Prospectus

Development of a Chest Tube Stabilization Device for the Reduction of Pain
(Technical Topic)

Biopower: How Pharmaceutical Data Aggregation Affects Physician-Patient Behavior
(STS Topic)

By

Charlotte Anne Miller

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Technical Project Team Members:

Maeve Isabella Coleman

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.

Signed: Electronically Signed on 11/4/2020
Technical Advisor: William Guilford, Ph.D., and Mark Roeser, M.D.,
STS Advisor: Sean Ferguson, Ph.D.,

Introduction

A chest tube thoracostomy is a common procedure used to drain excess fluid or air in the plural cavity surrounding the lungs. These tubes and drains are held in place with a subcutaneous suture that causes a tremendous amount of pain and discomfort to the patient. Thus, our capstone project aims to design a chest tube stabilization device that transmits any pulling or tugging forces on the tube to the device itself. Reducing pain associated with any procedure has direct effects such as improving the patient's level of comfort or making the dressing changes more feasible. With less long-term pain and subsequent wound trauma, the need for powerful prescription painkillers might be alleviated as well.

While the proposed design project serves as a direct solution to control postoperative pain, the STS research thesis will reveal changes in physician-patient interaction and physician prescribing behavior during an emerging era of datafication in medicine. Our prescription drug crisis is more than individual addictive tendencies or reckless physicians; the current healthcare atmosphere values quick pharmaceutical fixes, so doctors can reach as many patients as possible, while simultaneously valuing a capitalist economy where corporations can make profits off the exorbitant prices of prescription drugs.

I will take a conceptual orientation in my analysis of biopower to draw connections between increasing datafication in medicine and population-scale shaping of behavior to improve population health metrics. Specifically, I will investigate the ways in which physicians' prescribing tendencies have been documented and how that data is leveraged for strategic pharmaceutical marketing targeted towards those very same physicians. For example, Purdue Pharma, the manufacturers of OxyContin, used pharmacy data to identify physicians with high rates of opioid prescriptions (Van Zee, 2009). Between 1996 and 2001, the company held more than 40 national pain-management conferences for physicians at lavish resorts around the

country. During these grandiose, all-expenses-paid vacations, Purdue Pharma emphasized the benefits of strong painkillers while simultaneously downplaying their addictive or fatal effects. These marketing campaigns and manipulations successfully put physicians under the spell of a powerful entity; prescriptions for non-cancer related pain increased roughly 9.2-fold in the five years that Purdue Pharma held these symposiums. Marketing tactics such these can ultimately alter a physician's understanding of their role in pharmaceutical interventions for patient health indicators and influence physician-patient interactions in a way that impacts the broader population.

Technical Topic

For younger individuals, trauma is the leading cause of death, with approximately 25% of those cases being attributed to primary thoracic injuries (Kesieme et al., 2011). Chest tube thoracostomies are the most common procedures in thoracic surgery, yet anecdotal observations from healthcare professionals indicate pain as the chief complaint associated with the tube itself. Specifically, a small subset of doctors, nurses, and caregivers have attributed this discomfort to the subcutaneous suture holding the tube in place. Although the amount of pain is highly dependent on the patient, the chest tube has been shown to play a significant role in downstream discomfort. One study showed that patients with small-bore, 12F chest tubes (n=54) reported less pain than the large-bore, 24F drain group (n=56) by a difference of 6.0 mm on the visual analog scale (VAS) for pain (Rahman et al., 2015). However, small drains have a higher complication rate and are not suitable for large pneumothoraces or to drain highly viscous fluid from the pleural cavity (Orlando et al., 2020). Thus, in many scenarios, there exists an inherent tradeoff between pain and chest tube functionality

Under the guidance of William Guilford, Ph.D., Assistant Dean for Undergraduate Education in the School of Engineering, and Mark Roeser, M.D., Assistant Professor of Pediatric Surgery, Maeve Isabella Coleman and I will develop a novel stabilization device for the thoracostomy tube. This sheath-like device will provide a foundation to keep the tube stationary and transmit any forces from the subcutaneous suture to a larger skin area surrounding the insertion site. Ultimately, a decreased force impinging upon the suture and skin will help reduce pain and the likelihood that the thoracostomy tube becomes dislodged.

