Pulse Waveform Analysis Instrument for Cardiovascular Heart Disease Assessment

(Technical Paper)

Investigation of Medical Device Price Regulation and its impact on Accessible and Equal Care in different countries

(STS Paper)

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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

As one of the leading causes of death in the United States, every year roughly 700,000 people die from cardiovascular heart disease (CHD), but 200,000 of these deaths are preventable (AMA Physician Communications, 2014). Certain demographics, like those with lower income (household income is less than $52k), do not have benefits of early detection and treatment (Snider & Kerr. 2022). Their inability to get treatment due to unaffordable health care results in an increased risk of CHD progressing worse than those who were able to prevent it early on (World Health Organization, 2021). Early detection of risk and treatment can reduce the rate of premature death, thus there is a need for a device that is able to repeatedly measure heart metrics to allow people to understand their risk of heart disease early on. The goal of this project is to improve upon a prototype of a pulse waveform analysis instrument to non-invasively and accurately measure pulse waveform velocity (PWV) and calculate a patient's risk of death from CHD.

Additionally, CHD leads to an industry cost of $219 billion a year. This total includes the cost of healthcare services, medications, and premature death. The United States' healthcare consists mainly of secondary and tertiary treatment, which often leads to increased expenditure. Secondary treatment involves seeing a specialist like a cardiologist, while tertiary treatment involves specialized care like surgeries. There are procedures that can analyze PWV which would dictate possible treatment planning to prevent the worsening of CHDs. However, these may be costly for people, for instance cardiac catheterization scans can cost around $5000 (Oseran et al., 2022). One solution to decrease costs of healthcare spending would be to invest in point of care devices that would promote early diagnosis (St. John & Price, 2014). Japan, although having a similar capitalistic society (Ikegami, 1991), has opted for a system that focuses on primary health and preventative medicine thus leading to decreased healthcare costs. As Japan opts to increase primary medicine, this aligns with the goals of the pulse waveform analysis device to prevent the worsening of diseases in terms of health and cost. The Science, Technology, and Society (STS) portion of the project will aim to investigate the differences in healthcare systems and medical device price regulations between two countries, United States and Japan, and how different social groups approach the usage of medical technology.

Pulse Waveform Analysis Instrument for Preventative Medicine

PWV is the velocity of the blood pressure wave as it travels through a vessel (Pereira et al., 2015). Large artery stiffness, measured as pulse wave velocity, has been proven as a risk factor for cardiovascular heart disease (Milan et. al, 2019). Current methodologies for determining a patient's CHD risk consists of diagnostic procedures such as catheterization, magnetic resonance imaging (MRI) scans, or ultrasound screenings. However, catheterization, which is the gold standard method for measuring PWV, is a very invasive and expensive procedure which requires a thin tube to be inserted into the heart vessels. Photoplethysmography (PPG) has been identified as a solution for a non-invasive measurement of PWV. PPG utilizes the emission of red and infrared light into a tissue and measures the changes in absorbance of each wavelength using a photodetector (van Velzen et al., 2017). There is a need for a non-invasive, safe, and accessible way to measure PWV using PPG with minimal error in order to assess people's risk of death from heart disease and encourage early prevention and treatment.

This project aims to create an instrument that utilizes pulse wave analysis and concludes the cardiovascular risk of the patient. The device uses an Arduino-linked pulse oximeter to measure a person's peripheral PWV. Once the peripheral PWV is captured, a transfer function is applied to transform peripheral to central vessels and data processing is applied to reduce noise.

The waveform needs to be transformed to the central vessel form because its shape and characteristics are more well understood. The shape of the waveform is analyzed using machine learning algorithms to determine the current risk of the patient's cardiac health. There will be PWV data collection of patients before and after cardiac procedures in the University of Virginia hospital to enhance the training model. Furthermore, it would be ideal for the transformed waveform to be displayed on a portable screen and become user friendly. Making the device intuitive for residents and others would increase accessibility of cardiac health detection by lowering the skills needed to use. Other than healthcare professionals, there is a possibility of this device being used within a household setting for people to regularly check their cardiac health without having the need to go to the hospital, furthering the convenience of the device. This would act similarly as other point of care devices like the blood pressure cuffs or heart rate monitor. Ideally the interface of the device should be easy to use so that even people without a medical background can understand its functions.

This device has potentially significant societal implications, since it will allow greater access to accurate cardiovascular disease screening. However, there is a need to take into account important ethical considerations, both for research, collecting data, and the development of the medical device. Ethics training relating to Health Insurance Portability and Accountability Act (HIPAA) and Institutional Review Board (IRB) protocols, which ensures the confidentiality and protection of patients in biomedical research and clinical trials (Center for Drug Evaluation and Research, 2019), were required for this project. This will present limitations on the scope of data collected which might influence the algorithm to detect cardiac risks as some demographics might be less represented. Additionally, there have been studies investigating the racial biases present in the usage of pulse oximeters on African Americans (Chalkias et. al, 2021). This is due to the fact that the light source used to detect oxygen levels cannot be interpreted as accurate on people with darker pigmentation. However, since the objective is to analyze the shape of the pulse waveform and the ratios of different key characteristics, it is unknown if patients with darker skin will affect the readings. If enough data can be collected from people within these demographics, the algorithm can be adjusted accordingly to take into account patients with different skin colors. Although there are relevant social and societal relations to this technical project, the following portion of this paper will be focused on the role of healthcare pricing and other social groups/factors on the usage of MRIs and other medical technologies.

