Design and Manufacture of Wearable Devices

Privacy Concerns Due to the Widespread Use of Medical Wearable Devices

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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

The largest problem presented by the ever-increasing use of wearable devices is the privacy of the collected data. While the wearable devices present a potential for an increased degree of care provided, the privacy concerns that stem from the constant data collection is unavoidable (Dinh-Le, Chuang, Chokshi, & Mann, 2019). The technical innovation made by wearable devices has the potential to create large rifts between different groups of Americans if not properly mitigated and fought against.

Wearable devices allow healthcare providers to remotely collect data on their patients, allowing for a higher level of care and a handful have already been implemented in the United Kingdom (Vijayan, Connolly, Condell, McKelvey, & Gardiner, 2021). Additionally, the data can be collected over a significantly larger window as compared to a simple check-up or doctor's visit. Those with a chronic illness would not have to go into the doctors' office as much, as the data can be taken and analyzed remotely, allotting those patients with a higher level of autonomy. Even those without chronic illness can benefit from the remote tele-health possibilities. The general population can be more aware of the data that their bodies will have. For example, a wearable device to measure blood pressure, or heart rate allows a quick check of basic health functions and would allow one to see trends over time.

One challenge needed to overcome is the reliability and manufacturing scalability of the devices. By analyzing and refining prototypes to reduce flaws and increase reliability, the devices can be utilized to provide constructive data to be analyzed. Additionally, streamlining the manufacturing process, and creating different stuff to use, the advantages of the devices can be fully reaped to provide better physical therapy rehabilitation (Tectales, 2020).

Wearable devices present an opportunity for healthcare providers and government officials to easily gather information about its subjects and as such provides an informational and financial incentive for them to offer such services. Those without the financial means for alternative healthcare plans will have no other option for care other than to give up their data.

Americans already distrust the government, with 55% of Black Americans not trusting the healthcare system and 1 in 5 unvaccinated Americans not trusting the CDC. Evidenced from the COVID-19 pandemic and vaccine rollout, a surprising number of Americans do not trust the CDC and the healthcare advice from the government. If these Americans cannot trust the Center for Disease Control (CDC), how will they react to the technological advancements provided by wearing devices that constantly transmit healthcare data to their healthcare provider or the government? The devices provide a notable increase in care provided to patients while decreasing the amount of privacy allotted to the patients. In order to fully utilize the innovation of wearable devices, the privacy concerns generated by these devices must be mitigated.

While widespread use of wearable devices in healthcare will provide greater, more comprehensive coverage to millions of Americans, there may be rifts created and exacerbated, between socioeconomic statuses, races, and geographic location due to the different healthcare methods used to treat patients. Improving the reliability, accuracy, and manufacturability of the devices is a must to further implement the devices in healthcare scenarios. In order to fully utilize the advancements from wearable devices the downsides of privacy concerns must be addressed.

Technical Topic

Even after the height of telehealth services in April 2020, telehealth is up 38x since before the pandemic and still has greater benefits to be reaped (Bestsennyy, Gilbert, Harris, & Rost, 2021). In doing so, there are significant challenges that must be overcome to provide the same quality care remotely instead of in person. Wearable devices specifically allow doctors to gather, analyze, and treat patients remotely. As seen with the COVID-19 pandemic, patients and doctors can seek and receive treatment without fear of infecting others or being infected themselves. Patients, and by extension society, are open and searching for alternatives to the traditional doctors' visits. Between 40 and 60 percent of Americans are searching for a broader virtual health solution, including virtual visits and potential for lower costs as well (McKinsey).

One consideration is those that may not have a doctor near them, specifically those that live in rural areas. With an internet connection, these people have the option to receive as specialized care as those living further away. The patient could be mailed the sensors, self-apply them, and follow up with doctors to monitor general health and specific conditions. The alternative is the patient having to travel great distances to receive care that can only happen in office, instead of monitored remotely. As such, one's geographic location is independent of the relative level of care that can be received. As a result, patients must travel to receive care only when absolutely necessary, based on their self-gathered data, instead of regular visits or for smaller concerns. Additionally, these patients can be connected with any specialist they might need, instead of being required to travel to receive specialized care.

