Enhancing Medication Accessibility: Designing a Child Resistant Pill Bottle Cap for Diverse Users

A Major Qualifying Project

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Abstract

Elderly adults and those with low dexterity in their hands and wrists struggle with opening pill bottles. Current designs involve the use of these fine motor skills. The team designed a pill bottle cap to reduce the strain, allowing patients to access necessary medication while maintaining a child-safety lock. Based on preliminary results, the design can be a new and useful way of approaching this problem.

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These individuals were integral to the entire process and the team attributes the success of the project to them.

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1.0 Introduction

Opening pill containers can be difficult for many elderly adults and people with low dexterity in their hands and wrists. For example, child-safe push-twist pill bottles are medical containers that are designed to require fine motor skills and strength in order to keep medication secured away from children. But, these containers hinder users with low grip strength, stopping many of them from being able to open their medication independently. Although there are many other options for prescription containers, this group of patients still faces issues with accessing medication.

Other existing packaging for prescription medications include a variety of pill bottles, vials, and push-through and peel-off blister packs. Although these packages have been used for years, there are still flaws with their designs. There are many external tools on the market that try to mitigate these issues and these tools have different shapes, sizes, and mechanisms. For example, several tools use a clamp that assists users in prying open pill bottles, but many of these tools still require grip strength to use correctly. Alternatively, some engineers are in the process of designing ‘smart pill bottles’ that use biometric scanners to improve ease of medication access while also keeping it secure. This design would provide many benefits but is still in the testing phases and can be costly for patients due to its technology. This limits the amount of people that can obtain this kind of medication accessibility and security.

Studies show that current prescription container designs influence prescription adherence rates in elderly adults and those with low dexterity. In a survey conducted in 2017, about 76% of disabled participants that were 50 years old and older reported being unintentionally nonadherent to their pill regimen and 4% said they were intentionally nonadherent (Fain & Farmer, 2017). The

participants that were unintentionally nonadherent had difficulty with opening pill bottles while participants that were intentionally nonadherent chose to take their medication later.

Current prescription container designs also do not provide enough security for children to not gain access to them. Pediatric poisoning has become one of the most common and preventable injuries with over 300 accidents a day (Petit‐Frere & Miltenberger, 2021). These poisonings are caused by children's access to medications, cleaning products, and toxic chemicals. In conjunction, in a study out of 419 caregivers (parents/guardians), only 25% reported that they stored their medications in a secure place (Salzman et al., 2019).

The overall goal of this project was to create a device that allows patients to access their prescriptions independently. The product was designed to minimize hand and wrist strain while opening, be inexpensive, portable, have no drug interactions, and maintain child resistance. Surveys were sent to caregivers, parents, patients, and pharmacists to understand each perspective. Feedback informed the team that child-safety containers were difficult to open and required hand and wrist strength. Mechanical testing was performed to test the design’s portability and child-safety. These tests showed that the pill bottle’s locking mechanism is strong enough to withstand constant moving, multiple drops, and pull force from an above average three-year-old child. Human testing was conducted to test the design’s accessibility, usability, and safety. Young adult and elderly adult patients were able to open the pill bottle and found the device to be simple and comfortable. Pediatric testing found that children between the ages of two to seven could not open the bottle without a demonstration. Throughout the project, multiple iterations were designed and printed to perfect the design.

2.0 Background

This chapter gives an overview of the target audience of the design, existing pill bottle designs, drug interactions, prescription adherence, the necessity of the design being childproof, and ethics and regulations. All of these concepts were instrumental in providing the team with the necessary background knowledge in order to execute a successful design process. Through the knowledge gained in this preliminary research, the team was able to identify the clinical and engineering need which was used to inspire the final design.

2.1 Target Audience

In this project, the target audiences are elderly adults, people with low dexterity in their hands and wrists, and other people that might struggle with child-safe pill bottles. In the United States, more than 131 million people (66% of all adults) use prescription drugs ("Prescription Drugs," n.d.). For this project, the target audience ranged from abled and disabled young adults to elderly adult patients who lack strength and dexterity. These groups are most impacted by the design but the team recognized that any person regardless of age or health can benefit from this device. In order to understand how to redesign the pill dispensing system, it was necessary to understand the obstacles and struggles that the target audience has with existing pill containers.

