<u>Problem Statement</u>

"How might we reduce unintentional addiction to opioid drugs among individuals seeking medical attention for pain?"

Problem
The opioid epidemic impacts many individuals especially those **who** get prescribed opioids for pain management either for chronic pains or various medical procedures. Opioids are highly addictive drugs and are **what** instigate addiction and overdose in patients due to how they bind with receptors on nerve cells and create a chemical induced pleasure in the body that relieves pain. The wicked problem really emerged **when** deaths related to the misuse of prescription opioids rose in the early twenty-first century. Doctors were even concerned as early as the 1970s when there was a heroin epidemic. **Where** the problem is very relevant is the United States of America. This can be seen by national media coverage and how it is central to many major politicians' agendas. Urban centers have the highest rates of overdose, however, there is concern of a spread of the epidemic to rural areas that have fewer recovery centers and less government funding for the issue. **Why** is this issue a Grand Challenge? To name a few roadblocks to possible solutions includes legislative restrictions, monopolization by the pharmaceutical industries, stigma in communities about those seeking help for addiction, etc.

Significance
The increase in overdoses due to prescription opioids in the United States in recent years is a tremendous cost to both human life as well as government funding. One in four patients who are prescribed opioid drugs for pain in primary healthcare settings become addicted to the drugs. Opioid addiction is a gateway to the use of heroin with as many as 23% of prescription drug users becoming heroin abusers. Furthermore, drug overdose is the number one cause of accidental death in the US.[1] Also, government funding for the opioid epidemic has increased in recent years, however, so has the number of individuals fallen victim to addiction. Some examples include how in 2016 alone, the CDC distributed more than $30 million to 29 states through its Prescription Drug Overdose Grants. Through the Health Resources and Services Administration, $94 million was awarded to health centers to increase treatment methods in overlooked areas. However, the investment by the government and taxpayers seems to be in vain because overdose deaths involving opioids have increased by 80% in recent years.[2]

The root of the opioid problem in America began in the 1990s when doctors prescribed enormous amounts of prescription drugs. After the war on drugs began, strict

government policies involving the prescription of opioids raised costs for the pills and many turned to cheaper alternatives such as heroin.[3] Also, opioids create a chemical induced euphoria in the brain which fuels the fire of addiction. Addiction is very hard to define because it really differs on an individual basis but an overall definition is reliance on a substance. Addiction to anything, including opioids, can be predisposed genetically, a product of a person's lifestyle, or induced by their environment. The movement to solve chronic pain began in the late twentieth century was called Pain as the 5th Vital Sign pushed drug companies for a way to treat the 34 million patients that were suffering from chronic pain in the US. When OxyContin was brought into the market in 1996, the potential benefits were invaluable to the public, however, it soon became the most abused prescription drug in history and the utmost cause of overdoses.[4]

If the opioid epidemic were better addressed, there would be a significant decrease in deaths and overdoses due to opioids. As of now there are 12 million Americans reported abusing prescription opioids, and nearly four and a half million suffering from addiction. Nationwide approximately 20,101 people died due to prescription medication overdoses and 12,290 died due to heroin overdoses and these numbers could easily increase next year. The economic strain the epidemic is placing on our nation is great as well with nearly $55 billion spent on treatment and prevention of prescription opioid addiction.[5] Allowing better treatment plans as well as taking preventative measures towards addiction would allow the American populace to take back their lives. Also, it would allow people affected with chronic pain to benefit because they could more safely find relief from their ailments. All in all, more people die from prescription opioid overdose than from heroin, cocaine, and all other drugs combined.[6] The epidemic is evident and America needs a solution more effective and efficient than the government can provide.

Stakeholders
One of the most important people who is involved in the opioid crisis is a pain clinician. We got in contact with Dr. Mark Feeman, a pain clinician in the Atlanta area and we were able to get a lot of perspective on his thoughts about how the government and citizens are handling the prescription opioid epidemic and how it has affected his practice. He said that there is a lot of up and coming federal regulation on prescribing opioids that are good to an extent, however, they are excessive and can cause people who really need them for chronic pain to be denied access. Also, the regulations cause the pharmaceutical companies to bump up expenses and insurance companies will no longer cover the drugs for underprivileged people who then cannot afford treatment.

