaction from asking the FDA to change its regulations to placing the blame on hospitals for using the pulse oximeter.

Discussion

This section will first describe in detail how each group responded and then will go into what broke down between each of the groups.

Medical Organizations

The medical organizations' reasons for creating the posts were similar; all noted new research. However, the context of how they discussed the new research was not identical. Most of them (9 of 11) discussed how the COVID-19 pandemic has changed how patients interact with pulse oximeters and how pulse oximeters have a greater role during the pandemic. The World Health Organization says they are "a critical tool for managing patients with COVID-19 due to their role … and monitoring treatment with supplemental oxygen (Pan American Health Organization, 2020)," and the California Society of Anesthesiologists said, "The issue got little

attention, however, until the pandemic brought both oxygen saturation and racial equity to the forefront of health care (Moore et al., 2023).” Both statements show that COVID-19 is the reason they are responding, and the bias of the pulse oximeters is such a big deal now when they released the article. However, neither the APA nor APSF mentions the COVID-19 pandemic as a reason for writing the article. They instead discussed and interpreted the FDA’s February 2021 statement, which is interesting due to the magnitude of the pandemic and the reason for the FDA’s statement, to provide guidance during the pandemic.

The medical organizations respond to each in their unique way, but the majority urged the federal government to increase the diversity of the clinical trial groups (7 of 11), while fewer (4 of 11) asked manufacturers to reduce their bias and become more equitable for patients of all skin tones. This difference indicates that medical professionals may place more ownership of the bias on regulatory agencies than on manufacturers or researchers. This is an important finding because it will help federal agencies understand that they are important to fix the bias in the medical field and that going directly to manufacturers may be an underutilized solution for bias in the medical field. The Federation of American Scientists said, “health stakeholders—including patient advocates, medtech companies, clinicians, researchers, and policymakers—collectively commit to systematic evaluation and remediation of bias in health technology, change is possible (Wickerson, 2022).” They ask many different parties to play a role in solving and were the only organization to ask researchers and manufacturers to create new products that solve the bias. The APSF and the CHEST Physician both talked about how the FDA’s medical device performance metrics are too low when looking at low blood oxygen saturation and could be another reason for the poor performance in the pulse oximeters. The AMA also offered a unique recommendation for the FDA to have independent real-world verification of performance and post-market

surveillance. These diverse perspectives indicate that the AMA, APSF, and CHEST encourage more strict performance metrics in medical device approval, even though the US medical device approval process is known to be very strict globally.

Federal Agencies

The federal agencies were directly responding to the new research and the implications of the bias during the COVID-19 pandemic, which occurred a total of 8 times in 3 of the 4 articles. Specifically, they responded to the Sjoding et al. study, discussed the research, and concluded that the pulse oximeter does not measure equally for all races. This is important to note because federal agencies' guidance and information are often strictly followed especially in global events. The only article that did not discuss COVID-19 or new research about the pulse oximeter was the guidance released from the United Kingdom. Instead, it listed possible reasons for inaccurate results including skin tone, low perfusion, and nail polish. The article tells the public to not use a pulse oximeter unless it is prescribed by a physician. This difference in advice may be because it the differing role the UK government plays in healthcare since it is public compared to the privatized healthcare system in the US. Overall, it was clear that the federal agencies were responding to the new studies and how the pandemic affected their guidance.

All of the articles besides the guidance article from the UK encouraged further research to confirm the initial finding and understand the significance of the bias on patient outcomes. The UK's NHS wanted "further research in this (pulse oximeters) area, with larger and more diverse populations (National Health Service, 2021)," and Senator Warren asked, "the FDA to conduct a review of the interaction between a patient's skin color and the accuracy of pulse oximetry measurement (Warren et al., 2021)." These quotations represent the main response

which was more diverse populations and a better understanding of the significance of the research. Only one of the articles from the federal agencies encouraged manufacturers to change their policies and improve their devices. This finding indicates that agencies have taken initial ownership of solving the bias of the pulse oximeter. This can show that the agencies appear to guide their citizens, physicians, researchers, and manufacturers. Another important finding is that every article besides Senator Warren's letter encouraged the use of pulse oximeters, although some had reservations. The NHS suggested the "readjustment of (clinical) thresholds for seeking care for ethnic minority groups (National Health Service, 2021)," but the FDA suggested using multiple readings and looking for trends as their immediate solution. This difference might show how countries' responses need to change based on their healthcare system. Since England has a public health system it is easier for the UK government to change treatment thresholds without worrying about insurance approval whereas in the US it is much more difficult for the government to change private insurance thresholds, which greatly impacts patient care.

