Undergraduate Thesis Prospectus

Healthy Hearts: Improving Pediatric Heart Transplant Survival with Data Analytics

(technical research project in Systems Engineering)

Damage Control: Big Pharma's Response to the Opioid Epidemic

(sociotechnical research project)

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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General Research Problem

How can the efficacy of the U.S. healthcare industry be improved?

The United States healthcare system is rife with technical inefficiencies and social inequities, from inequitable access for all to increasing medical costs. The U.S. ranks last overall in healthcare quality when compared to six other industrialized nations, despite having the most expensive healthcare system (Schneider et al., 2017). Technical inefficiencies include insufficient tools to assess donor-recipient compatibility in pediatric heart transplant cases, and high waitlist mortality. Other inefficiencies occur post-surgery as many patients are prescribed opioid medication. Over the past 20 years, over prescription of opioids, due in part to misinformation from their manufacturers, has caused a serious opioid epidemic (CDC, 2019).

Healthy Hearts: Improving Pediatric Heart Transplant Survival with Data Analytics

How can pediatric heart transplant analysis be improved to increase the survival rate at UVA Children's Hospital?

Pediatric cardiologists Dr. Mike McCulloch and Dr. Jeffery Vergales want to improve heart transplant survivability. Under advisors Mike Porter from the Systems Department and Pete Alonzi from the School of Data Science, students John Bullock, Gracie Wright, Megan Grieco, and Wesley Roberson and I investigate factors in heart quality to optimize donor-recipient suitability and increase the cardiologist's confidence in transplant decisions.

Children in need of a transplant are placed on a waitlist until their doctor is notified of an available heart and accepts. If the doctor rejects the heart, it is offered to the next highest recipient. This process continues until the heart is taken or discarded and removed from the list (Organ Procurement and Transplantation Network, 2020, 98). Despite advancements in the

medical field, the utilization rate for pediatric heart transplants remains low. The number of available donor hearts discarded reaches as high as 45% in the United States (Gossett et al., 2020, 1). Due to the high rejection rate, a child in need of a heart transplant can spend up to 6 months on the waitlist, and an estimated 17% of children die while on the waitlist (Almond et al., 2009). For the purposes of our research, we investigate these shortcomings and present our findings and recommendations. The main objective of this study is to increase the overall survival rate for pediatric heart transplants. Subsequent goals include maximizing donor-recipient compatibility to decrease the number of discarded hearts and reducing time spent on the waitlist per patient.

Previous studies have been conducted on heart transplant utilization; however, most of the research focuses on adults rather than children. Nevertheless, relevant research has found high variability in the selection of available hearts by doctors and asserted the need for a standardization for heart assessment (Godown et al., 2019, 9). A study in 2020 attempted to address this by evaluating current risk models for transplant selection. The model used was designed to predict the mortality of a patient one-year after surgery, but the study found the model was weak in discrimination and was not calibrated (Gossett et al., 2020, 4). This further emphasizes the need for a more complete evaluation method, especially in pediatrics.

As part of a broader effort to increase the survival rate for the patients on the waitlist and those undergoing surgery, we investigate the factors contributing to the successful heart transplants and provide deliverables for cardiologists to optimize donor selection. Using data obtained from the U.S. Department of Health and Human Services, we will use Rstudio and UVA's high-performance computing system Rivanna to run our analyses. Our efforts are divided into two parts: the development of a multi longitudinal study examining the donor heart function

from time of death to surgery to determine expectations, and an analysis of heart recipient data to identify which factors contribute to a successful transplant. Once further data exploration is completed, we will have a more concrete plan on the types of analyses to run. Our expectation by the end of the study is to deliver Drs. McCulloch and Vergales with a scoring system that assesses the likelihood of mortality within one year after surgery, given recipient and donor data, and provides a rating on a not yet determined scale. We anticipate our scoring system will meet the needs of our clients by increasing their confidence in heart selection and reducing the number of hearts discarded.

Damage Control: Big Pharma's Response to the Opioid Epidemic

Since 2010, how have U.S. pharmaceutical companies sought to contain reputational damage from the opioid epidemic?

