REDESIGNING THE INCENTIVE SPIROMETER

ACCESSIBILITY WITHIN THE MEDICAL DEVICE INDUSTRY

A Thesis Prospectus
In STS 4500
Presented to
The Faculty of the
School of Engineering and Applied Science
University of Virginia
In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science in Biomedical Engineering

By
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November 1, 2021

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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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Of the approximate 200 million major surgeries performed each year, about 16% of those patients will experience some complication within 30 days. Postoperative complications disrupt patients' recovery progress and negatively impact other aspects of life. Though some complications are well-understood, postoperative pulmonary complications (PPC) are under-reported (Patel, 2016). To avoid developing PPC, patients typically receive a rigorous recovery regimen along with pertinent medical devices. From surgical gloves to incentive spirometers to ultrasound technology, medical devices are integral for patient recovery, therapies, and treatments. As such, it is essential for medical devices to be as accessible to the general public as possible. For able-bodied individuals, it is quite easy to forget the physical privileges granted to them, one privilege includes being able to access and use certain medical devices.

The technical and STS projects focus on two separate yet related topics. The aim of the former is to improve patient adherence, and the aim of the latter delves into the lack of accessibility to medical devices for disabled individuals. The overall research motivation for both the technical and STS projects is to ultimately improve patient experience. By attempting to improve patient adherence to a medical device, patients will ideally be less likely to develop PPC and avoid any adverse complications following surgery. Furthermore, in addressing the shortcomings of medical devices for disabled people, medical device technology design can evolve to become more inclusive and accessible.

The STS research project is tightly coupled to the technical project of redesigning the incentive spirometer not only because both are related to medical technology, but because the problem discussed in the STS research project arises from the technical project. Pacey's Triangle as well as an STS Framework illustrating technology and social relationships will aid and guide the STS research project. The technical project exemplifies the lack of accessibility of medical

devices, since the original design process did not take into account end users with physical

