The Medical Network: An Analysis of the Factors Influencing Medical Prescriptions (STS)

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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

I was born with the neurological condition known as Charcot-Marie-Tooth disorder (CMT). For as long as I can remember, I have suffered from severe foot and ankle deformation. I have visited many medical professionals, some even known as CMT experts, who all seemed to recommend different treatment routes that varied in severity and potential results. I was stuck comparing recommendations that included full reconstructive surgery, custom ankle orthotics, and "sticking it out" with the ankle brace I purchased at a local drug store. With several experts contradicting each other, who was I supposed to trust? How could there be such variability in these impactful medical decisions? Now, picture the individuals who don't have the same privilege of hearing the opinions of multiple medical professionals. Think about the instances where a physician's treatment decision is life altering. This is why the variability matters.

The type of treatment two individuals receive for the same injury or condition 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). To explore this issue, it is crucial to look at the organizations that are major stakeholders in the treatment process. Pharmaceutical and medical device companies use tactics to win a physician's loyalty to their treatment products, even if it is not the best option for the patient (HHS Office of Inspector General, 2019). Additionally, private insurance companies require physicians to request approval before they can prescribe a treatment to a patient. In both of these instances, a private entity has major control over the decisions made by medical experts. In this paper, I will be using Actor-Network Theory (ANT) as a framework to examine how the interactions

between medical professionals, medical device companies, and insurance providers can affect the selection and outreach of medical device treatments.

Actor-Network Theory in Healthcare

Actor-Network Theory is defined by Cresswell et al. (Cresswell et al., 2010) as the study of inanimate entities and their effect on social processes. They establish an actor as the source of an action and argue that they can only have an impact in combination with other actors. This brings light to the idea that entities or factors that may seem external have the ability to shape social interactions and decisions. Ultimately, our society is made up of several networks that may contain humans, concepts, or ideas as the actors in each network. The idea behind ANT is to explore these networks and how the actors within may influence the decisions or outcomes of the overall network.

Creswell et al. drift away from traditional ANT studies that adhere to strict principles when applying this framework to healthcare and instead focus solely on the implementation of Information Technology in healthcare settings. I will be following their methodology of applying a simplified version of ANT to healthcare by focusing on a specific set of actors and their corresponding interactions. Through this framework, I will be examining medical device companies, insurance companies, and medical professionals as the relevant actors in this network. I aim to use these relationships to help postulate the influence corporate entities have on the treatment decisions of physicians.

Medical Device Distribution Concerns

The distribution of medical devices begins with the corporations who design and manufacture them. These companies serve the role of developing the innovative solutions that medical professionals will use to treat their patients. However, this process is very different from 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 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? By dissecting the specific interactions that occur between medical professionals, medical device companies, and insurance providers, it becomes clear how the outreach and distribution of medical devices can be corrupted.

Current Regulatory Processes

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. While the FDA is crucial for ensuring the safety of medical devices, their system is extremely simplified in the way that devices are solely given approval or denial, with no method of comparison between approved devices.

With the FDA serving as the sole regulator of medical devices, the primary concern present is that once devices make it past the FDA, there is little government intervention on the distribution of 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. Unfortunately, this gives way to the potential for tampering and bias influence on clinicians treatment decisions.

The Network of Influential Entities

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. While each actor focuses on a different stage of the medical device process, all three interact constantly with each other, introducing the ability for influential decisions and behaviors regarding the distribution of these devices.

The Tactics of Medical Device Companies

This process begins with the medical device companies who are tasked with creating innovative and effective medical solutions. Despite their benefits 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).

In the past decade, tactics imposed by pharmaceutical companies, especially regarding the opioid epidemic, have made the dubious relationships between physicians and corporations very evident. However, many of the studies conducted have solely focused on these relationships with pharmaceutical companies and have neglected similar interactions with medical device companies. This is overly concerning because physicians have heavy involvement in the treatment, training and innovation of medical devices, even more so than pharmaceutical drugs. Medical device company's representatives spend lots of time training physicians on how to use their products, giving them lots of exposure and opportunities to influence physicians. Bergman et al.

conducted a study comparing medical device company and pharmaceutical company payments to physicians in order to analyze the significance of medical device spending. Using 2014-2017 data from the Centers for Medicare and Medicaid Services Open Payments Website, they found vendors promoting medical devices paid \$904 million to physicians compared to \$821 million from those promoting drugs. While these dollar figures are not significantly different, the pharmaceutical industry is significantly larger than the medical device industry which reveals a much higher spending percentage from medical device vendors. Another important find from this study was a direct correlation between physicians with higher Medicare billing and the payment amounts they received. This means that physicians who were more successful in distributing a vendor's products received significantly higher payment amounts than their colleagues (Bergman et al., 2021).

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 and willingness to spend money can influence a physician's treatment decision. This relationship can make a physician more likely to prescribe a product due to their ties with a corporation, rather than the true effectiveness of a device.