Other major players in the opioid crisis are pharmaceutical companies due to the fact that they monopolize the production and distribution of opioids. In 2010, 254 million prescriptions for opioids were filled by pharmaceutical companies and they generated revenues of $11 billion from opioid sales.[7] These drugs have really taken over the painkiller market and companies kickstart sale of these drugs in sometimes unethical ways. Because of all of the profit pharma makes off of opioid production and distribution, they would be more reluctant to support any solutions involving research into alternative painkillers and probably wouldn't support different packaging that would make pills less accessible but more expensive to produce.

A person seeking medical attention for pain would want the best treatment for their pain as well as would not like to be addicted. This is our target for our project. The people whose intentions are actually to seek help for short term or chronic pain and are not seeking the euphoria and addiction. They would support any measures that kept them protected from addiction to a reasonable extent. However, if the solution was too expensive for insurance to cover or hindered them for treating their pain, they would not be supportive. This is due to a mental block where pain is imminent and all controlling so a patient would do anything to ease their own discomfort.

The federal government is invested in a "War on Opioids". Many new acts have been put into place such as the Comprehensive Addiction and Recovery Act (CARA). Also, the CDC released guidelines for the prescription of addictive substances for primary care physicians to pain clinicians. The government has made it their personal agenda to start to fund projects to increase treatment projects and to begin prevention projects. There is much new regulation on the horizon as well that we will have to look out for as we plan our solution.

Context and Existing Solutions
Government legislation has recently implemented specified prescription pads for pain clinics that prescribe patients controlled substances. Theoretically, this is intended to make it more difficult to fabricate prescriptions so those suffering from addiction aren't able to utilize pharmacies to continue their abuse. Other government regulations have ensued, preventing patients from being prescribed opioids from multiple doctors. This intends to reduce the number of addicts as it makes it easier to streamline treatment of pain in the medical field and allows doctors to more easily monitor their patients. Naloxone is a so-called "antidote" to opioid overdoses. This drug is able to counteract opioids by blocking opioid receptors and reversing their effects. However, few people have access to naloxone. Many who currently have the drug at the ready include first responders and physicians who work in emergency rooms.[10] Methadone clinics are also

becoming more common in large urban centers. Basically, people who are addicted to opiates go to these clinics and go through replacement therapy. This essentially means that they are being weaned off of higher dosage opioids with a lesser substitute. Over time this reduces their addictive tendencies and helps them to recover fully.[11] Also, the CDC has come out with new guidelines for primary care physicians to utilize when they are faced with prescribing controlled substances. Many of these recommendations focus on prescribing opioids to patients who will be experiencing chronic pain for more than 3 months after a procedure or an injury rather than a shorter period of time. It also deals with addressing risk and dosage and how to prescribe on a patient to patient basis.[12]

Why is it still a problem?

There are a plethora of reasons why this issue has yet to be solved including some very challenging barriers and obstacles which require tremendous effort to overcome and encompass in one solution. One component feeding into the issue is that there is an overwhelming 75% of opioid abuse being created solely from individuals taking prescriptions which were meant for family members and not themselves.[8] Because of this, a large portion of the responsibility for appropriate prescription use and care falls on the person to whom it was prescribed which leaves a large gap for intervening in these situations. The variability in the environment makes for extremely hectic and unexpected events which is almost impossible to standardize into just one solution. Another big obstacle contributing to the issue is that physicians and family practitioners lack the specialized education on addictive substances and aren't properly prescribing opioids to patients. Our solution focuses on this particular part because of the substantial impact it would have on both the medical professional as well as the family by being able to connect them to each other for much needed communication. However, other apps have been attempted to connect doctors with other doctors and/or pharmacists with other pharmacists and haven't seen any noticeable impact. We intend to produce an application specifically designed to connect all three: the patient, prescriber, and pharmacist. This would allow for increased collaboration and in turn would facilitate the creation of a more holistic picture of a patient rather than just his/her file. Another hurdle which would heavily come into play is government regulation, more specifically HIPAA. Confidentiality and absolute security is vital to any application. Any solutions which dive into personal medical files, information, history, and communication must be federally approved and have a background check conducted to ensure it meets HIPAA guidelines and regulations.[9] Once implemented, this solution would also be able to address the issue of lack of resources and education mainly for rural areas by providing an outlet for information through smart phone and/or computer.