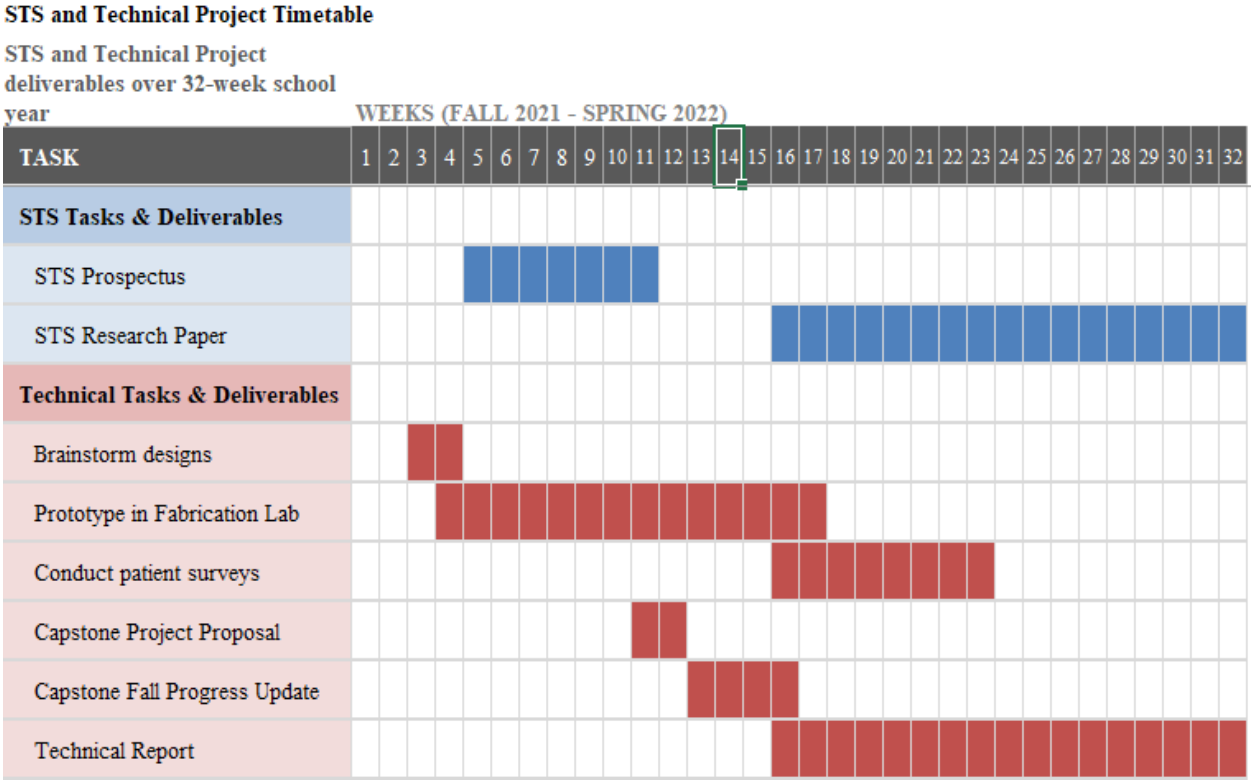

Figure 1: Gannt chart of STS and technical project work. This chart represents the approximate timeline of major deliverables for both STS and technical projects. (Talicuran, 2021)

disabilities. Figure 1 depicts a Gannt chart representing the overall timeline of both the technical and STS project; which will be completed during the Fall 2021 and Spring 2022 semesters, both of which are 16 weeks long. Also included in the timeline are other STS and technical deliverables throughout the semesters.

REDESIGNING THE INCENTIVE SPIROMETER

After undergoing abdominal surgery, patients often experience decreased lung compliance as a result of pain, alveolar collapse, known as atelectasis, and a compromised ability to reach maximal inspiration (Westwood et al., 2007). Such conditions are examples of PPC, which refers to a group of conditions damaging the respiratory tract; other conditions include a

lack of oxygen in tissue (hypoxia), bronchospasm, and pulmonary infection (Patel et al., 2016). PPC occurs in up to 40% of patients that have undergone abdominal surgery, not including patients recovering from some respiratory infection. Conditions in PPC range in severity and create the need for additional drugs and therapies, longer hospital stays, and can result in death.

Recently, the COVID-19 pandemic made PPC more relevant than it has ever been before. In an observational study conducted by COVIDSurg Collaborative, researchers reported the clinical outcomes of COVID-19 patients who underwent surgery. Out of 1128 patients, 577 patients experienced at least one PPC; a little over a half of patients with perioperative SARS-CoV-2 infection experienced complications and a high mortality rate. Furthermore, COVIDSurg Collaborative even states that the "postoperative outcomes in…patients are substantially worse than pre-pandemic baseline rates of pulmonary complications and mortality" (Nepogodiev, 2020, p. 36). Given the urgency of the pandemic, it is imperative to use any strategies or devices to prevent PPC from developing at all. The incentive spirometer is a plastic, handheld medical device that is typically used to lower the risk of developing PPC; Figure 2 illustrates a common design of the incentive spirometer. The primary role of the incentive spirometer is to exercise the lungs and expanding alveoli in the lungs that may have collapsed due to general anesthesia. In addition to restoring the lungs to proper

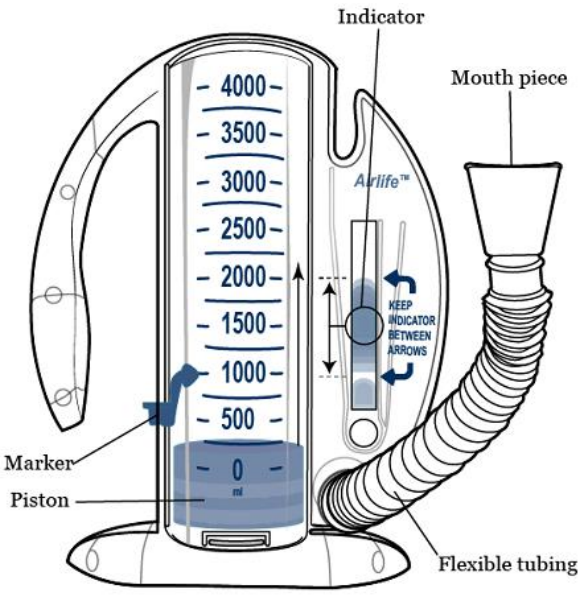

Figure 2: Typical incentive spirometer design. (Memorial Sloan Kettering Cancer Center.)

condition, the incentive spirometer also decreases the occurrences of PPC that may occur during recovery (Westwood et al., 2007).