The Influence of Insurance Companies

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 treatment is prescribed.

Several studies have been conducted to explore how a patient's economic status alters the treatment they receive from clinicians. Hajjaj et al. explored many of these studies in the past to determine how a non-clinical influence like insurance coverage changes a doctor's treatment decision. Evidence points towards a lack of insurance leading to physicians changing their prescription strategy, a reduction in quality of care and overall less received inpatient and outpatient services (Hajjaj et al. 2010). Of the studies explored, the most concerning results were from a series of breast cancer studies conducted by Roetzheim et al. Data comparing uninsured and insured patients being treated for cancer confirmed that uninsured patients were less likely to receive treatment consistent with the current standards of care, and actually had a higher mortality rate from cancer (Roetzheim et al. 2000). This leads to the conclusion that not only does health insurance alter a clinician's treatment decisions for a patient, but it can also impact the ultimate health outcome of the patient.

Furthermore, these insurance companies' decisions to cover certain medical devices and not others reveals an interesting dynamic between them and the medical device companies that produce the devices. The criteria insurance companies use to judge devices heavily impacts the design side of production, as companies need to ensure that their products will be covered. 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 is a way of quantifying the relationship between these corporations 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 Bias of Clinicians

While medical devices and insurance companies can have a major influence on clinician decisions, ultimately clinicians themselves have the biggest impact on the treatments provided to patients. Clinicians, like all humans, are full of implicit biases based on a number of factors, and with such a large number of clinicians in our country, it is impossible to address all of these. The primary areas of bias that have been studied and are the most prominent in the realm of treatment decisions are racial, sex and socioeconomic bias. While some of these biases have more drastic influences than others, all have the potential to impact the decisions made by clinicians on how to treat their patients. The biases regarding race, sex and social status are mainly implicit, meaning clinicians are unknowingly demonstrating bias in these areas. Technological bias is much different and is usually the result of experienced doctors not wanting to change the treatments they have been providing patients.

Implicit bias is most commonly measured through the Implicit Association Test (IAT), which measures implicit preferences by bypassing conscious processing. Several studies have been conducted to determine implicit bias among clinicians in the areas of race, sex, and social status. Green et al. compared explicit and implicit race biases among physicians and linked this to their treatment decisions. Physicians demonstrated a mean IAT score of 0.36 for favoring white Americans and a score of 0.3 for black Americans being less cooperative with medical treatments. These scores demonstrate a strong bias in both areas, and the study went on to further show that the physicians' pro-white bias aligned with their likelihood to treat a white patient with thrombolysis over a black patient (Green et al. 2007). Haider et al. demonstrated similar IAT results relating to social class biases, with mean IAT scores of 0.71 favoring those in higher social classes (Haider et al. 2015). Implicit biases are also heavily seen in sex, and Borkhoff et al. used logistic regression analysis to measure the effect of patient sex on physician's recommendations for total knee arthroplasty. The results showed 42% of physicians recommended surgery for the standard male patient but not the female, and only 8% recommended surgery for solely the female patient (Borkhoff et al. 2008).

While the presence of implicit bias among physicians is concerning, it is not drastically different from the implicit biases that exist among our population as a whole. What is more concerning about these studies is how they were able to obtain statistically significant data showing that biases within physicians actually change their treatment and diagnostic decisions. This confirms that bias between clinicians exists and has real impact on the treatments they provide to their patients, adding yet another factor in this network that alters these decisions.

Discussion

After dissecting the network that exists in the medical device industry through evidence and analysis, we can now see the presence of external influence on the treatment decisions of clinicians. By exploring the interconnected web of relationships present between the three most important actors to this specific network, the industry was examined from the start of the process to the finish, or from device creation to device distribution. The data ended up showing that each of these entities, especially the profit driven corporations, were using strategies to benefit themselves, often at the expense of the patient in need.

Medical device companies are the first external force to act on the network by trying to maximize their distribution and profits on their products. By doing so they are knowingly putting clinicians in the middle grounds between a desperate patient, and a money driven corporation. They deploy their strategies in the form of offering lucrative benefits to clinicians and in return they have seen a significant increase in a clinician's decision to use their product. On the opposite end, insurance companies are at the freedom of deciding what patients and devices they want to financially cover, giving them immense control over a clinicians need to provide affordable care to patients. Simultaneously, the clinicians themselves have shown an alarming amount of bias where their treatment decisions are altered by a patient's race, socioeconomic status or even gender.

When looking at each of these entities and the strategies or behaviors they exhibit, it is evident that this network of relationships has a direct impact on the treatment decisions carried out by clinicians. The influence of these interactions on the

behaviors of physicians has become such a concern that numerous states have adopted laws aimed to combat this by requiring full disclosure of what goes on between these entities (Conn et al, 2011). Unfortunately, the cut throat tactics of for-profit corporations will remain the same, and as long as there is competition present in the medical device industry, these entities will continuously deploy any strategy possible to gain an edge and control the network.

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