Proposed Work

Goal
Our group aims to reduce unintended opioid addiction by utilizing technology to increase communication between the entire network of parties involved when an individual begins taking opioids to treat chronic pain. This web includes the patient, the prescriber, the pharmacist, and it easily links to other vital resources such as psychiatrists, counselors, pill drop-off sites, and treatment centers. As a result, patients will be made more aware and reminded of the serious risks associated with opioid usage, which will hopefully discourage misuse. More concretely, this increased communication will aid prescribers,especially primary physicians who lack the resources to implicate thorough abuse prevention and monitoring programs, to have a better understanding of the needs and behaviors of their patients without having to significantly alter their current practice. Furthermore, having a quick and easy way for pharmacists to alert doctors of any concerning signs they may have noticed in a patient not only helps the doctor better monitor the patient, but it also increases the acknowledgement of opioid addiction as a prevalent and precarious disease across the health field. Ultimately, our app would combine features that improve the monitoring of prescribed opioids, the support team of individuals at risk of addiction, the availability of resources and education for those already addicted, and increase the knowledge and conversation on opioids to eliminate the social stigma and silence that currently exist.

Objective 1: App Development

Background
        In order to develop the mobile phone health app that we are considering, we will need a number of resources. We first will need a baseline for the code we will need to create the app. We can obtain this from a number of resources available at Georgia Tech or from a private company that provides mobile app building applications. We will also need to collect the code for each function of the app that we want to incorporate; for example, we will need to obtain code that can be used to collect patients' data in an easy to read format. We would also need a to hire a professional coder or find willing Georgia Tech computer science students who would be interested in joining our project team. We would need these individuals in order to take the baseline code we collected and format it into a unique and specialized software that will fulfill all of the aspects we want the app to include. We assume this process could take about three to six months to complete and can cost anywhere from zero to ten thousand dollars.
After programming the app we will need to obtain intellectual property rights, copyrights, trademarks, and patents to protect our product. We think this legal process could take

up to a year and can cost as much as ten thousand dollars unless we can find Georgia Tech opportunities to help us.

After coding we will need to invest time in designing graphics for the app and creating a brand for our product such as a logo, name, and catchy slogan. We hope to also look into branding resources provided by Georgia Tech.

The app development step is important because it allows us to create a baseline product that we can later test and market to see if it is effective and whether or not it will become popular with patients, doctors, and pharmacists. It will also allow us to create a brand and product that we can promote across campus and throughout the community. Creating a product that we can introduce to medical professionals to see how they react and get input on the aspects they like and dislike will also be very beneficial to our team.

Methods

1. Talk with professionals that have created health apps before to get their input and collect research on how to create and code a mobile phone app
2. Create a list of all the functions and aspects we want to include in our app (i.e. a data log page, a resources page, a pill-check function)
3. Create a rough design of how we want to organize the app and link all of the aspects
4. Start programming the app
5. Test the code
6. Reanalyze the program based on the test
7. Get professional input on the finished program and add necessary changes

Outcomes

The anticipated outcomes of this step would include an initial program and mobile app that we can test with patients in a soft launch. We also hope to measure the practicality and effectiveness of the app in our problem space and see how it will help reduce and model opioid addiction. After this step we will also have a product and brand that we can market and talk about with professionals and researchers across campus so we can also get their input on the solution.

Anticipated problems

The problems we anticipate to face include app development issues, intellectual property issues, and patient confidentiality issues. Throughout the programming process we expect to face a number of coding complications trying to figure what programs and functions are the easiest, fastest, and most effective for the purposes of our app. This process will involve a number of trial and errors. On the topic of patient confidentiality issues, we will need to find a secure server that will allow our app to hold patient's confidential medical information without the fear of hackers.