One of the main target groups for the project was disabled adults and those who otherwise have low dexterity. These patients face challenges with grip strength which is required to maneuver the device to access their medicine. For example, individuals who suffer from rheumatoid arthritis (RA) struggle to open pill bottles for multiple reasons. Due to the nature of this autoimmune disease, they often have pain in their hands and wrists. In a study out of 221 inpatients with RA, 26.1% of patients reported problems with their fingers and 14.8% reported

problems with their wrists when performing daily tasks such as "'hair dressing', 'washing one's body', 'taking on and off one's shoes'" (Ishikawa et al., 2018). The leading problems that were encountered by participants during the study were pain and loss of power, with 38.8% and 32.8% of patients reporting these issues respectively. Overall, with pain, loss of power, and an overall decreased range of motion (ROM), the patients lacked the prehensile function needed to open the bottles and access their medications (Ishikawa et al., 2018).

Elderly adults experience pain and difficulty in their hands and wrists as well. In a study done with older women, women with RA, and nurses to assess their ability to open various packages, it was found that patients were unable to open pill bottles or struggled to do so. Overall difficulty in opening packages related to their limited pinching ability as well as overall greater strain in their upper extremities when opening packages was found to be higher in both arthritic women and older women. In the upper extremities, the ROM was also increased in older women and women with RA when compared with nurses. On average, older women and women with RA had an 8% and 6% increase in forearm rotation, a 5% and 22% increase in ulnar-radial deviation, and an 11% and 48% increase in palmar-volar flexion respectively. Overall, due to increased strain, ROM needed, and pain in the upper extremities, most of the target audience experiences difficulties in opening current pill packages (Sormunen et al., 2014).

2.2 Existing Designs

There are several designs for holding medication that are currently in use, such as push-through and peel-off blister packs, vials, and bottles. Before further development of the design, the team needed to research other competitors on the market to see where their successes and weaknesses lie.

As discussed in Section 2.1, a study was done comparing older women, women with RA, and nurses' abilities to open various packages. This study found that 13% of the arthritic female participants were unable to open screw-cap bottles and 20% could not successfully open the plastic dropper packaging. About 1 in 15 older women and 8 in 15 women with RA also needed assistance in opening the packages (Sormunen et al., 2014). This study used the following four containers: a glass bottle with a screw cap, a pill plate, a disposable plastic dropper, and a plastic jar with a hinge cap, shown in Figure 1. Each of the containers have different methods of opening. The glass screw bottle can be opened by gripping the bottle with the non-dominant hand and screwing with fingertips on the dominant hand. The pill plate can be opened by using both hands to push the individual pill out of the packaging. The disposable plastic dropper also requires both hands to open, but the package is torn off with the end of the dropper broken off. The plastic jar with a hinge cap is opened using fingers to pry open the top of the cap. The data from this study showed that different types of packages and locking mechanisms affect the ease of use for target audiences.

Figure 1. Four types of packages in the study. From left to right: glass bottle with screw cap, pill plate, disposable plastic dropper, and plastic jar with hinge cap (Sormunen et al., 2014).

There are several iterations of assistive devices that help open pill bottles currently on the market, all varying in shapes, sizes, and mechanisms. For example, there are several products that act as a clamp that latches onto the cap of the bottle and pries it off. These products have been effective for patients, as they have several positive reviews and purchases off of retailer websites. They are all relatively low-priced, ranging from around $5 to roughly $30. All of these products

have different benefits based on their design, shape, and size. Some products are shown in Figure 2, ranging from a circular clamp with a magnifying glass to a crowbar-like device. While these can be effective in opening pill bottles, they still require strength and rotation of the wrist. For example, for the bottle opener in the bottom left image of Figure 2, the retailer description explains, "It still requires some Strength to Grip the lids, otherwise it may slip around" (*Amazon.Com: Otstar Jar Opener*, n.d.). The team recognizes that while these products can be beneficial to their users, there is still room for improvements in both the patient care and overall design.

