Redesigning the Incentive Spirometer to Increase Patient Adherence (Technical project)

The Implications of Race-based Adjustments in the Spirometer (STS project)

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 Chioma Illoh

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Team members: Megan Bower, Chioma Illoh, Wendy Lin

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.

ADVISORS

Dr. MC Forelle, Department of Engineering and Society

Dr. Masahiro Morikawa, University of Virginia Family Medicine

Introduction

Chronic lung disease is a general term to describe disorders that affect the lungs and other structures of the respiratory system. Common respiratory diseases include asthma, chronic obstructive pulmonary disease (COPD), and pulmonary hypertension("Chronic Respiratory Diseases," n.d.). There is no direct cure that can reverse these diseases, but there are certain treatments that can reduce symptoms and can help improve lung function("Chronic Respiratory Diseases," n.d.). An example of this is incentive spirometry. Incentive spirometry is a common patient-administered therapy prescribed by physicians to improve lung function after any illness, injury, or surgery that has affected the lung and upper chest area ("Incentive Spirometer," n.d.). This therapy uses a device known as the Incentive Spirometer (IS) for lung-related diseases like COPD, cystic fibrosis, sickle cell anemia, and COVID-19 ("Incentive Spirometer," n.d.). In fact, a study proves incentive spirometry is helpful in enhancing pulmonary function and speech production in children with cerebral palsy (Choi, Rha, & Park, 2016). Another study also found that by adding the incentive spirometer as part of the pulmonary rehabilitation process, it could decrease the occurrence of pulmonary complications and decrease the length of stay in a surgical high dependency unit (Westwood et al., 2007).

Despite the seriousness of these diseases and the effectiveness of this device, patient adherence to this therapy is low. Reasons behind poor adherence include patients forgetting to use the device, patients not using it effectively or properly, and patients not using them as frequently as they should (use of the spirometer is for 1-2 hours a day or however many times the doctor prescribes) (Eltorai et al., 2018). Low compliance to this therapy can result in serious complications like pneumonia and atelectasis. This can result in re-hospitalization and a more expensive treatment plan compared to just using the IS. As a result of poor adherence, physicians may be hesitant to prescribe this device especially if they do not expect the patient to use the device often or properly.

To diagnose these chronic lung diseases, pulmonary function testing (PFT) measures lung volume, capacity, rates of flow, and gas exchange. This test can help the doctor determine a diagnosis and determine if there is an obstructive or restrictive lung disorder ("Pulmonary Function Tests," 2019). A common type of PFT is spirometry which consists of a mouthpiece connected to an electronic machine. This medical device will measure the amount of air you inhale, how much you exhale, and how quickly you exhale. Though this test is helpful in determining a lung-related diagnosis, the test results are not disease-specific even though the results may show an unusual pattern (Respiratory Health Spirometry Procedures Manual, n.d.). For example, if the spirometer records a low Forced Expiratory Volume (FEV₁) measurement, the physician must determine if the cause is asthma, chronic bronchitis, or another pulmonary related issue. Another limitation to the spirometer is that spirometers use race-based correction which adjusts spirometer test results based on the assumption that Black patients have a 10-15% smaller lung capacity and Asian patients have 4-6% smaller lung capacity compared to white patients (Anderson, Malhotra, & Non, 2021). Despite spirometry test results not being diseasespecific, doctors are unaware of this adjustment and rely on these results in making a diagnosis which can be problematic for chronic lung diseases that can get progressively worse overtime if not treated as soon as possible.

For my technical report, I plan to describe how redesigning the IS with a gamified component will increase patient adherence. For my STS topic, I will discuss the racial bias embedded within pulmonary testing, specifically the spirometer. I will describe this racial bias and propose new measurement classifications to create more accurate and inclusive data.

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Technical Topic

In general, the IS improves lung function by improving lung ventilation, recovery from anesthesia, loosening mucus and other excess fluids from the lungs ("Incentive Spirometer," n.d.). The IS measures how much air the patient can breathe into their lungs; a higher measurement on the IS means the lungs are functioning and working better ("How To Use Your Incentive Spirometer | Memorial Sloan Kettering Cancer Center," n.d.). There are two distinct types of IS medical devices with the overall function of improving lung function and exhalation volume. This is because the volume-oriented IS improves lung function by improving diaphragm movement while the flow-oriented IS works to increase muscle in the upper chest. In a study, researchers from the volume-oriented incentive spirometers increased abdominal motion more than the flow-oriented incentive spirometer (Parreira, Tomich, Britto, & Sampaio, 2005). Despite the critical role that the IS plays in regulating respiratory health, patient adherence to IS exercises is low. One study showed that "over one-third of patients denied using IS during their postoperative care "(Martin et al., 2018).