Objective 2: Soft Launch

Background

        For this step we will need to obtain a number of patients willing to test the product over a period of months. We will also need marketing tools such as flyers, posters, advertisements to promote our product to get patients and doctors involved. We may also need to travel to a number of medical facilities to promote our product and ask patients for their involvement. Finally, we will need support from large medical companies and possibly the government in order to have them help our product gain popularity

        This objective is necessary to test and improve our initial product. It will allow us to gain customer feedback and solve any glitches with the programming that customers may face while using the product. This soft launch will also allow us to market our product and get patients interested in using it. Getting patients to test the product for a period of time will allow us to get more resources and professionals involved which would lead to more revenue and feedback from the medical community. Moreover, a soft launch is important when testing an app because it allows us to test the program in the real world on a number of different devices.

Methods

1. Obtain a patient test group
2. Have patients run the program for 3-6 months and report any issues they face and what aspects they like and don't like about the product
3. Analyze the issues and feedback on the product and plan how to fix and improve them
4. Redevelop the app based on the necessary changes
5. Finalize the app
6. Prepare a market launch
7. Market the product
   a. Gain medical industry backing
   b. Obtain sponsors to help with advertising events
   c. Promote the product to doctors and medical professionals in the area
   d. Gain the help of opioid addiction experts and introduce the app at conventions and opioid addiction events
   e. Gain government support for the product
   f. Determine which advertising methods are the most effective and change our strategy accordingly

Outcomes

        The outcome of this objective would be a finalized product that can be distributed to all patients using opioids. After completing this objective, we will be able to analyze the effectiveness of our solution of our problem space. It would also allow the

opportunity for big data collection on opioid use and opioid addiction which could alternatively be used to model future patient behaviors and help doctors when prescribing opioids in the future.

Anticipated problems

The anticipated problems we foresee with this objective include the risk of patients being opposed to using the app. We hope through advertisement and other marketing methods to be able to show opioid using patients the importance and usefulness of the app, and therefore will try to avoid the issue as best we can. Our team may also run into the issue of patients not wanting to participate in the soft launch. Without an initial group of test patients, we will not be able to analyze any problems that the software may have or gain any feedback on the functionality and platform of the mobile app. With the advertisement aspect, we may run into the issue of resources and funding. With a large institute like Georgia Tech, we hope to use our community to help us promote our product and get as much help as possible. Finally, gaining medical industry and government backing may be difficult if they are opposed to the product our fail to see its purpose.

Project Team

The ideal project team would fulfill about 10 different roles underneath the categories of coding and development, business, data analytics, research, and leadership. A team of this size could be managed with one person who is solely devoted to communication and unification such as a secretarial group "leader" role. However, we believe the group would be most effective at a smaller size so long as no one member has absorbed too many roles. The following breakdown could be made possible among a 6 person team.

Two people could fulfill the necessary roles for coding and app development. These two individuals would need to have a strong background in coding, know how to create an application for a smartphone as well as a computer-friendly interface. They would have experience in this area and be interested in continuously learning how to improve and write more protected code. At least one of them would need to be familiar with firewalls, encryption, and other security features.

1. Phone App Developer- This person would be the main designer and expert for the mobile application that will be used primarily by patients
2. Website/Computer Software Developer- This person is the expert for the Doctor and Pharmacist aspect of the application that will be accessed by a computer rather than a smartphone.
3. Security- This is the head person responsible for creating an extremely secure network that will comply with government regulation. They need to

constantly update to prevent hacking and breaches of privacy. This person will be responsible for working with both other developers for any and all added security features such as verification of professionals before being able to access patients' information.

There is also a need for a business skill set to help with law related details as well as marketing,negotiating, and finance. However, in a six person team, one business expert could absorb both of the following jobs:

1. Legal Expert- This person would work to understand all the laws pertaining to confidentiality, medical records, and the legal power that pharmacists and doctors have in terms of prescribing, referring, conferring with one another, etc. This person would also be responsible for handling a patent if that ever became necessary.

