An Investigation of the Societal Implications of Addiction Treatments in the US Healthcare System

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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

Cocaine use in Virginia has been steadily increasing since 2013 with a 33% increase in fatal overdose from 2019 to 2020 as well as nationally in the United States (NIDA, 2023). There is currently no FDA-approved pharmacotherapy for cocaine use disorder (CUD). The need for ultrasound treatment for substance abuse disorders stem from decades of health disparities and systemic racism in the US healthcare system. The lack of effective treatment options has created a pressing need for new approaches.

Crack and cocaine came into the market in the early 1980s with cocaine use hospitalizations and deaths reaching a new high by 1987, the same year that the War on Drugs, in which the crack epidemic was claimed, began by the Reagan Administration. The prevalence of solid form cocaine began the rise of the use of cocaine addiction, and the use primarily being focused in low income, and highly diverse neighborhoods across the country. The war on drugs became a stronghold of the health disparities in the US for people of color, and have yet to improve many decades later. Our project is working to bridge the gap between substance abuse disorders, and the access to treatment.

I am working alongside two other fourth year biomedical engineering students, Mackenzie Zimmerman and Janine Icalla, to help the University of Virginia Center for Leading Edge Addiction Research (UVA CLEAR) develop an articulating arm system that can be used in their current clinical trial that explores how Low Intensity Focused Ultrasound (LIFU) can be used to target the dorsal anterior insula (dAI) in order to modulate neuronal activity in hopes of decreasing cocaine cravings (Namkung, et al. 2017). The articulating arm system that Mackenzie, Janine, and I are designing and building is to allow high range of motion (so the transducer location can be manipulated to be within precise range of the patients dAI). However, it must easily be mobility in that it can easily be used within a clinic, doctors office, as well as other locations (Barney, 2023). The articulating arm system captures the core design requirements, which are to maintain the stability and precise positioning with an ergonomic design.

Technical Topic

LIFU produces robust inhibition with high spatial specificity and deep focal lengths. The other non-invasive neuromodulation interventions (such as transcranial magnetic stimulation and transcranial electric stimulation) have significant limitations in which the LIFU technique does not such as poor spatial resolution and attenuation at depth. The LIFU system that is currently being used in the UVA CLEAR provides ultrasound waves for neuromodulation within a millimeter resolution and can be focused anywhere in the brain safely and effectively. These limitations make it difficult to affect discrete cortical areas without inadvertently stimulating unintended circuits. The limitation however, of the millimeter resolution, as well as the highly specific spatial resolution, is that the current system, affectionately referred to as "WALL-E", needs to use spatial transducers, as well as locate a patients insula in a highly spatial aware way, as well as securely hold the transducer in that position for the duration of treatment (about 10 minutes). There is no current model in which UVA CLEAR's team has been able to successfully secure the transducer to patients, and therefore they are out of bounds of the target of the dAI. There is no direct harm caused to patients by this problem, however, it is no longer targeting, and reducing the area of the brain in which can modulate down the cocaine cravings.

Through prototyping, as well as various design and development techniques, our capstone group aims to develop an articulating arm system in order to securely place the transducer to a patients' heads. An articulating arm system is a multi jointed adjustable arm holder that is often used to hold surgical or other equipment; common examples are microphone stands of the light they use to shine on your teeth at the dentist. An articulating arm system was chosen as it allows for portability, as well as an ergonomic and user friendly design. But more importantly, it allows for a high range of motion which can be manipulated by a provider to be within the correct position, and resolution range to target the dAI. The first round of prototyping is expected to be completed by December 2023, with a final product and model to be used for the duration of the clinical trial by May 2024, at the latest. The major challenge is going to be allowing this arm to have a high range of motion, while also balancing a high level of security and that the transducer cannot move and must be rested, tightly, against the patient's head. However, it must be very easily moved as Virginia Tech University would likely be using the device as well. The challenge is going to be about what materials to use, how to create highly mobile joints in the articulating arm, with the materials we have at hand at UVA.