In 1996, pharmaceutical company Purdue Pharma introduced opioid painkiller OxyContin. By 2002, prescriptions of opioid medications had exploded, increasing by 45 million since 1996 (Rummans et. al., 2018). Over the past two decades, the United States has incurred an estimated 450,000 opioid-related deaths (CDC, 2019), causing public outcry and demands for government action. At the center of the crisis are pharmaceutical companies which, to expand the opioid market from terminal cancer patients to chronic pain patients, adopted aggressive marketing strategies, including misrepresenting the risk of addiction and shifting blame to patients (Marks, 2019). A total of 48 states are suing Purdue Pharma for OxyContin's contribution to the opioid crisis (Lovelace, 2019), and Gallup revealed that the pharmaceuticals industry was the least esteemed by Americans (McCarthy, 2019). Facing public disapproval and criticism, the pharmaceutical industry defends itself and seeks to restore its reputation.

Researchers have studied damage to companies' reputation and its effects. Van den Bogaret (2018), investigating these effects in pharmaceutical companies, found that public backlashes diminish revenues directly and can also stimulate demands for restrictive regulation, diminishing future profits as well. She observes: "reputational discourses are shaped not only by individual or group perceptions but also by larger societal discourses … which shape reputational discourses and thus social reputations" (Van den Bogaret et al., 2018). Van den Bogaret recommends that to rebuild their reputations, pharmaceutical companies stress that their products save lives.

Like pharmaceutical companies, tobacco and soft drink companies have also had to respond to public disapproval. Van der Eijk (2018) reports that in 2000, 13 tobacco industry affiliates joined the United Nations Global Compact, which establishes ethical business practices for corporations. According to van der Eijk, the companies were striving improve their image and to gain influence in the World Health Organization (WHO). According to Gertner (2018), amid an obesity epidemic, Coca-Cola has managed criticism and averted public regulation by engaging in self-regulation, including restricting its own advertising to children under 12.

U.S. pharmaceutical companies, known collectively as "Big Pharma," are represented by the trade association PhRMA. PhRMA has supported select federal regulations. In 2017 it endorsed a White House initiative intended to mitigate the opioid epidemic: "We applaud the President's Commission on Combatting Drug Addiction and Opioid Abuse for putting forth a wide range of policy solutions to address this growing crisis" (PhRMA, 2017a). PhRMA's state and federal policy recommendations include proposals to fund education in prescription opioid abuse, to extend insurance coverage, and to improve access to treatment (PhRMA, 2016). According to Big Pharma, no single company is to blame for the opioid epidemic, and the

pharmaceutical industry is an ally in combatting it: “The challenge in front of us requires that everyone be at the table.” Pharmaceutical companies can “help states, cities, towns and families change the trajectory of this crisis” (PhRMA, 2017b).

The Food and Drug Administration (FDA) regulates pharmaceuticals for safety and efficacy; the Centers for Disease Control (CDC) and sponsors research and issues public health guidelines. Before the COVID-19 pandemic, FDA characterized the opioid epidemic as “the deadliest, and most complex public health crisis facing America,” and it has affirmed FDA a commitment to reducing the rate of new addiction (FDA, 2020). CDC stresses the dangers of opioid addiction and advises patients and prescribers about opioid misuse (CDC, 2020). Using public health data, it publicizes risks and issues policy recommendations intended to mitigate the epidemic (CDC, 2019). Prescription Addiction Intervention Now (P.A.I.N.) is an advocacy demanding accountability for the epidemic. It accuses pharmaceutical companies of malpractice (Di Liscia, 2020). It demands that the Sackler family, the principal owners of Purdue Pharma, “forfeit all profits from Oxycontin as restitution to the communities and families that they’ve destroyed” (PAIN, n.d.). The American Medical Association (AMA) represents the interests of physicians to policymakers in Washington. AMA has criticized CDC’s handling of the opioid crisis, arguing it mischaracterized opioid treatment. It recommends for CDC to “make significant revisions to its 2016 Guideline for Prescribing Opioids for Chronic Pain to protect patients with pain from the ongoing unintended consequences and misapplication of the guidance” (AMA, 2020).

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