Figure 2. Assortment of competing designs (*Amazon.Com: Apothecary Container Opener*, n.d.), (*Amazon.Com: Otstar Jar Opener*, n.d.), (*Medi-Grip Bottle Opener and Magnifier*, n.d.).

A remarkable solution to this issue grew in popularity on the social media platform, TikTok. A user with Parkinson's disease posted a video of him struggling to open and take his medication due to tremors and the lack of control in his hands. This post went viral and caused a wave of engineers and designers to create different designs for a new pill bottle that can be helpful for individuals with tremors and motor skill deficiencies. One design that stuck out was

from a designer named Brian Alldrige. His design was unique in the fact that it is very simple but effective. The bottle features a rotating bottom that isolates a single pill with a tube that runs along the duration of the length. This allows one pill to be distributed at a time and the patient to not have to dig through the bottle to obtain a small pill. This design was a success, as it raised awareness for the community of Parkinson's disease patients and raised money for the Michael J. Fox Foundation through sales of the newly designed bottle (Sanchez, 2021). This design assured the team the need for a new pill bottle dispense was very apparent and present to assist this target population.

Overall, although there are many designs that exist on the market, there are still issues with patients being able to access their medications. Due to the restrictions surrounding the ability for children to open prescription pill packaging, most current designs rely on mechanical force, strength, or dexterity to open them. This is an issue for the target audience as many elderly adult patients, or those with limiting disabilities, struggle to muster the strength or dexterity required to open the bottle. This causes the patient to experience pain, loss of strength, or other factors that can limit their ability to access their medication. Overall, due to these issues presented by the target audience, the team wanted to redesign conventional pill bottles to allow better access to these patients.

2.3 Drug Interactions

To design medication containers, the materials must be chosen carefully to prevent interactions with the drugs it will hold, as well as light. Prescription drugs, over-the-counter drugs, and dietary supplements use different materials for their containers, but all make sure that they do not interfere with the efficacy of the drug to keep the patients safe. Important factors that

are considered when it comes to the production of the drug are physical and chemical stability, serving as a basis for drug expiration dates (Liu & ODonovan, 2023). The goal of drug packaging is to maximize this stability and shield the drugs from environmental factors like light and temperature. The most common materials that are used are polyvinyl chloride (PVC), polyvinyl dichloride, polychlorotrifluoroethylene, aluminum foil, and cyclin olefin copolymer (Liu & ODonovan, 2023). As for the caps, some common materials that are often used are polypropylene and polyethylene (*Two Common Materials for Medicinal Bottle Cap-Xinfuda*, n.d.). Some other factors that are considered for the packaging are moisture exposure, package leaching, and its role as a barrier to medication adherence.

There are four categories of drug-plastic interactions: leaching, chemical reactivity, permeation, and sorption (Smith, 1979). Plastic containers have a possibility of leaching onto drugs. A commonly used medical plastic is PVC, but to have varied physical properties, it uses additives. Chemical agents such as plasticizers, stabilizers, colorants, and other agents are added using heat and pressure to allow for their special properties (Smith, 1979). If the liquid drug solution reacts with the plastic, the plastic may lose its protective and storage capacities (Smith, 1979). The chemical reactivity that alters the properties of the plastic focuses on the chemical interactions between the plastic and the drug. Permeation refers to when there is a loss or gain of water, oxygen, or volatile organic materials that causes the drug to deteriorate in the container. Fluid loss for PVC or polyethylene can be prevented using an “outer protective envelope” (Smith, 1979). Sorption is either the adsorption or absorption of the drug product into the plastic container, which affects the concentration delivered to the patient.

In addition to the material of the container, external factors such as temperature, moisture, pH, oxygen, and light also play a role in interference of the drug. The stability of the medication

is affected when the temperature increases because it causes an increase in the hydrolysis rate of the drug. If the drug is water-soluble, the dosage can undergo physical and chemical property changes. The pH influences the deterioration rate of hydrolyzed solution drugs. The presence of oxygen will facilitate the oxidation process in the drug. Lastly, when exposed to light, the rate of decomposition of the drug increases. All of these external factors affect the drug in a multitude of ways (F et al., 2020).

