

Aiding prescription drug adherence through the Creation of Digital Pill Cap
Grand Challenges Proposal
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Team 5: Immunity

How Might We— How might we track and aid adherence to prescription drugs by students at Georgia Tech.

I. Introduction

Scope: We hope to first implement our digital pill bottle-cap design through Stamps Student Health Services at Georgia Tech.

Rationale: The World Health Organization states that only around 75% of people typically follow their doctors' orders in taking prescription drugs.

Impact: Studies show that non-compliance in the US causes 125,000 deaths annually. It accounts for 10 to 25 percent of hospital and nursing home admissions. The New York Times declared noncompliance the world's "other drug problem".

II. Background

Prescription drug abuse is the “intentional use of a medication without a prescription; in a way other than as prescribed; or for the experience or feeling it causes” (NIDA). Prescription drug abuse is a serious and widespread issue in the United States. According to the American College of Preventative Medicine (ACPM), 7 million people, 2.7 percent of the population, abuse/misuse prescription drugs every month. 5.3 of those 7 million abuse pain relievers. Prescription drug abuse is the most common form of substance abuse. In fact, rates of prescription drug abuse are higher than cocaine, inhalant, hallucinogen, and heroin use combined (ACPM). This type of abuse is a widespread problem that is detrimental on both an individual and societal level.

Prescription drug abuse is driven by three factors: misconception about safety, increased environmental availability, and individual motivation by abuse. Between 1991 and 2010, prescriptions for stimulants increased from 5 million to nearly 45 million and for opioid analgesics from about 75.5 million to 209.5 million (NIDA). With this heightened availability, it is easy for people to obtain and abuse prescription drugs.

This kind of abuse is detrimental because it affects all facets of society, particularly teens. Among adolescents, prescription and over-the-counter medications account for most of the commonly abused illicit drugs by high school seniors. Nearly 1 in 12 high school seniors reported nonmedical use of Vicodin; 1 in 20 reported abuse of OxyContin (NIDA). When asked how prescription narcotics were obtained for nonmedical use, 70% of 12th graders said they were given to them by a friend or relative (MTF 2011). These abuses translate into other aspects of users lives. Among those who abuse prescription drugs, high rates of other risky behaviors, including abuse of other drugs and alcohol, have also been reported (NIDA). In addition, it

detriments the economy. In 2002, abuse of prescription drugs costs were nearly \$181 billion in the United States (ACPM). This abuse extends to the individual, with direct healthcare costs of an abuser estimated to be \$15,884 compared with \$1,830 for non-abusers. Prescription drug abuse is the fastest growing substance abuse issue and this issue must be accounted for due to its heavy impact on society at an individual and holistic level.

While society has taken note of drug abuse, preventative measures have not been discussed. "These drugs are very available, and highly addictive," said Max Crowley, an NIH Research Fellow at Duke's Center for Child and Family Policy. "There's a growing national debate about whether we should restrict access to these drugs, but at the same time, the drugs are hugely important for pain management. What's being left out of the debate is the role of prevention." In addition, current approaches towards preventing drug abuse are ineffective. Programs that aim to curb teen prescription drug abuse have vastly differing success rates, ranging from big drops in drug abuse to no measurable effect (Duke). New preventative methods have to be broached. The barriers to appropriate prescribing are listed by the ACPM as the following: Conflicting (or absent) evidence on effective pain management, dual, conflicting roles for prescribers, regulatory requirements, inadequate time to develop and coordinate an integrated or multidisciplinary treatment plan, availability of unused medications at a patient's home. A new approach that addresses these barriers should be developed.

<http://www.acpm.org/?UseAbuseRxTimeTool>

<http://www.drugabuse.gov/publications/topics-in-brief/prescription-drug-abuse>

<http://www.sciencedaily.com/releases/2014/02/140218143400.htm>

<http://www.monitoringthefuture.org/data/data.html>

<http://www.drugabuse.gov/publications/drugfacts/prescription-over-counter-medications>

III. Project Goal

Our primary goal is to successfully implement a means to accurately aid in the adherence and compliance of prescription medication. The proposed solution that we seek to deliver involves the implementation of a digital bottle cap and companion mobile application to track, analyze, and record prescription usage. We intend to work with Stamps Health Services at Georgia Tech to develop and test our solution, as well as other regional pharmacies. A notable end goal is to give appropriate medical staff the ability to monitor and recognize patient noncompliance so that they may assist their patients when necessary. An outline of our objectives exists in section V to provide a mid-level overview of our proposed approach.