An analysis on two leading healthcare leaders: The United States and Japan

Both the United States and Japan could benefit from the creation of more point-of-care devices similar to the proposed technology mentioned in the technical section. However, these two countries, although similar in economies and wealth, might benefit in different forms. Both countries consider themselves as health care leaders in their respective areas of strength and describe themselves as exceptional (Rodwin, 1993). Their differences result from the structure of their health system, policy makers, and the care providers. It is of interest to look into these differences in policies or health practices to determine if it affects the accessibility or quality of care in the patients of these two countries and thus what kind of technologies are used more frequently than others.

The United States has three main properties representing their healthcare system: low level of public expenditure compared to total health expenditures, high level of total health expenditures as GDP, and a lack of universal healthcare (Rodwin, 1993). However, there are few elements of national health insurance (NHI) like Medicare and Medicaid, but overall the US has one of the lowest share of public expenditures compared to other developed countries (Rodwin, 1993). Doctors are paid exceptionally well and can perform procedures at high profit margins, which encourages competition leading to high quality of care options for patients (Baker, 2017). However, compared to peer nations, the U.S. has among the highest number of hospitalizations from preventable causes and the highest rate of avoidable deaths (Tikkanen & Abrams, 2020).

People in Japan have one of the longest health expectancies in the world (Kondo, 2014). There are some factors that contribute to this like the hygienic culture, their diet, but arguably one of the biggest factors is their healthcare system. Japan implemented a nationally uniform fee schedule-- "uniform" meaning the same fee is paid by all insurers to providers no matter the location or doctor (Block & Joffe-Walt, 2009). Due to the goal of keeping healthcare affordable for all, there are bi-yearly negotiations between the government and physicians to discuss the cost of procedures. This led to some services like getting MRI scans being extremely cheap– as low as $160 (Watari et al., 2021)– which could have resulted in people getting these services more often simply to check up on their health (Matsumoto et al., 2015). These services became so popular and people in Japan get MRI scans twice as much as Americans (Norris, 2008).

When looking through the lens of Social Construction of Technology (SCOT), there are various social groups that can drive the development and design of technology to fulfill their needs. An engineer is not the only group that determines the final design of a device and what place it has once it has been introduced, as other groups might behave differently than what is expected. The development of the technology can be variable because of the fact that it is given meaning by different social groups, as defined by interpretative flexibility . Once a social need has been met, the role of the technology and its design will start to stabilize, or reach a conclusive and final design, and thus give it meaning based on its place in society (Bijker &

Pinch, 1984). Once a design has stabilized, its meaning will likely no longer be changed or interpreted differently in society.

To thoroughly understand this problem in depth, it is important to highlight the various stakeholders present: patients, healthcare workers (including doctors, nurses, technicians, etc.), hospitals, insurers, the government, and medical device manufacturers. Patients and insurers might opt to have the cheaper diagnostic tools in order to reduce costs while doctors and hospitals might want to perform more expensive procedures in order to produce a profit. The roles might also be reversed by doctors who might prefer to prescribe cheaper procedures to practice defensive medicine. These stakeholders shape how medical technology will be used and will determine what device manufacturers will create in order to enter the market in response to user needs. SCOT will be used to analyze these complex relationships between social groups and their implications on screening technology similar to MRIs or the proposed pulse waveform instrument and other artifacts.

Methodology and Research Question

How has different countries' regulation on medical service costs influenced accessibility to healthcare technologies?

This question is important as different countries struggle with balancing spending and delivering quality patient care. It is necessary to investigate how two countries shape the quality of care for their citizens through balancing technology innovation and policies as it is their responsibility to keep people healthy. In order to understand the question, evidence collection consists of analysis of surveys, policy documents, and documentary research methods. Literature studies on the number of MRI machines in the US and Japan, the number of procedures performed per capita, and the costs of these procedures will be compared to determine if there are any differences in access to these devices. Different data sets analyzed will be from the Organization for Economic Cooperation and Development (OECD) Health Data File to understand the types of procedures and frequencies of them per year between these two countries. Seeing if there are any differences between the datasets will support reasoning on why certain patients opt to have a certain procedure done or not and will help answer the question of whether or not cost of care has an influence on access to care. Lastly, podcasts and documentaries will be analyzed in order to get opinions from select people such as economists, physicians, and patients to determine the quality of care they believe the patients are receiving.

Conclusion

The ultimate objective of the technical project is to refine a working prototype of an instrument capable of measuring PWV and assessing current cardiac risks. The technical deliverable will represent a non-invasive device that is able to be used within a clinical setting with minimal training and high accuracy. This will fulfill the need of specific populations that are at an increased risk for CHD due to financial or environmental factors. Optimally, the use of a medical device to provide preventive care would mitigate the material and emotional cost of more intensive procedures in the future for all populations, but the role of different social groups can influence the power a medical device has on preventing and treating diseases. Determining the roles and actions of these social groups would give a better understanding in how medical services and procedures are shaped based on the culture and demand of different groups like physicians, government, and lastly patients. Understanding these complex relations between social groups and technology will allow us to further design new devices that will provide equal and accessible care for many.

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