Development of a Pulse Waveform Analysis Instrument

Investigation of Racial Bias in Modern Pulse Oximeters During the COVID-19 Pandemic

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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.

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Introduction

Cardiovascular heart disease (CHD) is the leading cause of death in the United States, with one person dying every 34 seconds due to the disease (Bruning & Sturek, 2015). While roughly 700,000 lives are lost each year from CHD, 200,000 of those deaths are preventable (Schieb et al., 2013). Most cardiovascular diseases can be prevented by addressing behavioral risk factors or medicinal treatment options, which is why it is critical to detect cardiovascular disease as early as possible (Van Horn et al., 2008).

A key marker of cardiovascular risk is arterial stiffness, which can be determined through pulse wave velocity (PWV) measurements. Current methods to directly measure PWV involve using invasive catheters and expensive MRI imaging techniques which represent central arterial stiffness. Indirect peripheral measurements involving cuffs and sensors located on extremities are more accessible, but the outputs are less stable (Segers et al., 2020). To address the gap between the current PWV measurement methods, I will propose a pulse waveform analysis (PWA) instrument that uses a single sensor and machine learning aspects to combine the accuracy of direct central PWV measurement with the accessibility of peripheral measurement technology in order to determine CHD risk.

The technical aspect of the proposed PWV analysis instrument uses a method called photoplethysmography (PPG), the same technology used in pulse oximeters. While pulse oximeters are simple and fast to use, there have been recent concerns over the racial bias built into the technological design. A recent report suggested pulse oximeters may be less accurate in people with dark skin pigmentation, leading to misdiagnosis and lack of treatment (Sjoding et al., 2020). The proposed PWA instrument is less susceptible to inaccurate readings as it only relies on one wavelength to take measurements as opposed to the two wavelengths the pulse oximeter uses. However, both methods still rely on PPG light absorption techniques, which is potentially affected by melanin interference (Cabanas et al., 2022). Failure to acknowledge the potential of marginalizing certain groups when assessing cardiovascular risk is catastrophic, especially when African Americans are 30 percent more likely to die from CHD than whites (Mensah, 2018).

To effectively determine cardiovascular risk, the technical and social aspects of the PWA instrument must be addressed simultaneously. By completing the design of the device, collecting patient data, and utilizing machine learning techniques, I will develop an instrument that can predict cardiovascular risk based on arterial health. Furthermore, I will use technological politics to analyze how pulse oximeters delayed and prevented COVID-19 treatment eligibility for patients with darker skin tones to better understand diagnosis capabilities in regards to CHD.

Technical Project Proposal

An important determinant and risk factor of the development of cardiovascular diseases is large artery stiffness, which is impacted by the composition and material properties of the arterial wall (Milan et al., 2019). Arterial stiffness can be evaluated by the pulse wave velocity, a measure of the speed at which the arterial pulse propagates along the arterial wall (Segers et al., 2020). The resulting pulse waveform shape and pulse wave analysis is used to find relevant clinical values including pulse pressure, aortic incident pressure, reflected wave amplitude, and traveling time of reflected wave. The values, data, and resulting graph are used to gain insight into cardiovascular disease and outcome (Gurovich & Braith, 2011).

The current gold standard methods either directly measure central aortic PWV using pressure catheters or MRI imaging techniques or measure carotid to femoral PWV using ultrasounds, tonometers, and pressure cuffs. However these methods are invasive, expensive, single-use, patient-limited, and require extensive user training to operate. Invasive pressure catheters are only used occasionally in various studies due to their complexity, cost, and ethical constraints. MRI imaging techniques require a specific temporal resolution which is difficult to attain and possess difficult logistics, so PWV measurements using this method are generally unavailable to the public (Segers et al., 2020). By continuing to rely on central PWV collection methods, many patients will be excluded and will not have access to continuous cardiovascular health monitoring.

Over the past decades, peripheral cuffs and plethysmograph sensors have been developed as a non-invasive, fast, and inexpensive way to measure indirect peripheral PWV. However, the devices have an ambiguous phenotype due to the uninterpretable ambiguity of the traveled wave path and limited correspondence with central waveforms, which are better understood (Segers et al., 2020). Further development of these types of peripheral devices will offer an affordable, portable, and user-friendly PWV measurement device for widespread clinical application. Successful PWA and waveform curve display by the device can be taken into account alongside other inputs such as age and blood pressure to assist users in the course of action if cardiovascular disease management interventions are needed, such as lifestyle changes, medication, or surgical operations to ultimately lower the number of CHD related deaths.

The goal of the technical project is to complete the design and testing of the PWV measurement instrument so that it is user-friendly and assistive when monitoring and diagnosing cardiovascular disease risk. Currently, the device uses an Arduino-linked pulse oximeter PPG sensor to measure a patient's peripheral PWV from one finger. The first task is to upgrade the device so there is a menu-driven screen interface with total user independence. The screen display should ideally feature the waveform after data processing to reduce noise so the user can view the plot in real time. Portable battery implementation and elimination of unnecessary wire attachments to the computer and wall outlet is also sought. The ability of residents and other doctors at UVA Health to use the device will be assessed, as well as the battery life and overall portability of the device.