IV. External Advisors

John Scuderi

Director, Health Operations

Certified Privacy Officer-Health Care Compliance Association

Having over 15 years of operational and administrative experience in hospitals and associated clinics, John

Scuderi is the point of contact of Stamps Health Services. He is incharge of Laboratory, Radiology, Pharmacy, Business and IT Services, Medical Records, Cashiers, Facilities, and Custodial Services. John Scuderi would help us achieve our goal by granting us access to the pharmacy along with certain information available only to Stamps staff and employees.

Nina Thoman

PharmD and PhD

Stamps Health Services- Pharmacy Manager

Chair, Advanced Specialization in Trauma & Disaster Studies

Receiving her PhD from Columbia University, Nina Thoman is extremely qualified to assist our group in getting involved with the Stamps Health Services Pharmacy. Also as a clinical consultant, she would be helpful in providing insight and statistics on our project.

Robert Butera

Group Chair, Electrical and Computing Engineering-Bioengineering

Wallace H. Coulter Dept. of Biomedical Engineering at Georgia Tech and Emory Laboratory for Neuroengineering

Being a Georgia Tech alumni and receiving his BEE with the highest honors, Robert Butera makes the perfect advisor as he can provide insights on the electrical engineering aspect of the design along with advice on the biomedical aspect. His research expertise will also play a large part in our project. Robert Butera received his MEE and PhD from Rice University and his Postdoctoral Fellowship from National Institute of Health.

V. Objectives

A. Research and Impact Analysis

Determine the most effective way of enhancing compliance by observing respectable research metrics and recognizing the most substantial errors in drug noncompliance among adolescents.

A big part of this observation will be understanding the habits of a sample set of college campuses, such as Georgia Tech, through discussion with pharmacy staff at the Stamps Health Center. Our initial research will involve conducting anonymous student body surveys and obtaining reliable metrics from our targeted pharmaceutical center(s). Additionally, while we may find that some solutions appear easier than others, it is important to analyze which will have the greatest impact towards our proposed goal and fine-tune the project's more detailed features with that data. This objective is crucial to the overall design and directed effect of our project, and without it we risk producing an inefficient and potentially useless deliverable.

Quantifiable Tasks:

1. Contact the pharmaceutical staff at Stamps Health Services to discuss our proposed solution (pill bottle cap that tracks, analyzes, and records usage) and learn about their input to how we may improve our design.
2. Observe the different procedures already in place at Stamps to help prevent noncompliance and determine if any of those features can become a factor into our own design
3. Monitor the statistics of people that return their prescription refills when they are informed to and report difficulties/problems with their drug use.
4. Create an applicable drug adherence survey with open-ended questions that can spark customer discovery conversations as well as a survey distribution procedure to anonymously target students at Georgia Tech. Some noted rewards could be drawing for 4x\$50 Walmart/Publix gift cards.
5. Distribute survey and monitor results.
6. Discuss the difficulty of implementing the cap and app in a pharmaceutical environment, as additional overhead such as calibrating the cap before use (with the app) and checking the metrics after use (with the app) would be required of pharmacy staff.
7. Determine appropriate means of use assistance within the application for prescription drug users (given they have smart phones), such as detailed descriptions on administration, push notifications for scheduled administration and reminder, the ability to upload progress reports from the cap, etc.
8. Follow potential consumers and take their input.
9. Make a chart to weigh the advantages and disadvantages of each proposed feature.
10. Finalize different design aspects, such as whether the cap should display the last-opened time, an approximate number of pills left, time until refill, etc.
11. Determine the appropriate waivers and usage legality paperwork required in having a patient use our system.

