Prospectus

The Design of a Mechanical Power Bank

(Technical Report)

Telemedicine: Efficacies of Healthcare's Newest Innovation

(STS Research Paper)

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Introduction

The way that people view being treated for medical issues has changed over time. In the age of technology where constant innovations are being created it is important to look at how these can transform the healthcare industry. Akili Interactive Labs is a company that is in the process of getting Food and Drug Administration (FDA) clearance on a digital therapeutic for pediatric attention deficit hyperactivity disorder (ADHD) (Goode, 2017). The company must go through the same tests and trials that any other drug or medicine would have to go through in order to get approved by the FDA (Science and Technology, n.d.) Akili could change what it means to be treated and what can be defined as a medicine.

As the Telemedicine team my colleagues: David Crowder, Vinny Sciortino, Vikram Seshadri, Daniel Wang, and I are on a mission to address the usefulness of telemedicine and smart health within the Charlottesville area. We hope to increase accessibility of healthcare of the Charlottesville populations by developing an interactive home experience centered around a digital platform that brings a more holistic doctor/hospital experience to individual homes. The platform would incorporate virtual diagnostics, distribution of prescription drugs, and scheduling for regional healthcare clinics. I am focusing on the way big players in the medical field and its users interact with telemedicine.

As a 4th year engineering student of the Mechanical Engineering department under Dr. Mike Momot I am working on a capstone project with my fellow colleagues: Maria Contreas, Rojeen Kamali, Grant Kim, and Rachael Osborne. The goal of the project is to go through the entire design process in order to create a versatile device that acts as an energy storage and charges via movement. We want to build an innovative technological deliverable that can incorporate a mechanical process to charging rechargeable batteries.

Technical Topic: The Design of a Mechanical Power Bank

How can my team design and manufacture a mechanical means of recharging batteries?

The goal of the project is to create a compact inexpensive Power Bank that can strap to a limb or object. The charge will be created through induction as a magnet moves through wire coils as the user moves. The target demographic is for hikers, runners, or other outdoor enthusiasts. There is a common reliance on technology as more and more innovative tech is put out on the market. Not always is there an electrical outlet readily available for recharging a device. Mechanical means of charging can be useful because it is possible with far less restrictions in terms of location.

The main characteristics of our design that we want to focus our efforts on include: durability, comfort, ease of use, adjustability, efficiency, versatility, and portability. We want to create a product that is comfortable for the user to wear, compact so that they can use it on the go, and efficient at charging a mobile electronic device. At a minimum the design must meet these certain criteria: remain functional after a 3-foot drop from a tabletop, be aesthetically pleasing, be ergonomic with no serious weakness, and last a minimum of 20 minutes of

continuous usage for longevity. There is also a financial constraint of $400 USD as the budget for the project over the year.

A similar product that used to be on the market is the nPower PEG (Personal Energy Generator) (Lasky, n.d.) The premise of the device was to capture and store kinetic energy created from walking, running, and biking and use it in order to recharge mobile electronic devices. The device cost $200 USD making it pricy and probably not for the average person. It is large with 10.5 x 2 x 1.5 inch dimensions making it inconvenient to carry. The nPower PEG is no longer available for purchase leaving room for our product to fill a demand (Rei, n.d.)

In order to tackle the process of fabricating a device that charges batteries using a mechanical means we will go through the design process. The steps include: identify opportunities, research the problem, develop specifications, ideation, screening/selection, rough design/testing, detailed design/testing, iterations, and manufacture. As individuals we will sketch ideas of different ways that we could make a device that can recharge batteries via mechanical means. A project screening will be done of the best ideas from each member of the group in order to narrow down the pool of ideas. We will use CAD software such as SOLIDWORKS in order to create a model of our design. We will convert the CAD model into model that can be 3D printed for any parts possible using the Makerspace or Mechanical Engineering Lab. All parts that can be procured on the market without having to design them will be in order to make the process simpler and the device cheaper.

By the end of the year we will have a deliverable final packaged device that meets or exceeds the designated criteria. The device can then be constructively critiqued in order to see the strengths and weaknesses on where it could be improved. The research conducted into the device and the device itself can go towards teaching future undergraduates in Mechanical Engineering at the University of Virginia about the design process.

STS Topic: Healing from a Distance: The Social Construction of Telemedicine and its Regulation

Introduction

Everyone deserves to live a long, fruitful, and healthy life. The healthcare system is like a maze in that is it very difficult to navigate effectively. In particular, the rise of digital health, a newly emerging field which integrates healthcare service with advanced digital technologies has caused significant economic, technical, and regulatory challenges.

The development of telemedicine provides a perfect example of illustrating the social-technical complexities. The definition of Telemedicine according to the World Health Organization (WHO) is “The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities,” (TELEMEDICINE, n.d.) The WHO definition indicates that telemedicine is not a traditional medical service which

requires patients' and physicians' physical presence. It instead fundamentally changes the interaction between healthcare provider, consumer, and government regulators. In this thesis, I want to address what forms of telemedicine have been implemented in the United States. I want to look at how these different forms of telemedicine have been regulated and by whom. I want to find out what types of medical issues are targeted by telemedicine. Lastly, I want to focus on how these existing methods and regulations have been effective or ineffective in assisting disenfranchised communities within the United States.