2. Negotiations and Finance- This person would be responsible for presentations and designs to market the app as an asset for doctors and pharmacists. They would set up and attend meetings with stakeholders and serve as a representative or voice for the group in business settings. They also would budget for any cost associated with creating an app, owning and operating a website, filing for patents, or anything else.
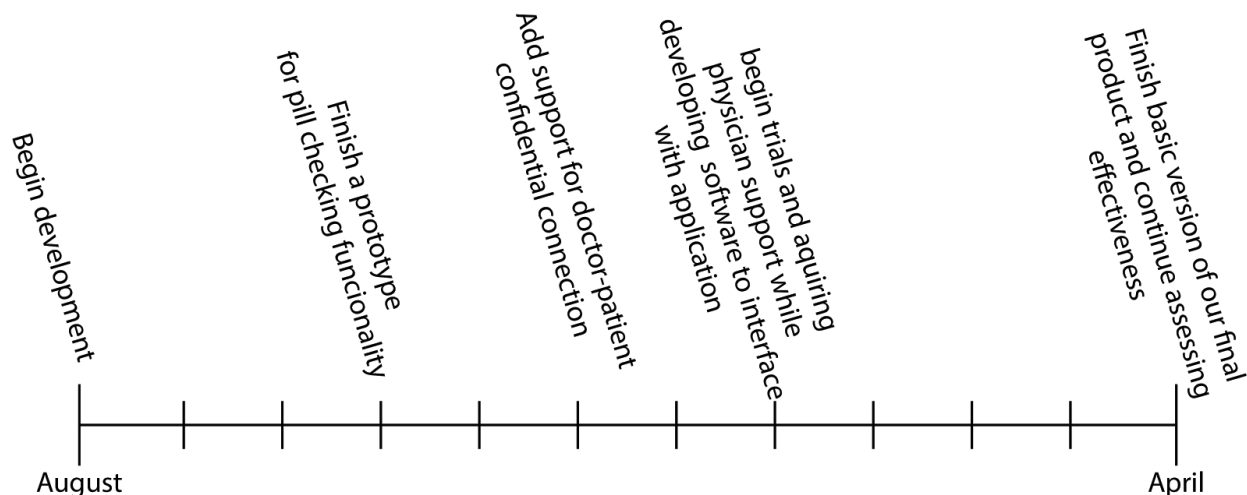
In addition, we would need a research team consisting of scientific and design experts. The skill set here is pretty broad and open, but ultimately they must be scientifically driven to conduct experiments but also engineer minded in the sense of quality control and efficiency. In a six person group, this team would be made up of two members, but their roles would overlap covering the following objectives together:

Scientific Design Team- This team would review research and scholarly literature to best understand the effects of opioids and dopamine production on the body. They will then be able to add scientific perspective and insight on the issue both for anchoring group meetings and for adding authenticity in meetings with potential investors. They will also use their expertise to work with the developers to ensure that the app best fits the needs of opioid users. This team is responsible for conducting many small studies to test the effectiveness of certain aspects of the app and gain constructive feedback for improvement. Likewise, they will lead quality control in terms of meeting the needs of doctors, pharmacists, and patients. In addition this team is responsible for designing simplified and concise education tools, brochures, and infographics for the app to make resources for patients more known and easily accessible.

Lastly, the sixth person would handle Data Analytics and Modeling. This person would work with the developers to incorporate the modeling, the scientific team to best identify what type of data is most pertinent, and the business team to market this feature of the app to investors. It is crucial that this person would have a experience with mathematical modeling and a strong data analytic skills on the computer. Because of the potential overlap in skill-set with the developers, this role could potentially be absorbed into a developing team, leaving the group at just 5 people instead of 6.

Along with fulfilling these roles, the project team must also have an advisor. Though we have not formally confirmed any advisors at the time, we have ideas for potential people to ask. Our first choice would be Rainey because she is our current advisor and already knows the problem space. Two other options could be Kantwon Rogers or Dr. Amber Robinson. The former is a CS professor at Georgia Tech making him extremely accessible and a great resource for coding insight. Meanwhile Dr.Amber Robinson, Ph.D, MPH, is a Georgia Tech Biomedical Engineering alumna who know works for the Center for Disease Control and Prevention in Atlanta as a behavioral scientist in their opioid addiction department. She would provide excellent insight and holds a strong network behind her.

Timeline:

Begin development | Finish a prototype for pill checking funcionality | Add support for doctor-patient confidential connection | begin trials and aquiring physician support while developing software to interface with application | Finish basic version of our final product and continue assessing effectiveness

August — April

<u>Budget</u>

Material and Supplies: No current materials and supplies are needed.

