



Engineering World Health, Cornell University Chapter

Drug Usage App - Sensory Monitoring

Proposal for the NIH: SUD Startup Challenge

12/22/2017

Introduction

Across the United States, researchers and fellow medical professionals are addressing the opioid epidemic, an issue that has been ravaging and claiming the lives of millions of Americans. Opioid usage and other drug addictions have been a major concern since the early 1990s (Van Zee), and there is still a long ways to go until there is a comprehensive understanding of the neurobiological basis of addiction, as well as realistic and sustainable interventions. All of these areas are being researched at the moment; however, an issue that is addressed less often is that associated with data acquisition. There is a critical need to develop and test improved methods of sampling, data collection and acquisition, estimation, and analysis in order for this research to be the most effective (National Research Council).

Our organization's goal is to improve the manner in which research data is collected. Under the current system employed by the National Institute of Health, participants must come to the research lab sites themselves to fill out questionnaires concerning their mental and physical condition, returning again if further examination is needed. While it is an effective strategy, it is one that is slow and time-consuming and can quite limit the scope of participants who are able to take part in these critical studies that are currently getting closer to effectively treating drug addiction in the United States. The reason that an efficient strategy has not yet been employed is that of the privacy concerns (Rodriguez). Since the federal government has limitations on the acquisition of data from private devices and servers, our strategy is to create a platform where we can send out questionnaires, with content controlled by the desired research team, in the format of a specialized iPhone application or personalized text messages. The responses would then be specifically rerouted to the servers used by the institutions conducting the research, encrypted back to the institution's servers, or stored locally on the device. This would enable the data to be collected easily in real time and would hasten the process of obtaining data in general. It would also be easier for the participants and encourage more to join given that they would not have to go through the burden of traveling to the research lab's site. The data collected would then undergo a data pushing mechanism to ultimately an excel data sheet where further analysis would be conducted. This method bypasses the slower FileMaker system that the NIH is currently using.

Our area of interest is unlike others in the sense that we are not focused only on improving the quality of research conducted, which would either way improve as our data collection and sampling population improves, but also the speed at which all the steps necessary are taken. It is a popular concept in engineering by which our capabilities are only limited by our technology at the time. The way that this idea is structured would enable it to be easily carried out by a small startup team or group of similar size. Overall, our method would allow the

following of the government's criteria for privacy while helping the NIH/NIDA carry out their procedures at a faster, more efficient pace.

Technical Competence

Cornell Engineering World Health is a student-run project team at Cornell University, based in the College of Engineering. We are a group of over 20 multidisciplinary students who work together to implement global health solutions. In the past, our team has worked on a wide variety of projects, both independently and with partner organizations. Our team is broken up into four major sub-teams: Electrical, Computer Science, Biomedical, and Business. Depending on the project being pursued, these sub-teams work together or independently, to maximize productivity. Team members devote large amounts of time to get projects completed. We regularly consult Cornell University faculty and industry experts to gain knowledge and better accomplish our goals.

The Computer Science sub-team has significant experience developing high quality software for medical professionals. In the past, they have designed a secure video telemedicine app, compliant with HIPAA standards, for a startup called Speetar. They have worked closely in the past with researchers from Cornell's Weill School of Medicine to better collect data for patients suffering from idiopathic intracranial hypertension. They will focus on completing the software component of this project.

The Electrical sub-team has developed prototypes of a variety of medical devices, from neonatal jaundice phototherapy systems, to water quality monitors. They have extensive experience working with embedded systems, and designing resilient solutions to health problems. Their role on this project will be to implement non-survey based data collection tools.

The Business sub-team works to reach out to potential customers, partners, and sponsors. It facilitates communication between the other sub-teams, and organizes proposals like this one. Its members all have technical backgrounds and will be able to facilitate smooth transitions within the project.

A video describing our team can be found at the following link:

https://www.youtube.com/watch?v=UF5ltywdy_0&sns=em

Product

The primary purpose of our system is to facilitate data acquisition in research settings, especially when participants are not physically at the research institution. The obvious mechanism for data collection in these ‘outpatient’ settings is through participants’ cellular devices. The ubiquity and capability of smartphones makes them a perfect choice for this application. We propose two possible methods of delivering survey questions to participants:

- A. An specialized iPhone application which participants can open, sign into, and answer relevant questions.
- B. Personalized text messages containing questions; participants would respond directly with their answers.