To further examine potential drug interactions, the team looked at a study conducted in 2020 that analyzed a transparent glass bottle, an amber glass bottle, a PVC amber plastic bottle, and a low-density polyethylene semi-opaque plastic (LDPE) bottle, both empty and drug-filled. These bottles were compared for compliance with Pharmacopoeial limits of percentage transmission. In terms of the results of the study, variations in thickness affected the amount of light transmitted through the bottles. The drug-filled bottles showed an increase in light transmission as a result of the interaction between drug and bottle components. In addition, the leaching from coloring agents into the solution during storage increased the transmission of light, which is detrimental to photosensitive drugs in the formulation. Also, the semi-opaque plastic, LDPE, had the highest light protective efficacy of the bottles studied, followed by amber plastic, PVC, and amber glass (Sabah et al., 2020). The team would use polyethylene as the material for the cap if it were to be manufactured as it provides high light protection compared to other materials.

2.4 Prescription Adherence

Drug packaging can be a barrier to medication adherence. Patients with impairments or disabilities may experience the most difficulty due to the design of prescription containers. In

order to understand the impact of drug packaging, the key differences between impairment, disability, and handicap must be understood. An impairment is a problem or an abnormality relating to psychology, physiology, or anatomy (Wakeham et al., 2017). A disability is a functional limitation when performing specific activities that are considered “normal for a human being” (Wakeham et al., 2017). A handicap is a disadvantage for an individual that is a result of an impairment or a disability, limiting or preventing them from fulfilling a life role (Wakeham et al., 2017).

Barriers that people with disabilities face can be either nonphysical or physical. Non-physical barriers include communication, policies, and cost (Wakeham et al., 2017). An insurance plan’s drug coverage and overall access may impact patient adherence as a non-physical barrier to medication accessibility. Physical barriers are inaccessible parking areas, uneven access to buildings, poor signage, and lack of access to transportation, and pharmacy products (Wakeham et al., 2017). Patients with limited strength or dexterity, especially in their hand(s), may be unable to open containers and packages, while patients with vision impairment can have trouble reading prescription labels. These situations can cause adherence issues and it is important to understand these instances to improve patient care.

Older patients with long-term disabilities face many challenges as well. These patients also have problems with prescription adherence and when compared to non-impaired, they scored worse according to the Morisky Medication Adherence Scale (MMAS) (Fain & Farmer, 2017). They are also more likely to be unintentionally nonadherent than intentionally nonadherent. A survey of 26 older adults was done with participants who were 50 years old or older and had a sensory or physical impairment that began before 50. These participants were individuals with mobility, visual, and hearing impairments and also had to be taking at least 3 medications that

they were responsible for. In this survey, approximately 76% of disabled participants said they were always unintentionally nonadherent while only 4% of disabled participants said they were intentionally nonadherent (Fain & Farmer, 2017). This group is unable to take medications due to their physical limitations and it is important to keep that in consideration when understanding medication containers.

There are non-adherent problems outside of patients with disabilities and impairments as well. A prospective cohort study was done to find and understand the risk factors for nonadherence to Warfarin, a medication that helps prevent strokes and thromboembolism. The participants were adults starting Warfarin at two anticoagulation clinics. Nonadherence was defined as failure to record the correct amount of pill bottle openings each day, with daily pill bottle openings measured using an electronic monitoring cap. Out of 22,425 adults, approximately 21% of patients were nonadherent (Platt et al., 2008). For specifically Warfarin, poor adherence can cause poor anticoagulation control which leads to a greater risk of stroke or recurrent thromboembolism. Nonadherence can be dangerous for some patients as their medication is vital for their health.