Equipment: We will need access to coding programs and app development tools which can be utilized through the development of the app of 3 to 6 months costing $0 to $10,000.

Services: We have the option of just having Harry focus on the coding which would eliminate cost. By outsourcing the coding to an app developer, the cost would be anywhere from $50 to $150 per hour with iOS apps taking 210+ hour and android apps taking 250+ hours. Therefore, the coder could cost anywhere from $23,000 to $69,000 which is not very feasible. In order to obtain IP rights like copyrights, trademarks, and patents, it could take 6 to 12 months and cost as much as $10,000 unless Georgia Tech would be willing to allow for us to use their legal team. Lastly, the design and graphics including logo, visuals in app, naming, and slogans could take 3 to 6 weeks and cost $0 to $1,000, but Georgia Tech resources could be taken advantage of to lower or even eliminate this cost.

Travel: No current travel plans are necessary.

Overall, total cost can possibly be $0 if everything can be coordinated and we can utilize all the resources we believe we can through the school. Although, if not, actual cost can range from $21,000 to $90,000 with paid app developer in consideration.

Expected Outcomes and Future Directions

Once everything is built and we have secured a server to run it on, we would have to seek out physicians to agree to test our system's effectiveness. We would accomplish this by beginning with a smaller sample size. Once the concept is proven we would move forward with implementing the app in other clusters of offices, slowly collecting data. Through our research and contacting the CDC, we discovered that it's currently extremely difficult to collect data around prescription opioid addiction since addicts are not incentivized to provide accurate data. We hope that our project will not only be useful to patients, doctors, and pharmacists, but also future researchers hoping to impact the opioid epidemic.

Sources

1. *Opioid addiction 2016 facts & figures*. Retrieved March 29, 2017, from American Society of Addiction Medicine website: http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf

2. *The opioid epidemic: By the numbers*. (2016, June). Retrieved March 29, 2017, from hhs.gov website: https://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf

3. Elkins, C. (n.d.). Searching for relief. Retrieved March 30, 2017, from DrugRehab.com website: https://www.drugrehab.com/opioid-epidemic/

4. Scruggs, K. (2016, May 8). The opioid epidemic: How did we get here? Retrieved March 30, 2017, from Huffington Post website: http://www.huffingtonpost.com/kristine-scruggs-md/the-opioid-epidemic-how-d_b_9865680.html

5. Tieman, D. (2017, February 15). 4 things governors can do to help combat the opioid epidemic. Retrieved March 30, 2017, from STAT website: https://www.statnews.com/2017/02/15/governors-combat-opioid-epidemic/

6. DuPont, S. (2015, September 22). Stemming the tide of prescription opioid overuse, misuse, and abuse. Retrieved March 30, 2017, from Health Affairs Blog: http://healthaffairs.org/blog/2015/09/22/stemming-the-tide-of-prescription-opioid-overuse-misuse-and-abuse/

7. The role of pharmaceutical companies in the opioid epidemic. (n.d.). Retrieved March 30, 2017, from Addictions.com website: https://www.addictions.com/opiate/the-role-of-pharmaceutical-companies-in-the-opioid-epidemic/

8. Szalavitz, Maia. "Opioid Addiction Is a Huge Problem, but Pain Prescriptions Are Not the Cause." *Scientific American Blog Network*. N.p., 10 May 2016. Web. 30 Mar. 2017.

9. Secretary, HHS Office of the. "Summary of the HIPAA Privacy Rule." *HHS.gov*. U.S. Department of Health and Human Services, 26 July 2013. Web. 30 Mar. 2017.

10. Naloxone. (2016, September). Retrieved April 18, 2017, from National institute on drug abuse website: https://www.drugabuse.gov/related-topics/naloxone

11. What to know about methadone clinics. (n.d.). Retrieved April 18, 2017, from American Addiction Centers website: http://americanaddictioncenters.org/methadone-addiction/clinic-facts/

12. CDC guideline for prescribing opioids for chronic pain. (2017, March 15). Retrieved April 18, 2017, from https://www.cdc.gov/drugoverdose/prescribing/guideline.html