Literature Review

There is a wide variety of illnesses that can be addressed by telemedicine. The Seattle Veterans Administration Medical Center employed telemedicine in order to provide follow-up care to patients with Parkinson's disease (PD) (Telemedicine for delivery of health care in Parkinson's disease, 2006). These patients were anywhere from 67 to 2400 kilometers from the medical center. The results of this form of telemedicine was 1500 travel hours, 100,000 km travel distance, and 37,000 USD cost of travel and housing all saved. Studies have shown that telemedicine can be very beneficial in the treatment of chronic diseases. Hepatitis C Virus (HCV) is a liver infection that can lead to liver damage due to inflammation within the infected person. The Extension for Community Healthcare Outcomes (Project ECHO) was a program developed in order to increase accessibility to interferon-based treatment for patients with HCV in rural areas of New Mexico (Current and Future applications of Telemedicine, n.d.) They used video teleconferencing as a means to increase the expertise of health care providers and HCV treatment initiation for patients. The Project also extended into Utah and Arizona showing high success rates for continual treatment of HCV and a sustained virologic response. Similarly, telemedicine was used in the treatment of Chronic Liver Disease Mexico (Current and Future applications of Telemedicine, n.d.). The technology is used as a remote monitoring system for patients with the disease or after a liver transplant. Daily weights, blood glucose reading, and vital signs are transmitted to a transplant center that sifts through the data to decrease the amount of re-admissions to the hospital. In a study of 20 liver transplant patients using smart tablets to transmit this information, patients with 100% daily interaction were not re-admitted.

The FDA has had to change the way in which it views what a medical device is because of new technologies. A subsection of the FDA, the Center for Devices and Radiological (CDRH) created a digital health program to assess and regulate digital health technologies (Center for Devices and Radiological Health Digital Health n.d.) The International Medical Device Regulators Forum (IMDRF) of which the FDA is a member come together in order to synchronize the standards of regulations throughout the world. They defined software as a medical device (SaMD) as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." (Center for Devices and Radiological Health Software as a Medical Device n.d.) SaMD presents a new issue in how to assess the safety and effectiveness of these new programs as medicine. There is a framework of criteria that a developer should aim to assess in the design of SaMD. Clinical Validity, scientific validity, clinical performance, and analytical validity are the four main aspects that need to be addressed (Whitten, Drori, Lacktman, Foley & Lardner LLP, n.d.) Clinical validity is

where the developer shows that the SaMD has usefulness in terms of its patient care. Scientific validity is when the developed creates an association between the SaMD's output and the intended condition that is to be treated. Clinical performance demonstrates that the SaMD does what it is intended to do and benefits the patient. Analytical validity is the way that the developer shows that the SaMD is able to generate the expected results via proper design.

With the creation of these new telemedicine technologies in the digital era problems involving privacy arise. The means in which the sensitive health information is being transmitted needs to have a high degree of security in order for patients to trust and advocate for telemedicine. There have been arguments for a single federal organization, the Federal Trade Commission (FTC) to coordinate the creation and enforcement of extensive privacy and security standards (Hale & Kvedar, 2014). While the FDA has a major regulatory presence in the healthcare industry, telemedicine changes the way privacy and security need to be handled and regulated.

STS Framework and Methods

This project takes the framework of the social construction of technology (SCOT, Figure 1) to investigate the interests and roles of the telemedicine constructors. The primary stakeholders that I am focused on include the FDA, pharmaceutical companies, insurance companies, and the patients. The FDA is a federal agency in the United States responsible for regulating drugs, medicines, medical devices, etc. for the sake of promoting public safety. Pharmaceutical companies spend billions of dollars on research and development for new drugs and technologies that are capable and efficient at treating medical issues. These big pharma leaders have also begun investing into other companies that use digital technologies as a form of healthcare. For instance, Proteus Digital Health partnered with Otsuka Pharmaceutical to address digital medicine tracking. Sandoz partnered with Pear Therapeutics to work on digital therapeutics (Licholai, G., 2019). Insurance companies cover a variety of medical, surgical, and dental expenses for a patient that has it. Twenty-six states have "Parity" laws that require private insurers to provide reimbursement for services delivered through telemedicine (Will My Insurance Cover Telemedicine, n.d.) There are nuances within each state that may vary. Certain states require an in person visit before a provider can be billed for telemedicine. The amount of coverage that insurers are required to pay can vary based on state law. More states are considering the adoption of these Parity laws because of the value of telemedicine. The patient is worried about getting the best healthcare possible in the most efficient and convenient way on an individual basis. The healthcare system becomes incredibly muddled because of its complex nature with so many different facets and players.