Anticipated Issues:

One of the problems that we anticipate to face is the cooperation of Stamps Health Center and students in our research and potential adoption. We are asking a significant burden of STAMPS to sit down and discuss our intentions, have them provide feedback and suggestions,

and allow us to monitor their procedures and patient use. Additionally, it may be the case that STAMPS simply doesn't believe that they would have the available time resources to handle the overhead that would be necessary in implementing our proposed system. Similarly, it may be difficult to convince students to participate in our survey. While this is not a project-ending factor, it is crucial that we have some sort of basis metrics that are applicable to our proposed solution--with the goal that the same survey would be distributed to gauge solution success down the road. To help pacify survey adoption woes, we plan to target freshmen in adopting our product during faset. To encourage this, we plan on providing a reward system, with a discount to participants or gift card raffles, depending again on the willingness of STAMPS to participate. Furthermore, it may prove rather difficult to gauge, in advanced, the potential effectiveness of our solution. In order to avoid such problems, it is important to dedicate significant interest and research into how we can circumvent each problem. For instance, it may be necessary to travel outside of our immediate geographical region to find a pharmacy willing to assist us, or poll various credible sources on how they feel our solution may affect prescription drug adherence.

B. Product Design

Design a physical bottle cap and coexisting mobile application to allow the tracking, analyzing, and recording of appropriate metrics, as well as notifications and usage instructions.

This objective is important to the actual usefulness and fruition of our project. If not executed carefully and with great quality, our solution could become either become ineffective or simply useless. It is the design of our actual product, and without it, we have no solution to offer.

Quantifiable Tasks:

1. Obtain pill bottles from Stamps that can be used for testing.
2. Tie in all of the research and features determined via the first objective to brainstorm and create ideal designs.
3. Sketch what our end products (cap and app) should look like, tying in design functionality and aesthetics.
4. Work with graduate students in Computer Science and Electrical Engineering to get a general idea of the technical aspects involved.

Anticipated Issues:

It may prove rather difficult to design the actual cap since only one of our group members has limited experience with digital design. However, with the assistance of a Georgia Tech faculty member or student, this should be resolvable. Additionally, it may prove difficult to implement some of the features, such as approximating the quantity of contents left in the bottle.

C. Product Creation and Iteration

Physically create the bottle cap from the design made previously.

This objective is important because it allows us to see the physical product. Without this objective, we won't be able to change things that are wrong with the cap that can't be seen on the computer; some things will only be noticed once the physical product is created.

Quantifiable Tasks:

1. Work with an appropriate staff member at Georgia Tech to discuss the proposed electrical design and implementation of the cap.
2. Design a cap that (potentially):
 - Connects to an app
 - Has a LED light that changes colors
 - Buzzes/makes noise
 - Noise to indicate time
3. Create an app that (potentially):
 - Allows pharmacists/users to load parameters and extract/analyze usage data
 - Can be configured to notify/remind users about usage, dosage, refills etc.
 - Allows users to contact appropriate persons for assistance
4. Use 3D printing to prototype our cap design.

Anticipated Issues:

As mentioned above, some problems with the product will only arise after the physical creation of the cap and app. Such features may need extensive testing and could potentially prove too difficult. The use of the Grand Challenge's 3D printers will be crucial in allowing us to rapidly prototype and modify our design.

D. Implementation of Deliverable and Feedback

Implement our proposed system at Stamps Health Center and gain preliminary feedback.

This objective is absolutely essential because it allows us to see how our solution is used in a real-world environment. It will also provide us with feedback on how to potentially improve future models and revisions. Without this objective, we won't know how effective our solution actually is and what we can do to improve it. Additionally, the first two objectives are meaningless if we never actually attempt to put our solution to use.

Quantifiable Tasks:

1. Talk to the lead pharmacist at Stamps and propose our solution to them.
2. If Stamps is interested, provide them with an appropriate sample size of caps and the necessary paperwork/legality forms, as well as appropriate test devices. Additionally,

- demo the solution's usage to them, and train them for implementation.
3. Talk and hold panels at new student events, such as FASET or Greek Peer Education on the importance of prescription drug adherence
 4. Continuously flier and distribute awareness material to new/current students
 5. Regularly collect feedback from the testing locations.
 6. Revise the product with improvements as determined by the provided feedback.
 7. Analyze the anonymous usage data to determine the effectiveness of the product and compile reports containing appropriate metrics.

Anticipated Issues:

As noted before, it may prove difficult to attain adoption, at least at first due to various reasons including time overhead or staff training. The task of attracting adolescent participants will most likely prove even more difficult. One potential solution is working with Stamps so that our cap is required on some prescriptions. While it is an end goal to make our cap necessary on highly-abused/dangerous drugs, it is not a reasonable procedure during the development/testing period--at least on a large scale. We hope to secure significant, if not widespread, adoption in our preliminary trials.

Fig. 1 Timeline of proposed work for the 2014-2015 school year.

References

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