To address this problem, we will design a gamified modification to the existing device to create a more engaging version of the Incentive Spirometer. Our IS will perform the same functions of a traditional IS, but will additionally have enticing, fun elements to drive an increase in patient adherence. Gamification is the process of incorporating game-like elements into things not associated with games. Researchers theorize that people respond better to gamification as it triggers real emotions such as happiness, intrigue, and excitement (Brown, 2016). The psychological impact of gamification will lead to better engagement by stimulating a person's instinct of exploration and curiosity. We plan to utilize the psychology behind gamification to

boost patients' adherence to the IS. We hypothesize that by using gamification as positive reinforcement and incentive, patients are more likely to use the IS properly, as recommended by their medical provider.

The aims of this project include:

- 1. Creating a functional Incentive Spirometer:
 - a. The IS must indicate the volume of air inhaled by the patient. This may be in the form of a physical indicator and/or a digital indicator displayed on the product.
 This feature must allow for the setting of a volume goal.
 - b. The IS must indicate the flow rate of air inhaled. This may also be in the form of a physical indicator and/or a digital indicator displayed on the product. This feature must dynamically indicate if the user's flow rate is in the ideal range.
- 2. Creating a gamified element that will engage users:
 - Gamified elements must appeal to a general audience with emphasis toward people 50 years or older. It should allow for repetitive use, and not hinder the safe functioning of the device as described in aim.
 - b. The cost of our device should be no more than double the cost of existing devices.
- 3. Gathering patient and provider feedback:
 - a. We will survey patients on their opinions and feedback on the prototypes. We aim to survey one hundred patients, who are currently using an incentive spirometer.We aim for an approval rate of at least 60 percent on our design.
 - b. We will share patient preferences with a group of providers and ask for their feedback and comments.

By redesigning the IS, we hope to increase adherence rate by 50% and make our design more engaging by 1) creating a functional IS capable of measuring volume of air inhaled and flow rate, 2) including a gamified element that appeals to adults and is easy to manufacture, and 3) gathering patient and provider feedback. Increasing adherence of the IS is a significant part of our goal because we want to prevent postoperative pulmonary complications like atelectasis, hypoxemia, and pneumonia. Pulmonary rehabilitation, especially with use of the IS, is vital in preventing these complications, but it also lowers mortality rate, shortens hospital stays, and prevents hospital readmissions. While the incentive spirometer is a breathing tool to exercise the lungs (See Figure 1), the spirometer is a diagnostic tool for diagnosing certain chronic pulmonary illnesses like COPD and chronic asthma. Therefore, addressing the limitations of both devices are important in the treatment of chronic lung disease (Franklin & Anjum, 2022).

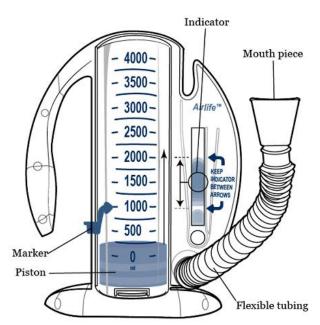


Figure 1.*Note*. A traditional Incentive Spirometer, labeled with its different components ("How To Use Your Incentive Spirometer | Memorial Sloan Kettering Cancer Center," n.d.)

STS Topic

Spirometry is a type of pulmonary function testing used to assess breathing patterns and measure the forced vital capacity (FVC) and forced expiratory volume (FEV₁). FVC measures the largest amount of air that a patient can forcefully exhale after breathing in as deeply as they can, while FEV_1 measures how much air that is forced from the lungs in one second ("Spirometry - Mayo Clinic," n.d.).

The spirometer has a long history, but its invention can date back to 1846. John Hutchinson invented the spirometer in 1846 by taking a gas meter and using it to measure the volume of exhalation. Within years of his invention, other people started creating improved versions throughout Europe and the United States. It was Hutchinson that first classified lung capacity measurements by occupation, but by the early 20th century, use of this factor stopped due to the increasing opinion that lung function differed by race. The idea that they were physiological differences between racial and ethnic groups however dates back to when there was a slave-based economy in the United States during the 1700's (Braun, 2015). It was Thomas Jefferson who first wrote down this assertion in his Notes on the State of Virginia book (1785). In this book, Thomas Jefferson lists physical distinctions between whites and African Americans like lung differences to justify slavery (Braun, 2015). Throughout the nineteenth century, influential people like Samuel Cartwright, Benjamin Gould, and Frederick Hoffman would use Thomas Jefferson's "findings" and false statistics to make the unsubstantiated argument that Black people had a lower lung capacity than white people (Braun, 2015). By the 20th century, this generalized argument applied to all people of color and as a result, academics began to establish this argument as a fact, making people believe the reason for this difference in lung capacity was because of emphasized innate or anthropometric differences.

