Development of a Dynamic Tensioning Ankle Brace for Chronic Ankle Instability

(Technical)

The Medical Network: An Analysis of the Factors Influencing Medical Prescriptions

(STS)

A Thesis Prospectus

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By

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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 healthcare industry is one of the largest and most influential in the country. The US saw over 860 million physician visits in 2019, with 85% of adults and 95% of children visiting a healthcare professional at least once (Center for Disease Control and Prevention, 2021). For obvious reasons, individuals in today's world trust these professionals when in need of medical treatment. However, the type of treatment two individuals receive for the same injury can differ drastically due to a number of factors including the medical professionals involved, the patient's monetary status, and the healthcare entities that dominate this field (Murshid, 2017).

Throughout my life, I have experienced this firsthand. Suffering from a neurological disorder causing severe foot and ankle deformation, I have seen endless medical professionals in varying hospital systems who all seem to recommend different treatment routes yielding highly varying results, but why? Society has developed this blind trust in the impactful decisions made by medical professionals without fully considering the different factors that may be guiding these decisions. In this paper, I will be exploring how the interactions between medical professionals, medical device companies, and insurance providers can affect the selection and outreach of medical devices.

For the technical project, my group is going through a full product development process of a novel ankle brace, providing maximum stability while maintaining high levels of comfort. This project has a focus on device design, but also entails significant research in the medical device market to ensure the success of the product by understanding how physicians decide when to prescribe a device and which device. Through preliminary research, I discovered that pharmaceutical and device companies use methods to win a physician's loyalty to their products, even if it is not the best option for the patient, directly influencing treatment decisions (HHS

Office of Inspector General, 2019). With so many entities influencing this field, simply creating a more effective device is not enough to ensure a product's success. To aid in the product development of our device, I plan to explore what factors can impact a doctor's likelihood to prescribe a certain device, mainly through the interconnected network between these physicians and medical device or insurance companies.

Technical Topic: Product Development of a Market Ready Ankle Brace

In a world constantly striving for technological advancement, the medical industry faces significant barriers in device innovation. These barriers stem from areas such as funding for large development expenses, public policy regulations on devices, and a high demand for safety, cost efficiency and effectiveness of devices (Herzlinger, 2006). External bracing is a subsection of medical devices that is mainly hindered by cost efficiency and effectiveness due to their FDA classification as low risk products with a fairly simple path to the market (Bergsland, 2014). At the root of these challenges is manufacturing methods, as almost all rigid braces rely on injection molding, an expensive method with limited scalability for custom products. 3D printing, a new type of manufacturing based on digital models, provides many benefits to medical device innovation such as rapid customization, greater cost effectiveness, and enhanced design collaboration (Ventola, 2014).

For our technical project we will be working with Icarus Medical Innovations, a company who has utilized 3D printing to create a novel class of unloader knee brace treating osteoarthritis. Previously, production of custom braces was time consuming and expensive, encouraging the distribution of less effective ‘off the shelf’ braces. Using an automated 3D leg scan to print methodology, Icarus can rapidly produce custom knee braces on a mass scale with significant

cost effectiveness. This provides immense potential in areas other than just knee braces, and our overall goal is to design an ankle brace for Icarus that can utilize this technology to bring these production benefits into another bracing area. Rapid customization is so important because it gives the ability to produce braces that are fully effective for all patients, regardless of the specifics or severity of their condition.

Our product development process began with research on all areas pertaining to our device design and the distribution of the device. This included broad level market research on the foot and ankle device industry, the specifics of Chronic Ankle Instability (CAI) and how these will affect our device design. My specific responsibility was to evaluate the underlying causes of CAI and patient feedback on current ankle braces to construct a set of user needs for our device. CAI has varying effects on patients, which makes the customization and adjustability of our product crucial in order to treat a wide range of patients. Patient feedback also led us to the conclusion that generating maximum comfortability of our brace, without sacrificing its level of ankle support is crucial. Another area that fed into our design specification is insurance codes, which public and private insurance providers use to determine if a brace qualifies for reimbursement and the value of reimbursement. This is critical in the medical device field as companies need to ensure their product will be covered by insurance in order to maximize patient outreach. Relevant codes to our product were identified and their requirements were integrated into our design specifications.

In the closing months of the semester, we plan to convert our user needs and background knowledge into a set of potential designs. My group will work with the Icarus engineering team to select the most promising designs which will undergo an iterative prototype design process. My focus in this stage is on the computer aided design (CAD) of the 3D printed pieces that will

be integrated into our brace. These pieces will be rigid components that give the proper support needed in our brace, but will also be completely customized to a patient's 3D ankle scan to ensure maximum comfort simultaneously.

We plan to enter the second semester with a prototype that is ready for the design validation stage of product development where we ensure our prototype satisfies the initial user requirements we sought to address. Patient trials of the brace will be needed to identify potential improvements in the areas of comfort, ease of use and stability provided. Using this data we will be able to progress towards a more finished product that can be pitched to medical professionals. Ultimately, we plan to have a final device that has demonstrated overall effectiveness and the ability for mass production, allowing Icarus to take it to market.