The second aim is to collect data from patients in the cardiology unit at the UVA hospital to validate a novel transfer function from peripheral to central vessels. Target patients will be identified via the Epic health system used by UVA Health. Statistical significance tests will be run to compare central waveform data collected from established gold standard methods to the transformed peripheral waveform collected by the prototype device to ensure they are comparable and accurate.

The final task is to analyze the shape of the waveform by machine learning algorithms to determine cardiac health. The model accuracy and sensitivity will be evaluated based on patient cardiovascular disease outcomes. This project is a continuation from previous BME Capstone teams and will be completed as a team of two students over the course of two semesters in BME 4063 and BME 4064.

STS Project Proposal

Due to the COVID-19 pandemic, the use of modern pulse oximeters increased in order to estimate blood oxygen levels and assess health conditions (Stell et al., 2022). Pulse oximeters use photoplethysmography, a method where light is used to measure the volumetric variations of blood circulation and provides valuable information about the cardiovascular system (Castaneda et al., 2018). For pulse oximeters, analyzing the amount of light that passes through the fingertip can be used to estimate the percentage of oxygen in the red blood cell. During the COVID-19 pandemic, pulse oximeters played a prominent role in guiding triage and therapy options (Fawzy et al., 2022).

The technology is understood to estimate oxygen saturation from finger readings, which is compared to arterial blood gas saturation values. The FDA reviews pulse oximeters and clears devices within a 2 to 3 % accuracy of arterial blood gas values. Since pulse oximeters offer an easier, quicker, and generally accurate alternative than taking blood samples, they were used to recognize the eligibility of patients to receive COVID-19 therapies in hospitals.

Pulse oximeters do estimate patient oxygen saturation levels and provide an efficient way to determine the degree of COVID-19 infection and consequences, but the technology also does significant social and political work. Pulse oximeter technology is generalized to all patients, even though there are individual variations among patients that affect readings. In December 2020, a report emerged from the University of Michigan that detailed the potential racial bias in pulse oximetry, with less accurate data reported for Asian, Black, and Hispanic populations (Sjoding et al., 2020). The data showed that in patients with darker skin, there was a higher risk of occult hypoxemia, a situation where the patient's oxygen levels are low but the device says the saturation is normal. Despite the warning and increased media attention to the questions surrounding pulse oximetry, it was still used to guide decision making for patients with COVID-19. Coincidentally, COVID-19 mortality rates were disproportionately high in the same racial and ethnic minority groups pulse oximeters fail in (Gross et al., 2020). If we continue to think that pulse oximeters accurately display oxygen saturation for all patients, we'll miss how it also works to shape power relations among racial groups during the pandemic.

Drawing on the concept of technological politics, I argue that pulse oximeters used in hospitals during the COVID-19 pandemic performed social and political work by privileging patients with lighter skin tones and marginalizing patients with darker skin tones, exacerbating the already defined problem of racial disparities in healthcare. Technological politics seeks to address how technological designs can be judged not only for their efficiency, productivity, and environmental effects, but also for the ways in which they embody power and authority (Winner, 1980). These politics, or power dynamics, serve to empower and provide advantages to certain groups while excluding and harming others who use the technological artifacts either intentionally or as an unintended consequence. To support my argument, I will analyze evidence from news articles covering the pulse oximeter controversy, press releases and statistics from health organizations such as the FDA, and journal articles and studies investigating the frequency and magnitude of pulse oximeter bias for COVID-19 patients. Comprehensive analysis will provide information about the potential association between pulse oximetry use in patients with COVID-19, clinical decision making, and the different outcomes racial and ethnic minority groups experienced during the pandemic.

Conclusion

The deliverable for the technical problem discussed in this paper will be the design and implementation of a pulse waveform analysis instrument that can display and assess cardiovascular heart disease risk by collecting patient's PWV data with pulse oximeter technology and applying machine learning algorithms to the gathered data set. The STS research paper will investigate how pulse oximeter use during the COVID-19 pandemic influenced clinical decision making and subsequently led to disproportionate health outcomes for patients with darker skin. Technological Politics will be applied to understand how the politics embedded in pulse oximeters perpetuated power relations during the pandemic by providing treatment advantages to patients with lighter skin while overlooking patients with darker skin. Despite using the same PPG technology, measures can be taken during the technical development of the PWA instrument when determining CHD risk to avoid the racial bias of pulse oximeters when assessing COVID-19 severity. The combined results will serve to address the issue of continuous and accessible CHD monitoring while taking into account the politics of PPG technology to avoid biased disease diagnosis.

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