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This racial difference argument has continued today when the use of these classifications would be more beneficial: social class, sex, or physical environment. Due to global standardization, there is a continuous practice of using race correction, which manufacturers program into the spirometer. The primary variable in measuring capacity is race/ethnic group, but there is no given reason as to why to factor this variable. Brown University professor Lundy Braun conducted a systematic review of 226 papers to show the prevalence of racial bias in relation to the spirometer and lung capacity. Braun found that there are ninety-four racial or ethnic groups discussed to compare lung function to Caucasians. Braun found that, of all the papers that were reviewed, only 6% of the papers analyzed socioeconomic factors as a reason for different lung capacity (Orenstein, 2013). Racial biases especially in the spirometer are significant because this device plays a crucial role in diagnosing patients with certain respiratory illnesses or diseases. According to Braun, the normal spirometer reading reduces the original result by 13% for African Americans and the problem with this correction is that it applies population standards to individuals with the belief that all people within a race are genetically the same (Orenstein, 2013).

Another example of misdiagnosis due to embedded bias, is a study that used artificial intelligence to analyze medical imaging data sets to make a diagnosis. Researchers involved with the study found a decrease in the performance of making a diagnosis for under-represented genders (Larrazabal, Nieto, Peterson, Milone, & Ferrante, 2020). The problem is that these AI systems learned from biased models and therefore reproduced social stereotypes to underperform in minority groups. This study depicts the implications of any type of bias within the healthcare sector.

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These studies have shown how minorities may not get accurate test results and as a result do not get proper treatment as soon as possible. The problem I am exploring in my STS topic is how the emphasis on race/ethnic groups adjustments for spirometer measurements lead to bias.

Research question and methods

The research question to my STS topic is: How are race-based adjustments in medical devices, which serve as pulmonary diagnostic tools (like the spirometer), perpetuating bias? Using the STS theory user configuration, I will show why and how racial bias still occurs in spirometers. User configuration discovers the boundary and relationship between the manufacturers and the user interprets what a piece of technology does and how it can be used (Woolgar, 1990). According to Woolgar, established parameters are what configure the user like the future requirements needed for that technology as well as the anticipated actions of the user (Woolgar, 1990). Though the manufacturer is aware of the user's character and capacity, a configured relationship is made by creating standard norms for the use of certain type of machine, so that there are certain behaviors that are encouraged and discouraged. Pertaining to my STS topic, user configuration will show how certain designs and parameters were established within the spirometer, so that race-adjustment perpetuates bias. I plan to inspect spirometry designs, especially the hardware of spirometry devices that embedded the race-based correction and help provide reasoning for this adjustment. I also want to explain how the users lack of knowledge about race correction has been used to further configure the user to make any patient of any race or ethnic group use their product without knowing about the adjustments (Woolgar, 1990) based on the idea that the user does not know best. Using this STS concept, I will analyze interactions with patients, doctors, nurses, and other healthcare workers as well as the people

involved with manufacturing and marketing these spirometers. Lastly, I will use the reading *When Old Technologies Were New* to discuss who the expert was and how the experts used their status to further propagate the idea that lung capacity for people of color was inferior compared to white people. I also want to consider the perspective of the outsider, which are the minorities (Marvin, 1990). This will further show that user configuration is based on the established boundary between insider and outsider (the user)

Conclusion

For my Capstone project, my group and I will create a new incentive spirometer with a type of gamified component attached to it. We will create a game that allows the patient to still focus on using the device properly, but also allows for the patient to stay engaged in the use of the device. By redesigning the IS, this can potentially help doctors who have patient adherence issues for the incentive spirometer. We hope to see a 50 % increase in patient adherence, which could lead to fewer hospital stays due to a decreased risk of pulmonary related complications. Anticipated deliverables for my STS topic include literature reviews and researching the manufacturers of the IS who have coded the race correction into their software in the spirometer. I hope to start a conversation about race-based correction in medical devices and show to manufacturers, doctors, and health technologists (the people who employ the spirometers) that it is not necessary. I also hope to introduce new classifications that are based more on the physical environment the patient is in.

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