Wearable devices encompasses a large breadth of topics. One section that is rapidly innovating with promising benefits is skin-like, lightweight devices. These devices are extremely lightweight with a small footprint, allowing wearers to resume normal activities while being monitored (Hammock, Chortos, Tee, Tok, & Bao, 2013). While healthcare technology is rapidly

trending towards this goal, current technology does not exist where the sensors can be worn and collect accurate data for weeks at a time.

Manufacturing of the sensors: Properly manufacturing the strain sensor requires care and precision. A design is 3D printed and Polydimethylsiloxane (PDMS) is poured and molded to produce the bottom layer of the sensor (Ray et al., 2019). Once cured, the mold is carefully removed and a mixture of carbon nano-tubes (CNT's) and additional PDMS is placed in the negatives left by the mold. A final layer of PDMS is placed over the CNT and PDMS mixture, completely enclosing the CNT's and producing the fully complete strain sensor once cured.

Design of the sensors: One specific application of this strain sensor is to measure muscle usage and extension for athletic and physical therapy purposes. Stain data gained would be analyzed to provide key metrics such as overexertion, providing physical therapists the data to progressively improve range of motion and exertion of specific muscles to rehabilitate patients. A strain sensor design, shown below, has multiple switchbacks that work based on electrical resistivity.
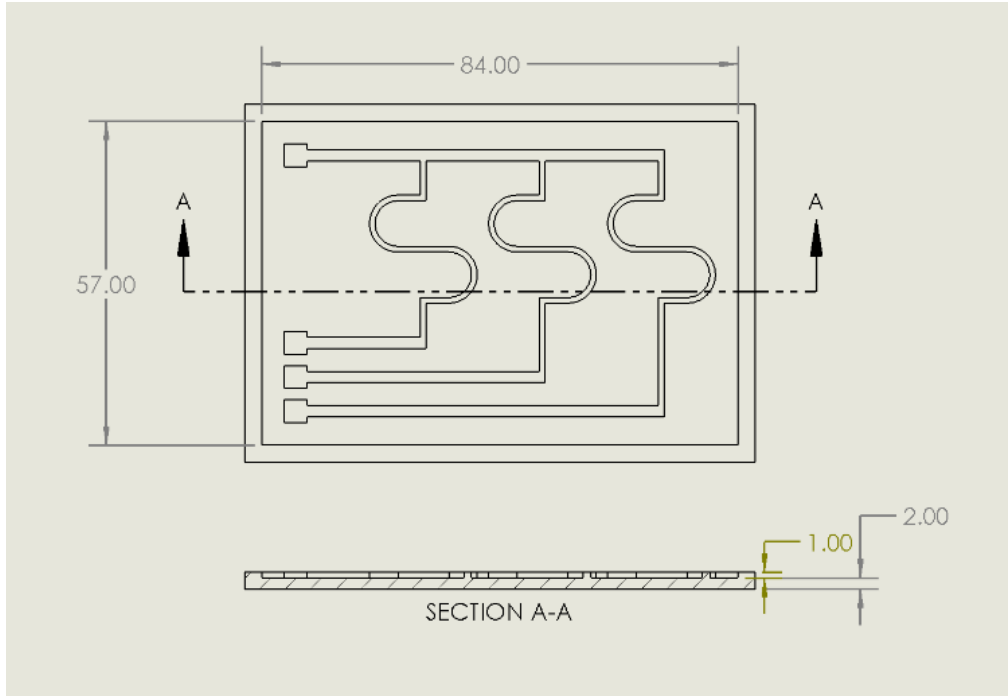
As the skin is stretched, the long straights of the sensor elongate, causing a deformation in the electrically conductive portion of the device, changing the total resistance of the path of CNT's present (Lipomi et al., 2011). Hence by measuring the change in resistance through the path and calibrating the data, the strain experienced on the skin can be measured. The many switchbacks and turns in the device to provide greater resolution in the data. Further research must be performed to optimize the size, turns, and switchbacks present in the design.