Despite how crucial this device is in recovery, the technical advisor for this project, Dr. Masahiro Morikawa, MD, MPH, the clinical director of UVA Family Medicine, noticed that patient adherence to using this device is consistently poor. Furthermore, in a study conducted by Eltorai et al. (2018) regarding incentive spirometry adherence, respiratory therapists and nurses agreed that patient adherence improve (p. 534). To do so, Eltorai et al. (2019) conducted another study introducing an alarm-like device that rings to track patient usage of the incentive spirometer, which did seem to improve patient adherence (p. 579). Dr. Morikawa took a different approach from Eltorai et al. and proposed that poor patient adherence can be attributed to the boring design of the incentive spirometer. Therefore, Dr. Morikawa believes that by redesigning the device and adding a 'gamified' component, patients would be more encouraged to use the device consistently, thus improving overall patient adherence.

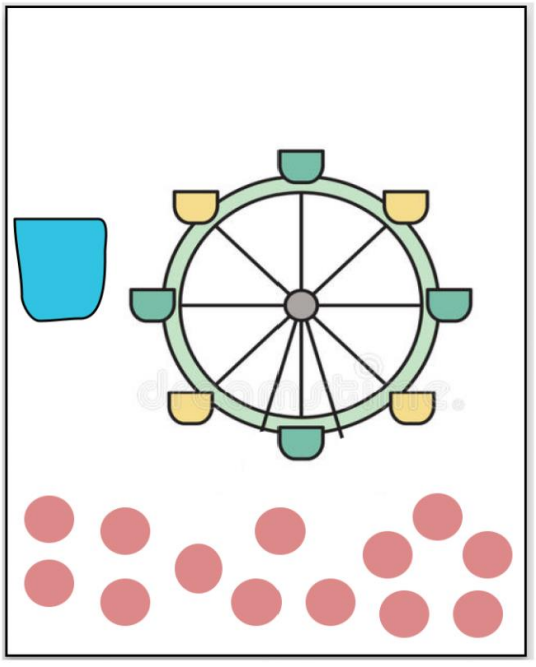

Figure 3: Preliminary 'gamified' incentive spirometer design. This design was created to convey the overall design idea. (Talicuran, 2021)

Two BME undergraduates started this project last spring, during which they brainstormed and finalized which general gamified design to use. While generating different design ideas, they researched what has been done before to make the incentive spirometer more engaging; some notable examples of prior art include an incentive

spirometer connected to a toy gun, printing designs on the outer casing of the incentive spirometer, and transforming the overall shape of the incentive spirometer (Ebel & Ebel, 2015). However, the undergraduates who first worked on this project concluded that those designs were insufficient because they were either too complicated, bulky, or not engaging enough. They brainstormed several potential designs for the project, but after consulting with Dr. Morikawa, the team decided to incorporate a Ferris wheel within the incentive spirometer. Figure 3 illustrates a preliminary design created by the original team before the Fall 2021 semester. The team had progressed to this extent in the project when the Fall 2021 semester began.

Thus, the next steps are to refine the Ferris wheel design and begin prototyping. So far, the team generated over 40 Ferris wheel designs, which will be narrowed down so the team can focus on a select few to prototype. Most of this prototyping is planned to take place within the Fabrication Lab at the School of Architecture, which houses devices such as laser cutters and vacuum formers to design a plastic medical device. Once the team completes a working prototype, IRB approval will be obtained to survey patients on their experiences with the redesigned incentive spirometer. From patient feedback the team anticipates that the new and engaging design of the incentive spirometer will improve patient adherence. Furthermore, patient feedback will help identify possible areas of the design that need improvement. The technical paper, which will be an engineering report, will be finished after the team gathers patient feedback.

ACCESSIBILITY WITHIN THE MEDICAL DEVICE INDUSTRY

The world is designed for able-bodied people; individuals with disabilities are forced to adapt to the environment rather than the environment adapting for the people. In an article from *The New Yorker*, “When the World Isn’t Designed for Our Bodies,” staff writer Katy Waldman

(2020) reviews and summarizes Sara Hendren's book, *What Can a Body Do? How We Meet the Built World*. Hendren argues that, although disability is in part a result of the physical, it also is a manifestation of how the built world accommodates those with disabilities and determines what a body can or cannot do. Hendren describes how societal norms and contexts shape the built world and how design is capable of accommodating the body. A recurring theme in her book is that "disability 'reveals just how unfinished the world really is'," and this theme can be narrowed down and applied to the realm of medical devices (Waldman, 2020, para. 14).