The Media

Due to the filtering process most of the articles noted the increased use because of the COVID-19 pandemic; however, unique to the articles from the media was distrust in healthcare providers, which appeared in 5 of the 7 articles. This distrust seems to originate before any of the research was published and appears to be due to large issues within the health care system. In the Boston Review article, Moran-Thomas said, "Physicians in a clinic may not distinguish errors stemming from an underlying condition and those caused by the device's bias on darker skin (Moran-Thomas, 2020)." This sentiment, which indicates reservations about clinicians' ability to treat patients holistically, was echoed by Craig LeMoult from NPR who explained a story about

a nurse disregarding a patient for being out of breath since his pulse ox readings were normal. This appears to respond to both the physicians and the FDA that say healthcare providers should continue to use the device but acknowledge the limitations. As seen above, the main reason for distrust was that they feared the care provider would not be able to recognize an underlying issue or they would continue to rely on the measurement from the pulse oximeter. There is a clear lack of trust that is likely to be drawn from previous interactions and historical wrongdoing, which is another major finding. Five of the seven articles indicated that the current research about the pulse oximeter was not an eye-opening finding in the medical field. Dana Smith said this was "the latest example of racially biased medical tools (Smith, 2020)." Both the articles from Washington Post and Boston Review explained that the pulse oximeter was racist from the beginning since it was originally designed and tested on fair-skinned populations. Both sentiments show that the public is primed to learn about new research that shows harmful bias in daily devices or procedures. This finding will better allow communication with the public since it shows that there is baseline negativity toward healthcare providers and racism in healthcare. This sentiment is further shown by the Boston Review and New York Times article worried about how pulse oximeters could lead to further bias and discrimination due to the rise of artificial intelligence in healthcare, which uses data from many medical devices and health records created by biased workers. The Wall Street Journal also discussed how insurance thresholds could perpetuate the bias and lead to differential treatments based on the patient's race.

The media's response is much simpler than the other two social groups. The media directs its attention to manufacturers and regulatory agencies. Three of the seven articles urge the FDA to increase the diversity in clinical trials and the manufacturers to create new bias-free

technology. Specific responses include fast-track and increasing funding for specific National Institutes of Health (NIH) grants and spotlighting innovative proof-of-concept technologies which are more accurate across skin tones. What is interesting there are no provided solutions to increase the trustworthiness of the providers, whom the public will directly interact with. This may be due to the difficulty of changing bias at the individual level, or patients have accepted the discrimination and believe they should fight for themselves; however, this is just speculation.

Interplay Between Groups

The interplay between the media, federal agencies, and healthcare providers during and after the COVID-19 pandemic was complex. While the healthcare providers and federal agencies responded to the new knowledge about the biases of the pulse oximeter, the media played a crucial role in raising awareness and holding the other groups accountable. Interactions were not always smooth. When the healthcare providers urged the FDA for more diverse clinical trial groups to reduce bias, federal agencies encouraged continued use of the pulse oximeter without making significant changes. This led to some criticism from the media, who felt the federal government should be taking more significant action to address the bias of the pulse oximeter.

Conclusion

In conclusion, blood oxygen saturation levels are a critical indicator of respiratory function, and the pulse oximeter is a widely used optical imaging device to measure blood oxygenation levels. However, recent research has found that pulse oximeters report significantly higher blood oxygen saturation levels in dark-skinned than in light-skinned populations. This bias leads to undiagnosed hypoxia, which may result in worse disease outcomes. As a result, the healthcare industry, federal agencies, and media responded to the new knowledge about biases of

the pulse oximeter during and after the COVID-19 pandemic. Medical organizations responded in different ways, but the majority urged federal agencies to increase the diversity of clinical trial groups and asked manufacturers to create new technologies to reduce bias. The federal agencies responded directly to the new research and concluded that the pulse oximeter does not measure equally for all races. The media played a crucial role in informing the public about the bias and raising awareness about the need for equitable medical devices. The findings of this research highlight the importance of addressing bias in medical devices and increasing diversity in clinical trials. Future technical research should focus on developing new technologies to address these issues and improve patient outcomes, ensuring the researchers validate the technologies on diverse patient populations.

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Appendix 1 – Citations of Articles Used for Content Analysis

Media

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