Our current design specifications are outlined from our capstone proposal. The majority of these constraints were laid out by our advisors at UVA CLEAR, Andrew Kostelac and Tamika Braveheart. In terms of being stable and holding the transducer in place, the arm must have a circular shaped end mirroring the same shape as the transducer. Depending on the design of the lens and the ultrasound parameters, the target can be as small as 1x1.5mm or as large as 10x16mm in diameter, which led us to specify our positioning error allotment as <1 mm (Focused Ultrasound Foundation, 2023). For the device to have a wide range of motion, there should be hinge connections that allow for back and forth and side to side motion, as well as revolving capabilities that allow parts of the arm to swivel. This parameter, and our corresponding ideal value, was determined by researching comparable models of existing articulating arms that have 360 degrees of uniaxial adjustment. Our load capacity parameter was developed on the principle that the device and its safety locking mechanisms must be able to handle at least the weight of the ultrasound transducer and ideally more than 5 kg, which is comparable to existing articulating arms, to prevent accidental movements and instability while procedures are being performed. For the device to be durable and withstand constant usage, drop, and transport damage, it should be made out of a form of metal that is resistant to easy deformation. Initial prototyping will use 3D print material, but end stage production should use titanium, stainless steel, or some other sturdy material to provide us with a more accurate estimate for our ideal tensile strength values. To ensure our device meets durability and longevity requirements, our device must be able to withstand at least 15 drops from above waist height without visible damage. For the device to be intuitive for users, all movements of the arm should be common sense – it should be obvious how the 360 degree motion works, how to move the arm up and down and side to side, and how to keep the arm stationary. Focused ultrasound treatment takes ~10 minutes; thus, our acceptable assembly time range stems from our desire to limit the total treatment time, including device setup, to ~15 minutes. For the device to be easy to transport across different clinical settings, it must be small enough and lightweight for the average adult to carry. Additionally, it must be easy to clean between patients, which is closely related to the material of the arm, as most medical devices are sterilized with disinfectant wipes. Lastly, the device must be affordable, which is especially important because many individuals with substance abuse disorders come from a lower socioeconomic background (Compton, 2007).

The project would not be made possible without Andrew Kostelac and Tamika Braveheart from UVA CLEAR.The topic primarily focuses on the design and building of the arm system. The LIFU system is currently in trial, and therefore out of scope of our project, but we are to be building a class I device under the FDA General Controls, as well as the ISO 13485.

Our device will be constructed using 3D printed materials and cost-effective parts sourced from reliable suppliers.

STS Discussion

“This is Your Brain on Drugs' ' commercial that aired in 1987 is the epitome of the War on Drugs declared by the Reagan Administration. The commercial illustrated a fried egg on a plate as your brain gets fried by the drugs. This period is a significant starting point, as it laid the groundwork for the disproportionate impact on substance abuse on marginalized communities. The defining features of the ‘war’, was harsh sentencing of drug possession and paraphernalia quickly skyrocketing the incarceration rates during this time. The Anti-Drug Abuse Act of 1986, for instance, established a notorious 100:1 sentencing disparity between powder cocaine and crack cocaine offenses. This meant that a person found with 5 grams of crack cocaine received the same mandatory minimum sentence as a person found with 500 grams of powder cocaine. This is significant because crack cocaine was highly available in marginalized and low income areas as it was easily and cheaply made, making the distribution spread like wildfire across these communities in the US, furthering the sociocultural debate, and creating people of color, at the targeting board for the War on Drugs.

Consequently, the use of crack cocaine sustained over the next few decades, which for a while sustained the use of cocaine over the decades. However, this study is not directly related to the use of crack over powdered cocaine, it is important to note how the socioeconomic status and use changes with time. Due to the increased cocaine usage in Virginia, it is important to note that as the economic climate is typically associated with increased drug and substance abuse rates.

This is a correlation to what is known as the Social Determinants of Health which include: economic stability, educational access and quality, healthcare access and quality, neighborhood and environment, and social and community context (OASH, 2020). Not only have the rates of cocaine use been deeply entwined with socioeconomic disparities, but it is further exacerbated by the healthcare disparities in the United States. Firstly, the highly potent level of crack made for a high return cycle of addiction, withdrawal, and relapse at a much faster rate than that of powder. When associated with the high criminalization rates, it was rare that addicts were getting medical care for substance abuse let alone were able to access it as it is found that in marginalized communities, there are significantly less hospitals, therapy or hospitals.