THE BUILT WORLD OF MEDICAL DEVICE TECHNOLOGY

In the same way that the built world forces the adaptation of the people, the design of medical devices also forces some disabled people to adapt. Able-bodied people are the ideal target audience in the minds of those who design medical devices. Thus, the limitations of medical devices regarding physical disabilities are often overlooked. For example, glucose monitoring devices, whose results are displayed on a screen, cannot be read by those with impaired vision or no vision at all. This is especially relevant for individuals with diabetes that require this device in order to observe blood sugar levels and manage the disease. One common complication of diabetes is diabetic retinopathy, in which the back of the eye, the retina, is damaged (NHS). Without proper treatment, this condition can worsen and eventually lead to blindness; in fact, according to the CDC, "diabetes is the leading cause of new cases of blindness in adults" (Centers for Disease Control and Prevention). Thus, how could a patient who has become blind from diabetic retinopathy possibly use the glucose monitoring device that is so integral for daily life? 40-45% of individuals with diabetes experience diabetic retinopathy; however, medical devices intended to treat diabetes are not accommodating to users with low vision (Abts & Butler, 2017). As another example, the design of the current incentive spirometer

is not conducive for those who are completely blind or experience low vision. To properly use the device, patients must gauge how fast or slowly to inhale by paying attention to visual cues represented by an indicator inside of the spirometer; however, if patients cannot do so, they would not be optimally exercising their lungs if at all. One approach a Azevedo et al. (2018) took to solving this particular problem in children with low vision was an interdisciplinary approach, which culminated in a "respiratory physiotherapy apparatus and sensorial toy," which relied more on auditory cues rather than visual cues (pp. 320-331).