Either process could be easily implemented on a participant’s device or a device owned by the research institution and loaned to the subject. The end user would be encouraged to complete these surveys by push notifications prompting them to participate. We believe these mechanisms would streamline the survey process and integrate them into the participant's daily routine of phone usage. This will increase compliance, increasing the consistency, quantity, and quality of collected data.

Researchers will be able to easily choose what questions they wish to direct to their research participants. They will be able specify what kind of input they desire, (e.g. multiple answer choices, 1 to 10 scale, short answer, etc.). The nature of the question delivery mechanism makes it extremely easy to get data back in real time. Data security could be guaranteed in a variety of ways. Method (A) could encrypt data and send it to the research institution’s servers, or store it locally on the device, hypothetically owned by the research institution, where researchers could access data upon completion of data collection. Method (B) would send responses directly to a server owned by the research institution. In any scenario, researchers would be able to easily access data, standardized in format and organized by patient. Additional features could be implemented after consulting with potential end users.

Moreover, this design could be extended to different, non-survey based forms of data acquisition. Studies might require consistent, or at least more frequent, collection of physical measurements of participants’ physiologies and behaviors. Devices like the Geneactiv wearable do so already. We propose developing a series of measurement devices that would enable consistent data collection in the same vein as the survey system proposed above. These devices could interface with the application described above - communicating with a smartphone via a physical connection or a Bluetooth connection. Alternatively, these devices could function in a

standalone setup: docked in a base station that charges each device and records data. Either option could be very promising.

These standalone devices would be able to take a variety of application-specific measurements and provide interesting, previously uncollectable data. We are planning a few basic devices to begin with that can easily link into drug usage research. We would like to build a tool to get a physical measure of craving, as opposed to a numerical scale given to patients. This device would possibly take the form of a stress ball, and allow participants to apply pressure proportional to the amount of craving that they feel. This might give better, more objective data on participants' cravings. This tool would use pressure sensing, implemented using force sensitive resistors, and Bluetooth communication to track and record data. A user could simply press a button, be prompted to provide a craving measurement, and then squeeze. We are also interested in implementing simple eye tracking and measurement. This system, mounted on a user's head, might be able to measure pupil dilation, eye motion, and blinking rate. This kind of data could facilitate research in the field by giving an unprecedented amount of eye-related data. The possibilities for extensions of this data collection system are enormous, limited only by the needs of research organizations.

Target Audience and Commercialization

Our system is intended for Substance Use Disorder (SUD) researchers. It is meant to help them more efficiently collect various kinds of data, even when trial participants are at their own homes or not physically present. As such, we intend to directly reach out to these kinds of researchers in an attempt to closely tailor our device to their needs. In an ideal world, we would establish a close contact with a single lab, to very accurately understand their needs. Moreover, we would need to understand exactly how to comply with the possible stringent regulations on research procedures. Once these obstacles have been tackled, we hope to broaden our search, and establish contacts with other labs to get a broad understanding of needs in the field. As a result, we will not only have a precise set of features to implement, but also a strong base of possible customers.

In the distant future, we could potentially broaden our customer base by targeting multiple types of researchers. We intend to make our code base open source, and make the app publically available in the app store. This will hopefully help grow interest into our project and increase our user base. The app would have a starting price of \$25.00 USD, and would have additional fees within the app, depending on what features a user would want to utilize. We believe that this would be an affordable price for a research group or university team who wanted to utilize our app. Additionally, revenue can be gained through advertisements within the app.

Using the aforementioned contacts, we would work to establish a balanced price point, which would allow us to maximize our profits while still helping researchers. Constant communication and consultation with these groups will be critical.

We estimate that the research and development of the app will take approximately 3-4 months, or the equivalent of an academic semester at a standard university. Simultaneously with the development of the program, we will be in touch with the aforementioned contacts to determine a compatible research team. From there, we will work closely to ensure that the app is customized and as applicable as possible to their needs.

We believe that our proposed idea will be one that can be feasibly implemented in a relatively short time span. Additionally, its scope is wide enough to address the extreme opioid pandemic as well as other drug crises in the United States. With the help of the NIH, we would be honored to pursue our plan to mitigate the current inefficiencies in data acquisition as well as inevitably improve the recent understandings of the neurobiology behind drug addiction.

References

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