2.5 Child Proof Necessity

Pediatric poisoning is a common and preventable childhood injury with over 300 accidents and two deaths occurring each day (Petit‐Frere & Miltenberger, 2021). Prescription drug use among adults is increasing and may contribute to this problem due to the higher number of medications in the child's environment (White & Kibalama, 2018). Caregiver behaviors are also overlooked when it comes to safe medication storage. Young children are prone to access pill bottles and other prescription containers due to their placement around the home. Out of 419

caregivers surveyed, about 25% stored medications in secure places and less than 3% stored them in a locked container (Salzman et al., 2019). Other surveys produced similar statistics; “out of 31 parents who had prescription drugs that could be used for non-medical purposes, only one respondent reported locking up her medications in a drawer in her bedroom” (Friese et al., 2013). In a national poll with 2,051 responses, 61% of grandparents reported that they keep their medication in a cupboard or cabinet, and only 5% of that percentage store them in a locked cupboard or cabinet (*Safely Storing Medication Around Grandchildren | National Poll on Healthy Aging*, 2019). Guardians and caregivers are encouraged to buy safety packaging, keep medicines out of reach (including vitamin supplements), teach children about the hazards of medications, and more (MacKay & Samuel, 2018).

If safety behaviors fail, the design of the prescription container can help deter children from accessing the medication. When creating an effective child-proof pill dispenser system, it is important to take note of what causes a child to be drawn to medication and the potential harm they risk when they come in contact with it. The act of childproofing involves creating either a physical barrier between the child and the hazards or a cognitive barrier that requires reasoning, reading, fine motor skills, and strength. Childproofing a home is extremely important, as homes include things that can crush, burn, electrocute, or choke a child. However, it can be difficult to achieve this because certain tasks may be more difficult to do for the intended adult users. For example, a pill bottle is hard for an adult with lower dexterity to open, which causes adults to leave their medication in a non-child-safe bottle.

In the U.S., childproof packaging is mandated by the Poison Prevention Packaging Act of 1970 (Tilliss, 2019). The protocol for demonstrating child-resistant packaging is 16 CFR 1700.20, *Testing Procedure for Special Packaging*. In the procedure, if a child can open the packaging, or

gain access to the contents during at least one out of two five-minute periods, it is considered a failure. For unit packaging, if the child can open more than eight individual units, or whichever number is determined for the study, within 10 minutes, it is considered a failure.

3.0 Design

This project aimed to create a device that allows patients to access their prescriptions with ease. By making a device such as this available, it may lead to patients more closely adhering to their drug regimen. Patients needed a new, less expensive, and easier alternative to the normal pill bottle that still is able to maintain a child-proof lock and is portable. A product such as this would allow patients to access their prescriptions independently with the least amount of force possible. In order for the team to design a new option for patients, it was important to lay out the objectives and criteria of the final design.

3.1 Objective 1: Patient Accessibility

Most patients, especially elderly adult patients or those with dexterity limiting disabilities such as Parkinson's or Rheumatoid Arthritis (RA), lack the grip strength needed to open current pill dispenser systems. In short, the team needed the system that required the least amount of force to open, especially from the fingers and wrists, where most of the target audience experiences various issues.

To design for the lack of strength and dexterity in the target audience, it was important to move away from designs that relied on the patient's strength as the primary driving force behind unlocking and removing the cap. It is near impossible to have no force required to open the device because, for a patient to be autonomous, there would still be effort needed to lift the bottle and dispense the medication. With this knowledge, the team wanted the force threshold to be as low as possible.

3.2 Objective 2: Child Proof

Due to the design goal of having a low dexterity or strength threshold in order to open the pill dispense system, the team realized that there was a possibility that children, especially those under the age of 5 years, would be able to open the system and therefore access the medications. As allowing children to access medication can be lethal, ensuring that the pill dispense system is as child-proof as possible was a necessity for the device. This objective, combined with the accessibility requirement, needed to result in a design that does not rely on physical strength or dexterity, like most of the current solutions. Instead, the device required relying on the cognitive differences between children and the target audience.

3.3 Objective 3: No Drug Interaction

The design should not allow for any negative interactions between the pill dispense system and the medication inside. This was a critical objective, as it focused on maintaining the physical and chemical integrity of the medications. Some of the major routes of unwanted interactions are UV light, permeation, sorption, and chemical leaching. As described in Section 2.3, these interactions can lead to chemical degradation, inaccurate dosing, and other chemical or physical interactions.