INVESTIGATING INACCESSIBILITY

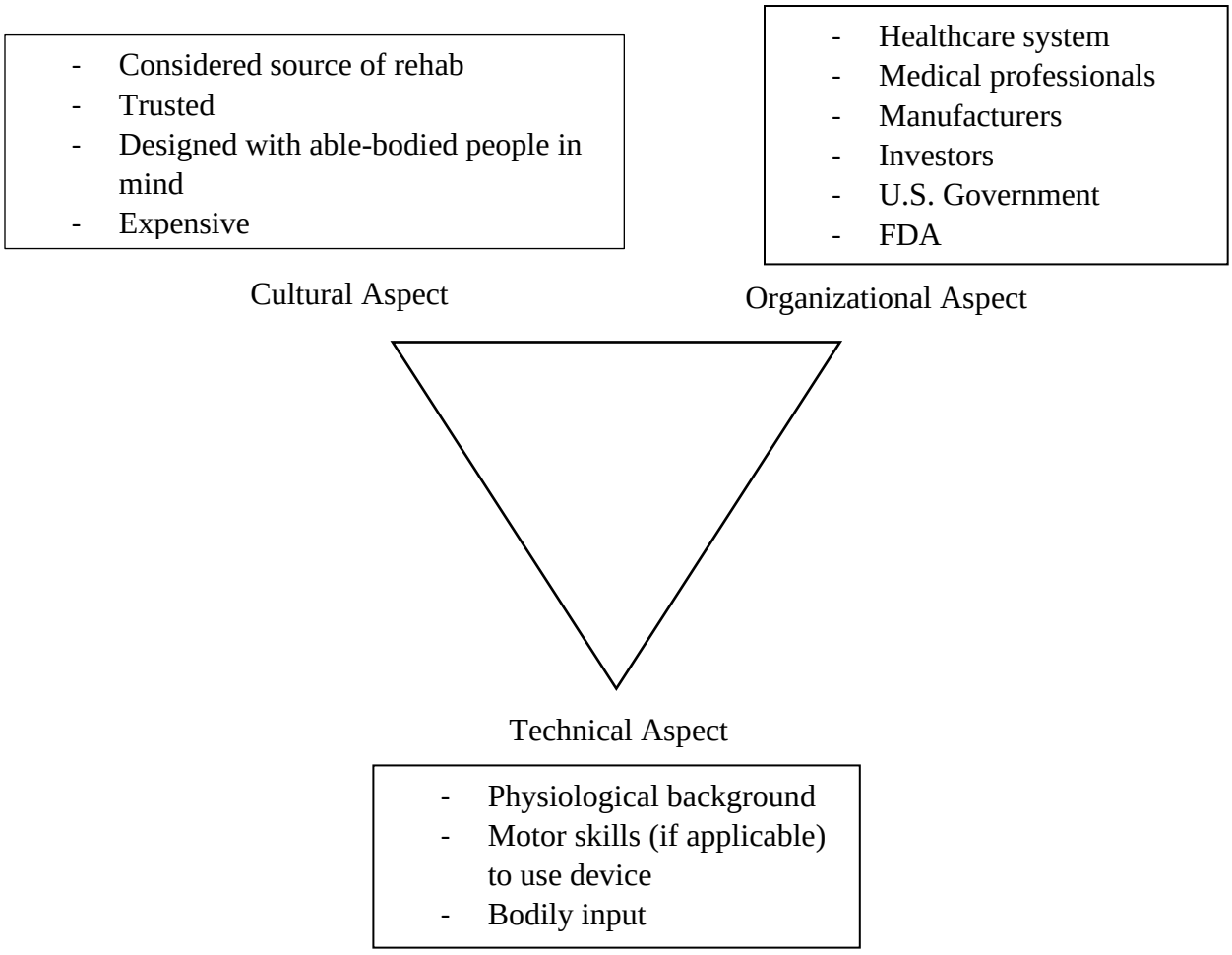

Figure 4: Medical Devices and Pacey's Triangle. Several cultural, organizational, and technical factors are at play within the medical device industry. (Adapted by Talicuran (2021) from Pacey, 1984)

As demonstrated by Azevedo et al., there have been efforts to address this issue, which shows that there is an awareness of the lack of accessibility of medical devices. If that is the case, why is it that currently there does not seem to be a movement to design medical devices to be more inclusive? Such complication can be illustrated in Figure 4 through the cultural, organizational, and technical aspects of medical device technology in Pacey's Triangle. The technical aspects of medical device technology are relatively straightforward, as they include anything technical such as tools needed to maintain the device, resources used up during use, and knowledge and skills required for use. The cultural aspects are more difficult to grasp, as they are mostly abstract, but such aspects include the fact that medical devices are trusted to improve one's health, can be considered a source of rehab, designed with able-bodied people as the primary user in mind, and more. Organizational aspects include a wide array of institutions and individuals. Just by studying Pacey's triangle, there are several potential sources of complicating the problem of increasing accessibility to medical devices. For example, within the organizational aspect itself, each organization or institution possesses its own set of priorities that can clash with those of a different organization. Reed Albegotti and Aaron Gregg illustrate an example of organizational conflict in their *Washington Post* article, "The U.S. paid a Texas company nearly $70 million for ventilators that were unfit for covid-19 patients. Why?" in which the government initiated an emergency contract to buy a type of ventilator previously deemed inadequate by medical professionals. Despite numerous concerns brought up by medical professionals, the government continued with spending millions on the ventilator, which was unsurprisingly insufficient for Covid-19 patients (Gregg & Albergotti, 2021). Although this situation is only tangentially related to the STS research topic, it demonstrates the fact that different institutions clash, and such organizational disagreements complicate achieving better

accessibility for disabled people. Furthermore, it is possible for parts of the organizational aspects to be unaware of the cultural aspects of a technology even though such aspects offer much to learned from and can facilitate decision making regarding that technology.

The number of individuals affected by physical disabilities is not insignificant, which begs the question, how can medical devices be designed to be more accessible to individuals with physical disabilities? Since a multitude of medical devices exist, the scope of the STS research will be aimed at Class II medical devices, which refers to devices that are not as common as Class I devices such as toothbrushes and bandages but can come into contact with a patient's internal organs (Fenton, 2021). Furthermore, there are a multitude of disabilities that exist; however, discussion will focus predominantly on physical disabilities. The purpose of this research is two pronged. First, this research will explore the social factors and processes at play regarding accessibility to medical devices and allow for a comprehensive understanding of this issue. Second, the information gained will guide the development

