Development of a Novel Cardiovascular Health Monitor

(Technical Report)

A Look Into the Pitfalls and Future of U.S. Medical Device Regulation

(STS Research Paper)

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Sociotechnical Synthesis

The technical component of this portfolio is focused upon the creation of a medical device, while the STS research component focuses on the usage and regulation of medical devices. As a biomedical engineer, my goal is to create technology that mitigates the effects of diseases and improves the quality of life in some manner. Because cardiovascular disease is the number one cause of death in the United States, it is an area of great interest to me. In order for any medical device to be used, it must first be approved and classified by the Food and Drug Administration (FDA). I therefore decided to research the current FDA policies as they will affect many if not all of my design projects throughout my career.

Cardiovascular disease greatly impacts people aged 55-65, and accounts for 1 in 4 deaths in the United States. Different devices are able to give a single indicator of cardiovascular health, but no one device non-invasively provides a comprehensive readout of the state of the cardiovascular system. My research team created a health monitor that non-invasively measures different cardiac health indicators, the focus being on pulse wave velocity, a measure of arterial stiffness and risk for cardiovascular disease. Using a variety of different sensors in conjunction with novel methods for measurement, this device was able to measure a patient's pulse wave velocity, metabolic equivalents of task, blood pressure, and blood saturation level. IRB-approved clinical trials for the device were conducted. The measurements from the device were analyzed, internal device error was calculated, and correlations with variables such as age, body mass index, and the onset of diabetes were calculated. The use of a novel method of pulse wave velocity in conjunction with other cardiovascular indicators allows for quick and non-invasive cardiovascular health assessments during clinical visits, and can ultimately aid in preventing cardiovascular diseases.

In the United States, the distribution of all medical technologies to market is regulated by the FDA. My STS research focused on how current FDA medical device regulatory policies are harmful to patients, investors, and healthcare professionals alike, and how they might be improved. The FDA's lack of complete surveillance systems for devices throughout their lifetimes particularly impacted safety, and the low cost of submitting a moderate-risk device as compared to a high-risk device incentivized companies to submit devices using the former application. Actor-network theory was used to describe the role and impact of technology in the healthcare environment, as well as how technology changes power dynamics. Employing technology-in-practice allowed for the examination of the goals that a technology can accomplish for users by their delegation of work to it. A policy analysis was conducted in order to determine the best alternative to the current FDA processes for medical device regulation and registration. Policies from Japan, South Africa, and Canada were compared to one another. Using three different criteria for analysis, Canada's policy was identified as the most suitable replacement which prioritizes patient health and safety while allowing and incentivizing innovation. Together, these projects offered insight into how technology affects public health both on a micro-level (interactions between healthcare providers and patients) and on a macro-level (influence of government on local hospitals).