STS Topic: An Analysis of the Factors Influencing Medical Prescriptions

The medical device industry is made up of a complex network of entities that stem much further than the local physician. It all starts with the corporations who produce these medical devices and serve the role of developing the innovative solutions that medical professionals will use to treat their patients. However, the distribution of medical devices is completely different than any other product based industry. The caveat here is that the users of these medical devices are typically not the purchasers, as medical professionals, insurance companies and regulatory bodies like the US Food and Drug Administration (FDA) ultimately decide which devices are provided to patients (Bitterman, 2010). These decisions, which can be so impactful on patient's lives, are based on a variety of social, economic and institutional factors that influence this network. This raises several questions about the interconnectivity between these highly influential entities that dominate this field. Is the distribution of medical devices in our

healthcare industry truly based on benefitting the patients in need? With the involvement of two profit driven actors, medical device and insurance companies, how much does profit play a role in patients receiving the treatments they are in need of? This paper aims to dissect the network that has formed between medical professionals, medical device companies, and insurance providers to determine how their relationships can influence the outreach and distribution of medical devices.

Before medical devices can even enter this distribution chain, they must pass through the regulatory processes put in place by the FDA. The FDA classifies all medical devices based on the risk they pose to the user in three categories: low, medium and high risk. Medium and high risk devices require pre-market approval from the FDA mainly through the form of clinical trials (Johnson, 2016). The point of this approval process is so the government can ensure the safety and effectiveness of all devices that will be used for patient treatment. Many of the medical devices that make it past the FDA are designed to treat the same conditions as other approved devices. Simply having this stamp of effectiveness from the FDA does not ensure it is the best option for a patient in its target user population. Due to this, medical professionals are given the difficult task of filtering through several approved devices to find the most beneficial treatment for a patient. Although the FDA approval process has significant influence on device design, for the scope of this paper I will be focusing on the decision that is made by physicians after a device has been approved as effective and safe by the FDA.

In the post approval phase of medical devices, this dynamic industry can be condensed into the three key players I have introduced: the medical device companies that produce these solutions, the doctors/professionals who prescribe these devices, and the insurance providers

who pay for the devices. The relationship between these three entities ultimately control the entire process from device creation all the way to patient usage.

This process begins with the medical device companies who are tasked with creating innovative and effective medical solutions. Despite their obvious benefit to society, they are still like other corporations in the sense that they are profit driven. They need their products to be successful and to generate income in order to continuously produce and design new products. John R. Williams of the World Medical Association analyzes the ethical issues that arise from the relationships between physicians and commercial enterprises in his article titled “Medical Ethics in Contemporary Clinical Practice”. Williams discusses the idea that a physician is caught in the middle of two opposing viewpoints, the medical device company who is trying to make as much money as possible on a device, and the patient who wants to pay as little as possible for treatment. He goes on to discuss how these companies often offer gifts and benefits to physicians with the underlying motive of getting the physician to prescribe their devices (Williams, 2007). While it is obvious to see why a medical device company would want to push for greater patient outreach of their product, it is alarming to see how their business driven goals can corrupt a physician's treatment decision. This relationship can make a physician more likely to prescribe a product due to ties with a corporation, rather than based on the true effectiveness of a device. The influence of these interactions on prescription behaviors of physicians has become such a concern that numerous states have adopted laws aimed to combat this by requiring disclosure of manufacturer marketing expenditures (Conn et al, 2011)

The next area to analyze is insurance providers and how they impact both the physicians and medical device companies involved. With such a high cost of development, medical devices can be extremely expensive and insurance providers function by helping patients cover the cost

of the treatment they need. In 2019, only 9.2% of the US population was uninsured, with a breakdown of 65% to 35% for private versus public insurance, respectively (Congressional Research Service, 2021). These insurance companies have very specific criteria to determine what devices they will cover and how much they are willing to pay. Physicians must consider the financial implications of their prescriptions, and due to this, insurance coverage of a device directly influences how often a device is prescribed.

The factors they consider heavily impact the design of medical devices, as companies want to ensure that their products will be covered by insurance. Insurance providers therefore have a direct relationship with the production and innovation of new medical devices. Jeffrey Clemens' study titled "The Effect of US Health Insurance Expansions on Medical Innovation" links the expansion of health insurance coverage directly to innovation of new medical devices, claiming insurance expansions have driven up to 25% of this innovation. Clemens also references a domino effect tying this correlation back to increased physicians' usage of these new devices (Clemens 2013). This study quantifies the relationship between these entities and shows how the coverage decisions made by insurance providers can impact a manufacturer's innovation choices, ultimately affecting the devices that are used by medical professionals.

The resources and evidence presented within this paper establish the network of relationships between physicians, medical device companies, and insurance providers as well as the impact these relationships have on prescribed devices.

Next Steps:

The next steps for the technical aspect of my project heavily revolves around the prototyping of a bracing solution for CAI. We are currently in the initial prototype stage and aim to reach our first functional prototype by the end of the semester. At the start of the second

semester we plan to begin testing of our prototypes through patient trials where the device is used in various physical activities and feedback is provided on the comfort, adjustability, and stability of the brace. Patient feedback will allow us to iterate into a professional design of the device with proven effectiveness. Towards the end of 2nd semester we plan to have our device to a point where it can be pitched to medical professionals to gauge interest and receive more feedback to ultimately finalize our design.

The next steps for the STS paper are to identify more sources that can provide specific evidence and examples of the relationships I am proposing. I would like to establish more hard data that directly shows how these relationships can alter the prescription behavior of physicians. This will involve tying the evidence from multiple articles together to formulate a concrete idea on why these relationships are so impactful on the present and future progression of medical device distribution. I would also like to explore how this relationship functions in the healthcare industries of other countries to hopefully draw even more conclusions about why the US system may be better or worse.

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