In terms of research method, I am going to use the follow methods to collect my research data. I want to gain a better understanding of what goes into the decision process of how telemedicine is regulated through the big players. I plan to contact the Food and Drug Administration. More specifically, I want to get into contact with the Division of Industry and Consumer Education (DICE) branch of the FDA. They answer questions about the uses and regulations of medical devices. I will also look into the various documents that go into the decisions made on how to regulate telemedicine. The Health Insurance Portability and

Accountability Act (HIPAA) will be one of the documents I will look at in order to see how the guidelines outlined affect how telemedicine is regulated. This law protects patient privacy while allowing certain electronic protected health information (ePHI) to be shared through digital platforms (hipaanswers, 2017). Additionally, I will look into documents released by the IMDRF and the Software as a Medical Device Working Group (WG) as it pertains to the possibility of a telemedicine software that could help the rural Charlottesville area.

Through my STS research, it has given me a better understanding of what telemedicine has and can do for the healthcare industry as a whole. There is a large number of moving components and player that each have a hand in bringing healthcare to people. I want to further my knowledge in telemedicine and its players in order to apply its uses to the Charlottesville community.

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Figures:

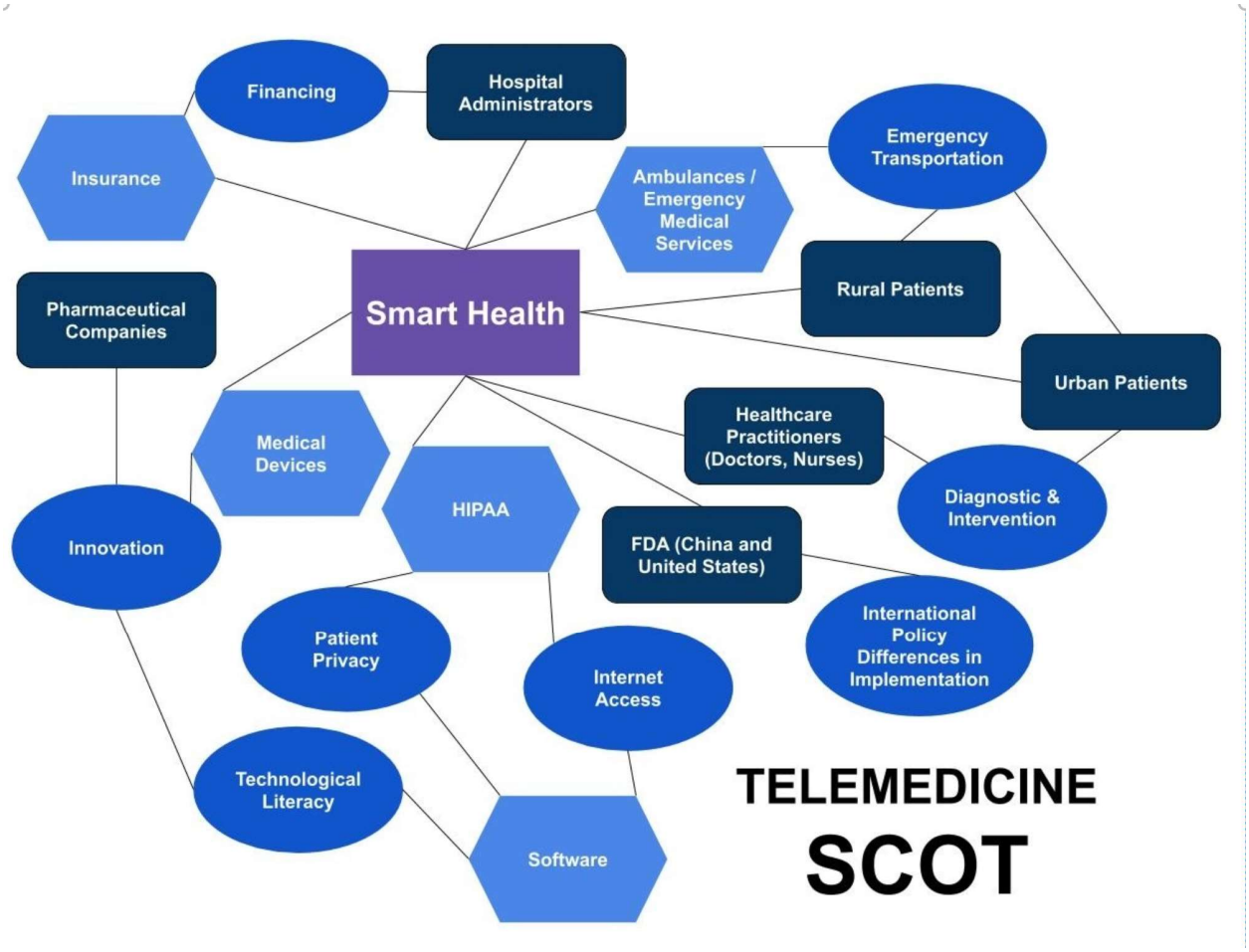

Figure 1 Social Construction of Technology Diagram for Telemedicine