Other areas of focus and innovation in the wearable device space focus on the power supply and telemetry sections of the devices. As the devices are extremely thin and meant to be unnoticable, any wires or batteries to the sensors provide a hurdle in the widespread adoption of these wearable devices as the comfort and convenience of the devices are significantly reduced. For controlled, short stint, physical therapy cases, current designs allow for research into the

The most important part of any design is the manufacturability of the device. Another problem presented by these skin like devices is the robustness and scalability of manufacturing. With more switchbacks in the device, the more precise and greater manufacturing capabilities are required due to the greater number of failure points. With more switchbacks in the design, either the physical size must increase, or the switchbacks must be thinner and tighter, leading to tighter manufacturing tolerances.

STS Topic

The technology created by these wearable devices and other monitoring systems in healthcare is extremely powerful, has the potential to save countless lives, and allows a higher level of care to its patients. In addition to the positives, there are significant privacy concerns stemming from the integration of these sensors and monitoring systems. Primarily affecting those in lower socioeconomic brackets and geographic locations, these groups will be unfairly negatively affected by the implementation of the devices. These repercussions may primarily affect those with lower socioeconomic status and could culminate in a greater discrepancy in healthcare between socioeconomic statuses. Other consequences of the growing use of wearable devices includes the divide between urban and rural areas receiving different styles of care.

MbientLabs is making strides using wearable devices and data analytics to provide increased care to physical therapy patients. Their device is called MIOTherapy (MIO) and requires a monthly subscription to use its software and hardware. Independent research from the University of California indicates an increased patient compliance from 20 to 80 percent (Odtmag). Wearable devices, specifically MIO, are already making improvements in the physical therapy section of healthcare therapy, including the monthly subscription. Patients that

cannot afford this style of care will not have the same opportunities as those with the money to afford this care. As wearable technology improves and becomes more integral in healthcare, those in lower socioeconomic classes will receive a lower quality of care as they cannot afford the more expensive options.

Seen from Catherine Lang et. al, the future of wearable technology in the physical therapy setting is wireless communication to healthcare providers to monitor progress and offer input remotely (Lang, Barth, Holleran, Konrad, & Bland, 2020). Many privacy concerns are prevalent, including who has access to this data, how to properly safeguard the data, and mmmmmm. As wearable technology is integrated further into physical therapy and healthcare, patients will not have the option to keep their data privacy. Healthcare providers will

White Americans are more likely to be vaccinated than black or Hispanic Americans, displaying the disparity present in race and the difference in healthcare treatment, wether intended or not. 55% of Black Americans do not trust the healthcare system, presenting a large rift that may be further expanded with the further implementation of wearable devices as compared to White Americans (Hostetter & Klein). Black Americans may not elect for the wearable devices, due to privacy concerns and distrust of the healthcare system. Therefore, there may be racial divides present in the diffusion and use of this new technology.

Another point brought into light is the government and healthcare provider overreach and distrust present and related to the improvements from wearable devices. As evidenced with the COVID-19 pandemic, even though the vaccine has been proven to significantly help against COVID-19, some Americans do not receive it for a variety of reasons. Less than one in five unvaccinated Americans don't trust medical advice from the CDC (Frankovic, 2021). If the

government regulates these wearable devices, how will they accept the fact that this technology provides a more comprehensive level of care and will eventually be federally regulated if these Americans do not trust the CDC itself? Now they are told to literally wear a microchip to monitor their health. While there is no concrete data for this speculation, if they do not trust a vaccine during a pandemic for microchipping concerns, how will they trust being monitored further in everyday aspects around their life? These devices give a higher level of personalized care, but at a massive privacy and trust cost that will be unacceptable for a large number of Americans.