In order for the team to design a device to avoid these interactions, a few steps must be taken. First, the correct material must be selected to construct the device. The choice of material will dictate if there will be any chemical interaction or degradation inside the container due to any potential reaction with the medication. There are multiple materials that do not seem to show any signs of medicine interaction, such as PVC, and others outlined in Section 2.3. These materials

are never fully transparent, as they need to protect the medicine inside from UV-based degradation, which covers another requirement for preventing interactions.

To design for the remaining requirements, preventing permeation and sorption, a few methods can be used. In order to prevent permeation, the primary method is designing a device that is leak resistant. This includes ensuring there is a tight seal around the opening in the pill bottle to prevent moisture or any other substance from entering or leaving the container. This will help ensure a stable environment that will prevent any degradation of the medication. Aside from this, prior to the patient receiving the pill bottle containing their medication, it can also be placed inside a secondary "outer protective envelope" that is designed to prevent permeation of the pill bottle and medication during transport and storage (Smith, 1979). As for sorption, there are currently no standardized methods for its prevention in pill bottles. However, by selecting an appropriate material that does not typically adsorb or absorb molecules, the rates of sorption in pill bottles can be limited.

3.4 Objective 4: Cost Effectiveness

The previous objectives involve the long term use of the pill dispense systems, which includes its overall cost. By keeping the cost of creating the pill dispense system down, it will lessen the overall cost of manufacturing while maintaining a cost-effective method for the patients to access their medications. This could be important to the target audience, who may not have the funds for a more expensive dispense system.

There are many different methods in keeping costs low for the target audience. By keeping the design as simple as possible while maintaining the other objectives, the amount of parts can remain low, leading to reduced production costs. The choice of material that the device is made

out of also relates to the overall patient cost, as it is usually the main driving factor behind the price of a device. By choosing a relatively inexpensive and available material, such as high density polyethylene for instance, the overall cost can be driven down and the savings passed on to the target audience.

One of the last methods to cut costs is to limit the variability in the manufacturing process. For example, if there are multiple sizes of pill bottles that need different sizes of caps, that would lead to an increase in the variability and types of machinery that would be needed to manufacture the different sizes and shapes. However, limiting this is not always possible, and must be compared to the disadvantages to a lack of manufacturing variety. Having more and differently sized pill bottle caps would allow for greater patient accessibility and reach a wider audience, however, would lead to increases in overall production costs.

3.5 Objective 5: Portability

It is ideal that the device is portable so as to not obstruct the lifestyles of the patient. A portable or mobile system would allow the patients to access their medications not just in their own households, but anywhere that they might need them. Portability can tie greatly into accessibility when it comes to medications that require frequent enough dosages that the patient carries the medication with them wherever they may go.

The design process being tailored to this objective requires several steps to be taken. Overall, the design needs to be as small as feasibly possible. Limiting the overall size of the device will allow patients to carry it with them in their daily lives. But, there are limitations with shrinking the device in terms of manufacturing and 3D printing accuracies, as well as the risk of lowering accessibility for the target audience. The smaller the device is, the less accurate and

precise the print would be, and the greater the potential that a target patient would struggle to handle the device. To successfully begin the design process, there must be a balance between design precision and obtaining these objectives.

3.6 Design Criteria

Overall, it is of utmost importance that the pill dispense system does not interact or interfere with the drug in any negative manner. Aside from that, it is important that the pill dispense system is accessible by the target audience while also denying access to children. Lastly, it should be cost-effective and portable in order to increase the ease of use and overall accessibility. Table 1 shows a Pairwise comparison chart that organizes and compares the design's main objectives and criteria in order of importance. Table 2 shows a finalized and condensed version of the Pairwise comparison chart, highlighting patient accessibility as the most important objective of the project.

Table 1

Pairwise comparison chart depicting and measuring the values of the team's objectives/criteria.