It is often found that substance abuse issues, while rapidly affecting vulnerable populations, are further exacerbated by the lack of access to proper care. For example, the Substance Abuse and Mental Health Service Administration in 2019 reported only about 10.8% of individuals above 12 years old who needed substance abuse treatment received it. Furthermore, white individuals were more likely to receive substance abuse treatments (11.9%) compared to black or hispanic individuals. From the same report, estimates of past year illicit drug use disorder among people aged 12 or older were highest for people reporting two or more races (5.0 percent) and for American Indian or Alaska Native people (4.8 percent) (Figure 4.1). The estimate of past year illicit drug use disorder was higher for Black people (3.4 percent) than the estimates for White, Hispanic, and Asian people (2.9, 2.8, and 1.3 percent, respectively), (SAMHSA, 2019).

From here, it can redefine how the UVA CLEAR team is working to improve these issues surrounding addiction treatment and research. The access and underlying physiology of addiction can be better understood with organizations such as this research, but it can be better improved if the trials include this diverse pool, as well as one that includes the vulnerable populations that are often affected as we have seen throughout the past decade. Some current issues the clinical trial we can already see, not including the patients demographic but some current limitations include that certain black hairstyles, specifically braids and afro styled hair interferes with the transducer which if we are capable of adjusting would be a key aspect to consider for our design. As well as the current demographics of cocaine use is not well reported in Virginia as of 2023. Lastly, I think it is important to note while I do not have access to patient and trial demographics, trial as well as any research is most successful if it reflects the population, but it is found there is a general mistrust of evidence based treatments, highest among african americans (SAMHSA, 2019), in which could be partially do the systematic mistreatment of black americans at the hands of scientific advancement in the past (e.g the Eugenics Trials at UVA).

Overall, I believe that this trial is an important step in making addiction treatment more accessible due to the promise technical prowess of Focused Ultrasound has as well its low danger, and specified parameters built into the trial. The lack of FDA approval for addiction treatment beyond therapy care, as well assisted detox has been proven but cannot control the physiological changes to the nervous system that occurs due to stimulants such as crack cocaine. The promise that ultrasound can give a low risk treatment plan to addicts would be really exciting, that our advisor has brought up that if the treatment could be given at home and not in clinic, the lack of craving of drugs, and knowing the addiction could be reversible is a promising idea, and argue that the economic stress would be unburdened.

Research Question and Methods

(1) **Develop an innovative articulating arm system capable of securely maneuvering an ultrasound transducer.** We will leverage CAD modeling, FEA, and 3D printing techniques to produce prototypes of an arm system that possesses the ability to securely and firmly hold the transducer against a patient's head for the entire duration of treatment (~10 minutes). We will be applying various forces representative of accidental head movements to assess the stability and security of the arm in a static position. Additionally, the arm system must possess an extensive range of motion to allow almost universal movement and enable the transducer's detection and precise positioning within the required range for effective LIFS treatment, assessed through the number of axial direction adjustments allowed and the extent of angular displacement along a given axis. (2) **Integrate the articulating arm with safety features and durable materials to promote the device's longevity in various clinical settings**. We will iteratively 3D model and print different locking mechanisms along the joints of the articulating arm system to determine the optimal safety features that will prevent any accidents and involuntary movement during treatment. To test the reliability of these locking mechanisms, we will be conducting extensive force and pressure tests both computationally and in real-life to determine the minimum force needed for stability and the maximum force the joints can withstand before failure. We will also explore various materials and construction methods (e.g. additive or subtractive manufacturing) to enhance the device for withstanding continuous usage and movement across different settings. (3) **Validate the reliability and ease of use of the articulating arm with patients and researchers.** Through both quantitative and qualitative validation measurements, we aim to receive feedback on usability from the medical professional and research team throughout the design process. These quantifiable measurements will include device set up time within a given limit (e.g. <3 minutes), and accuracy ranges in which the arm can articulate movement of the transducer as assessed by a software visualization tool that matches the location of the transducer with specified treatment target coordinates on the patient's

head. We also plan to distribute qualitative surveys after each design iteration to both clinicians and patients to ensure a continuous feedback loop on the advancements made on our system.

Conclusion

We, as a team, are hoping that the articulating arm system makes the system run not only more efficiently, but more effectively for the overall success of the clinical trial. The lack of pharmacological therapies for cocaine addiction, as well as many other addictions is stark, and the fatality of addiction even just in Virginia is a huge health crisis and if this device can even slightly make addiction therapy more accessible, it could have a huge impact on the culture and treatment of addicts moving forward.

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