Additionally, insurance companies will begin to incentivize these devices and sensors, as they will not only be able to provide healthcare at a higher level, but they will also have access to the valuable lifestyle data of the patient. As a result, those with a lower income will not have the option for increased privacy and will be forced to give up their privacy due to monetary restrictions. Inversely, those with the funds will have the choice between better care or retention of privacy. From this discrepancy, there will be different levels and methods of care administered to those of differing socioeconomic status.

With the design of the sensors, their lightweight capability, and the relative ease of installation, patients could apply the sensors themselves with the help of their doctor. With telehealth being such a huge market, specifically during the pandemic, if a patient feels that something is off, they can apply the sensor from the comfort of their home and send the data to their healthcare provider, allowing the greater option for telehealth as compared to previously. For physical therapy, patients could wear the sensor to measure their motion of joints and muscles and gradually work to rehabilitate them over time with data driven progressions. Additionally, patients could regularly wear the sensors, specifically while performing strenuous

activities or sleeping to help their doctors monitor the issues that face them. Patients could take a more proactive approach to their health and even when a doctor is not immediately available, collect data for the doctors to analyze once available. Overall, with the technology and prevalence of wearable devices, there will be more data collection which must be taken with care.

A downside with wearing these wearable devices is the extreme level of tracking on the patients. As doctors can monitor their patients remotely, they are transmitting data to be stored and used by their doctor (Fischer, 2021). Patients would be subjected to intense amounts of data collection, with potentially catastrophic side effects. If this data got leaked somehow, the hackers would have an extreme amount of health information that could be used maliciously. Some patients and their data could be subjected to experiments and studies without their consent. With the extreme amount of data collection possible, health insurance companies could look specifically into each patient, determine their risk, and refuse to cover services or increase prices on those they deem more at risk. Any cultural differences could cause price increases and could be discriminatory towards certain groups of people.

In anticipation of the legal and social issues presented from these wearable devices, there will be anticipatory governance to ensure the smooth rollout and gradual transition to wearable devices. If not properly mitigated, there will be significant consequences if the data collection process, analysis, and patient privacy practices are not governed correctly. As telehealth services have shown their potential during the COVID-19 pandemic, legislation must be passed proactively to ensure the health and safety of the American people.

Research Question and Methods

The research question that will be investigated and presented is how the data collected will be safeguarded and not used for harm. It will be just as beneficial to understand where the data will be used by healthcare providers to pinpoint where the greatest vulnerabilities lie. Using this information, it can be clearly shown where anticipatory governance must be applied to mitigate the downsides of the wearable technology. The research will be gathered by further academic research into the details of the data collection procedure and regulations to understand how the wearable technology data will be collected and potential weak points that legislation can regulate before privacy issues are exploited. Additionally, current regulations must be analyzed to understand how patient privacy will be affected by the technology and new required regulations.

Another key aspect that requires research is the impact of differing patient care on disparities in income, location, and race. As all three stated groups will be impacted differently, rifts may be potentially formed, stemming from the slightly different uses and implementations of wearable devices. While the level of patient care for each of the above stated groups cannot be changed, their impacts can be understood and mitigated such that wearable technology does not further the disparities and potentially closes gaps in the above groups.

Conclusion

With the benefits of wearable, remote devices, patients could be required to wear them more and more frequently at home and in certain locations. Under this amount of surveillance, the patients could feel uneasy and cause increased anxiety from the severe amount of data and the stress of providing reliable data to their doctor. Additionally, if they cannot see where the

data is being sent, how can they ensure that it is not getting into the wrong hands? How can one be protected against malicious intent, such as hackers, to steal their information?

For any of the above reasons, if the patient does not choose to use these wearable devices, they would not receive as high quality of treatment provided by the wearable devices. This late or non adoption of wearable device technology will unfairly impact Black Americans and those with lower socioeconomic status. Additionally, due to the increased monitoring and price of the sensors, the treatment could end up being higher cost and only available to those in a certain socioeconomic class. Either way, those who do not subject themselves will be at a disadvantage compared to those that do.

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