	Cost effective	Patient Accessibility	Child-proof	Portable	No drug interaction	Total	Weight
Cost effective	x	0	0	0.5	0	0.5	2
Patient Accessibility	1	x	0.5	1	1	3.5	5
Child Proof	1	0.5	x	1	1	3.5	4
Portable	0.5	0	0	x	0	0.5	1
No drug interaction	1	0	0	1	x	2	3

Note: If you rank row candidate over column candidate: 1. If you rank column candidate over row candidate: 0, If you rank both equally: 0.5

Table 2

A finalized table of the team's five objectives, and their respective weights corresponding to importance.

Objective	Weight
Patient Accessibility	5
Child Proof	4
No Drug Interaction	3
Cost Effective	2
Portable	1

Note: 5 being most important and 1 being least.

With the criteria and objectives discussed above, there also came various limitations when planning out potential designs. First, since the team operated in an academic setting at WPI, access to funding was limited to $1,000. Due to this budget, the team produced as few separate prototypes as possible. In a similar fashion, the budget played a hand in the materials and manufacturing methods available. The design relied on 3D printing using PLA filament made available to the team in the lab space. In addition, due to the simplicity of the methods available, the accuracy of the manufacturing instruments proved to be a limitation in the precision and detail of the final prototype. Lastly, the overall timeline of the project also caused scheduling issues if every aspect of the project did not move seamlessly. The Gantt Chart that the team created is shown in Figure 3, which lays out when the team expected to complete each piece of the project during the 2023-2024 academic year.

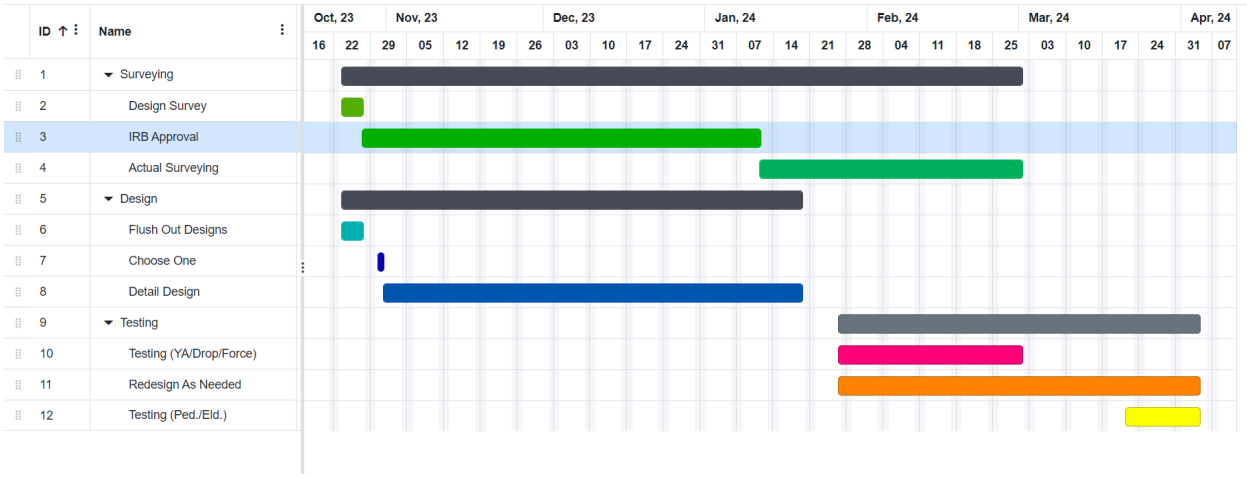
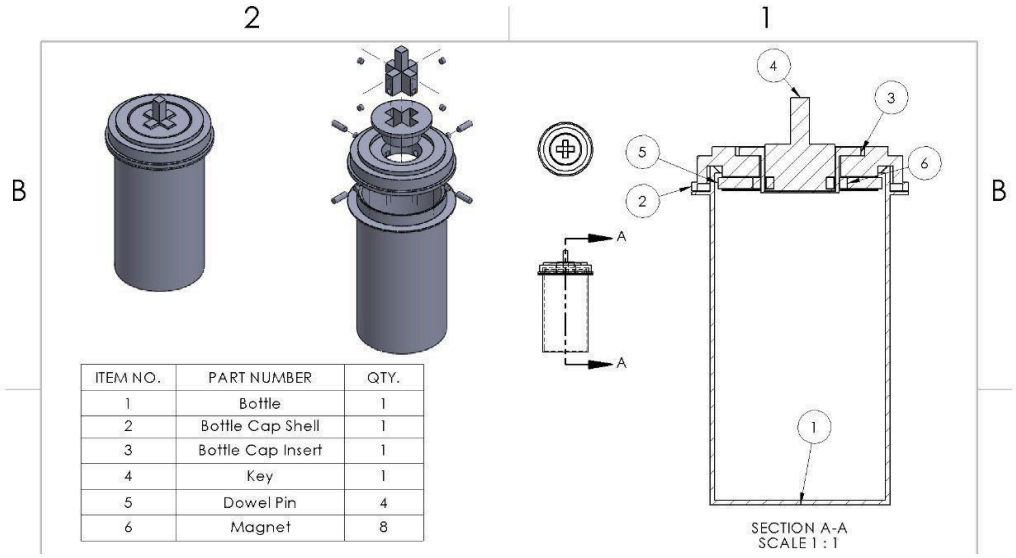