The effectiveness of the proposed design will be measured in two ways: force simulation and *in vivo* testing. Prior to any 3D printing or prototyping, a computer aided design (CAD) model will be built, and finite element analysis (FEA) will be used to reveal areas of high stresses, strains, and potential breaking points in the device. Once the stabilization device is constructed, it will be tested both *in vitro* and *in vivo*. An Instron machine will be used to measure the strength of the stabilization device and observe how it deforms under different conditions. After further refinement, two chest tubes will be inserted into either a swine or sheep model, and two different stabilization techniques will be used to mount the tube. The reliability of both protocols will be compared to determine whether our proposed device is more effective than the current technology.

In addition to developing a stabilization device, the current capstone project also seeks to fill the gap in understanding chest tube pain. Therefore, after gaining approval from the Institutional Review Board for the Social and Behavioral Sciences (IRB-SBS), a brief survey will be sent out to medical professionals across the Commonwealth of Virginia to inquire about any chest tube pain observed in patients. The information collected is intended to help solidify

the unmet clinical need, support anecdotal observations of pain, and most importantly, lay the groundwork for future pain studies from the perspective of the healthcare provider.

STS Topic

In 1995, James Campbell, M.D., founder of the Johns Hopkins Blaustein Pain Center, declared pain to be the "fifth vital sign" (Scher et al., 2018). As if in lockstep, medical prescriptions for opioids began to sharply increase (National Academies of Sciences et al., 2017). As one indicator of escalating painkiller prescriptions, Purdue Pharma's OxyContin reached sales of $1.1 billion in just four years after its 1996 debut (Van Zee, 2009). Their marketing plan largely focused on leveraging specific data on physician's prescribing practices to target subservient doctors and healthcare providers. This exploitation of healthcare data is not unique to Purdue Pharma, rather it offers just one example of how medical care can be shaped by those outside of medical practice. State policies that catalyze the development of tools underpinning biopower, such as collecting and selling patient health records or coordinating medical protocols and regulations, has opened the floodgates for large corporations outside of the government to exploit these tools in order to shape doctor and patient behavior around pain management.

Data Aggregation and Collection

Although the aggregation and collection of doctor's prescribing practices has drawn attention over the past decade, healthcare information organizations (HIOs) were established shortly after the conclusion of World War II (Greene, 2007). These data-mining companies, such as IMS Health, Dendrite, and Verispan, source information from pharmacies and insurance claims to create physician profiles that depict his/her preferred pharmaceuticals, flexibility in trying new therapeutics, and general prescribing tendencies (Fugh-Berman, 2008). These HIOs are hardly boutique organizations, rather they likely have data on every individual residing in the

United States. For example, IMS Health Inc., which is the largest of these healthcare information organizations, is located in Fairfield, Connecticut, and has data on about 70% of all prescriptions filled (Tanner, 2016). As of 2016, IMS Health Inc. has sold this information to over half a billion patient dossiers, which are largely comprised of drug and pharmaceutical companies.

Fugh-Berman (2008) and Robert (2006) detail the procedures of data collection and transmission of pharma scripting. Data aggregation begins at the pharmacy level. Pharmacies first sell patients' prescription records, including the dose and medication name to HIOs, such as IMS Health Inc. This raw data links the prescriber to the prescription through their state license or Drug Enforcement Administration code, not their full legal name. Thus, the HIOs purchase a Physician's Masterfile from the American Medical Association (AMA) to reassociate the doctor's numerical ID with their name (*AMA Physician Masterfile*, n.d.; *Data Services & Publications*, n.d.). The Masterfile contains information such as age, demographic, education, board certifications, etc. on all registered physicians (MDs and Dos) in the United States. According to the AMA, over 2,000 reliable sources are used to aggregate physician data, and there are currently more than 1.4 million doctors included in this database. This list is not limited to practicing physicians, rather it contains information from current medical students, residents, and even deceased doctors; the database is never purged. Over 80% of hospitals and 400+ healthcare plans utilize information contained in the Physician's Masterfile; this corresponds to over 450,000 profiles being sold to hospitals or insurance companies, creating a nearly universal database that healthcare companies and Big Pharma can exploit.