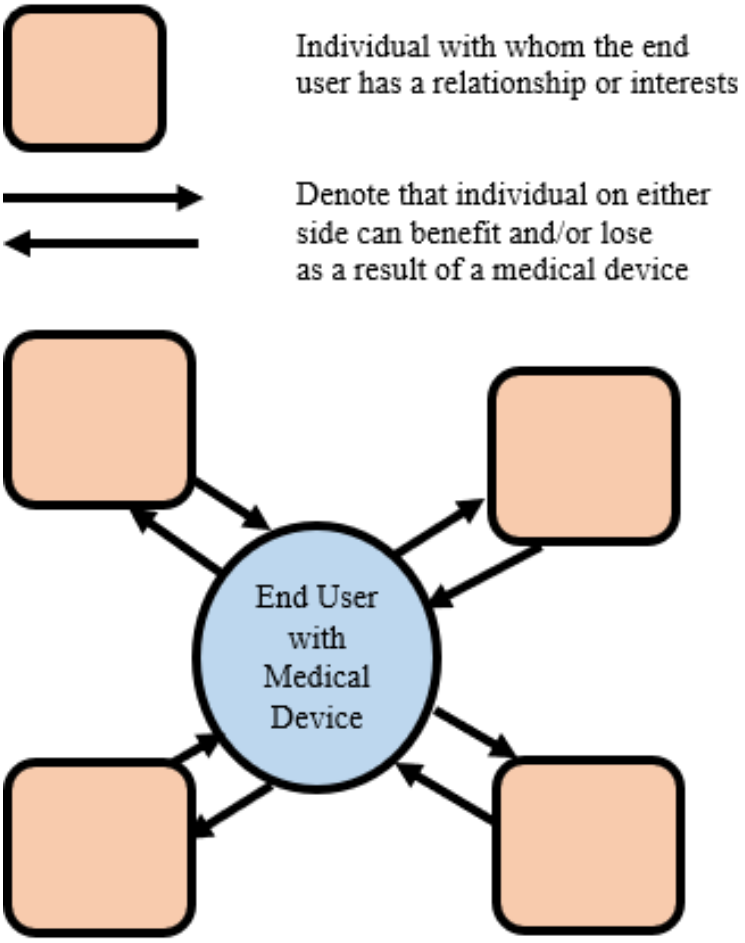

Figure 5: Medical Device Technology and Social Relationships. This particular framework focuses on the end user, which is the patient for both projects. (Adapted by Talicuran (2021), Carlson)

of strategies and a general framework of medical device design to ensure that the device is as accessible and inclusive as possible.

The research will be presented as an analytical paper detailing the current views of the issue and proposing possible solutions. The overall approach to research will be based on one of the given STS Frameworks detailed in the Carlson/Baritaud handout, framework III, which illustrates technology and social relationships. Figure 5 depicts this framework, which stood out over the rest, since the questions associated with it were centered more around the end user. The questions encourage discussion regarding the end users' own experience with a technology, how that experience shapes their social relationships, and whether the technology empowers end-users. This framework also encourages discussion about how different social relationships shape the end users' experience with technology and vice versa (Carlson, 2009). Examples of outside individuals include physiotherapists, physicians, government organizations, medical device manufacturers, and more. The aforementioned individuals and their relationships with the end users are complex and will be further explored in the STS project.

This framework is therefore relevant, since it is end users with disabilities and their lack of access to medical devices that is the central topic of the STS research. This framework questions whether a technology empowers the end user. For some disabled people and medical technology, it is not the case, which was seen with blind diabetic patients and their glucose monitoring device. Studies of this problem conclude that during the design process of medical devices, users and their perspectives must be considered to ensure accessibility. For example, Ghulum et al. (2009) noticed the limitations of medical devices, and they developed and proposed a framework for the involvement of users in medical device technology development (p. 514). The technology and social relationships framework will thus facilitate STS research.

PATIENT FOCUS AND CONSIDERATIONS

The technical project aims to improve patient adherence by engaging the user with a more gamified version of the currently existing design of the incentive spirometer. In doing so, the patients will be less at risk for developing PPC, ultimately decreasing adverse short term and long-term effects of PPC. The STS project broadens the perspective to study not only the incentive spirometer, but also medical devices as a whole and their inaccessibility to disabled individuals. The STS project will also go further in providing insight into how to possibly design more physically accessible medical devices. As mentioned before, both the STS and technical projects are tightly coupled, first obviously because both relate to medical devices in some way and second, the technical project gives rise to the issue explored in the STS project. In other words, the findings from the STS research project can in fact expose shortcomings of the design of the incentive spirometer in the technical project. Perhaps the design process used for the technical project contributes to the lack of medical device accessibility that the STS research project critiques. Thus, the STS research project offers perspectives from end users that the team for the technical project did not consider beforehand.

It is oftentimes easy to forget about the social aspects of the technology, especially the very people such technology is intended for: the patients, all patients. Both projects attempt to break away from such thinking, revealing limitations of medical device technology that had been previously ignored.

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