Once the HIOs gain access to physician information from the AMA, they compile physician profiles that contain not only the information found in the Masterfile but also

information from pharmacies about prescriptions (Fugh-Berman, 2008; Robert, 2006). Pharmaceutical companies then purchase access to these profiles and are thus able to strategically target their marketing to various physicians via office visits, phone calls, digital advertisements, and lavish conventions.

Biopower and the Biological Sub-citizen

The French philosopher Michel Foucault first defined "biopower" in 1978 as "the set of mechanisms through which the basic biological features of the human species [become] the object of a political strategy" (Michel Foucault, 2009, p. 16). He describes biopower as having two, semi-related "poles" (Peggs & Smart, 2018). The first focuses on the body as a machine whose capabilities can be programmed, modified, and optimized. Through treating the body as an object, its usefulness can be further integrated into efficient economic systems or political regimes. The second pole focuses on the body as a living organism with definite health metrics, such as reproduction rate, birth rate, death rate, life expectancy, and level of fitness. Thus, biopower includes legislative governance and regulatory affairs as two external, non-medical forces that ultimately shape medical decisions that affect the aforementioned health metrics. He also argues that the roots of this biopower era began during the classical period when "there was an explosion of numerous and diverse techniques for achieving the subjugation of bodies and the control of populations" (Michael Foucault, 1978, p.140). Therefore, biopower is largely focused on the population-scale shaping of behavior by nation-state practices, population behaviors, the commodification of bodies, and even the manipulation of scientific literature.

The increasing strength of biopower has made it impossible for individuals to become fully liberated biological citizens; they are often under the control of policy, privatization plans, or financial limitations. In this context, Sparke (2017) has determined three different influences

that prevent the biological citizen from full autonomy. One of these influences is described as "health disenfranchisement through exclusion and conditionalization" which refers to "health service cuts, user fees and privatization plans" that all have "exclusionary effects" and "embodied outcomes". Thus, data privatization in the pharmaceutical space serves as one factor stripping the biological citizen of authority over his/her own body through exclusion and conditionalization. Exclusion specifically refers to the rolling-back of public health services through austerity measures, such as cutting costs, minimizing corporate regulations, and reducing any oversight of data collection. Privatization of data by HIOs and the AMA have exclusionary effects on patients. For example, if doctors inappropriately prescribe drugs that lead to an addiction, individuals can expect to pay anywhere between $3,500 to $70,000+ annually on the cost of obtaining opioids to fuel the dependence (*The Cost of Addiction*, n.d.). While this is a huge upfront financial burden for families, the addiction can also reduce downstream economic and social productivity leading to further disenfranchisement. Secondly, outside actors influencing doctor's decisions creates a biological sub-citizen who is unable to access unbiased doctors and therefore unable to make deeply intimate and personal decisions regarding their own bodies.

While biopower refers to the state's process of controlling human bodies, biological citizenship expands upon this concept of biopower to examine its role in sociopolitcal inclusion (Schlosser, 2018). This citizenship project refers to a grouping based on biological or health-related characteristics. While citizenship categories include shared diseases, such as cancer or diabetes, biological citizenship also refers to any belongingness to a group that demands access to social welfare programs, healthcare, or legal counsel based on some biological basis (Petryna, 2004; Rose & Novas, 2005). Biopolitcal power and biological citizenship are intertwined in a

cycle; a rise in biopower can change population-scale behaviors, and in response to this change, biological citizens band together and either support or reject such changes. In other words, biopower serves as the government's way to shape "life," and biocitizenship refers to non-state actors that shape healthcare as well.

Next Steps

It can thus be argued that certain regulations and protocols have increased the biopower of the state, so much so as to target physicians and their patients through data collection and strategic marketing. This targeting creates the marginalized biological sub-citizen who slowly loses power over his/her own healthcare. In this following thesis, I will investigate specific policies, such as the AMA Prescription Data Restriction Program (PDRP), that restrict these data aggregation practices and research the success and/or failures of such legislation. I plan to focus on the Supreme Court case, Sorrell v. IMS Health Inc., as one example illustrating how the court actually protects the construction of technologies and data aggregation to shape behavior. I will also research the effects and implications of such an important Supreme Court ruling and how it has either created new forms of biological citizenship or further disenfranchised the existing populations. Finally, I will also be looking towards finding evidence where non-state entities, such as Purdue Pharma, play a significant role in this determination of physician practices as well.

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