Figure 3. Gantt Chart created by the team, outlining the timeline of the project from A Term 2023 to D Term 2024.

3.7 Alternative Designs

Throughout the project, the team created many iterations of the design in order to ensure that the final prototype accomplished each objective most efficiently. The team used current products to serve as inspiration when designing a working prototype with new child safety mechanisms. The ideas included various locking mechanisms, methods of dispensing, and other styles of child-proofing.

Since this was an extension of an existing concept created during a BME 3300 project, it is important to note the original design of the system, as well as why the group moved away from it. The original design, shown in Figure 4, consisted of a magnetic key that, when inserted into the corresponding magnetic lock on the bottle, would release the magnets from their “locked” position, and allow the user to open the pill bottle. This was a sufficient initial design that had strong promise in keeping medication locked away from children, while also allowing the target patient audience to access their medications through the use of a cognitive barrier.



ITEM NO.	PART NUMBER	QTY.
1	Bottle	1
2	Bottle Cap Shell	1
3	Bottle Cap Insert	1
4	Key	1
5	Dowel Pin	4
6	Magnet	8

Figure 4. Schematics of the original design, showcasing the corresponding shapes of the key and lock.

One of the major limitations to the child-proofing of this design was the key and lock mechanism, which consisted of a “plus” shaped key being put into a “plus” shaped hole. The issue with this opening mechanism was that one of the concepts learned by children early on in their development is matching shapes with corresponding holes, as shown in the children’s toy in Figure 5. The translatability with this skill could allow children to quickly adapt to this keyhole design and unlock it by putting the key into its respectively shaped hole.

Figure 5. Children's toy that teaches the concepts of shape interactions and fine motor skills, which would translate when attempting to open the original design (*Shape Sorter Toy*, n.d.).

3.7.1 Simple-Complex Spectrum

Other alternative designs included using various locking mechanisms, such as a numeric lock that one might see attached to lockers or bags, as well as less common mechanisms such as a biometric scanner. These two mechanisms, being on opposite ends of the simple-complex spectrum, both had their advantages as well as disadvantages. On one hand, a simple numeric lock would provide a safe method to accessing their medications. With there being 10,000 possible combinations that the child would have to attempt in order to access the pills, it would provide sufficient time for the patient to realize the child's actions. The limitations in this design primarily came from the concern that elderly patients were part of the target audience. These patients tend to have more trouble with their memory compared with the remaining target audience, and could quickly forget the passcode. The other concern would be accidentally leaving the lock with the passcode already aligned in the lock, which would allow the child to bypass needing the passcode and simply open the container.

3.7.2 Biometric Scanner

Another design that was considered was the use of a biometric scanner to open the bottle. This would by far be the most child-proof method, as it would only open to the patient's biometrics. It would also reduce the amount of force needed to open it, as there would not be any physical barrier once the scanner unlocked the bottle. The downsides, however, outweighed the advantage. For example, it would be the most expensive and the most difficult to manufacture option. It would require electronic parts that would have to be powered, and so if the device loses power it could restrict access to the medicine inside. Overall, due to its complexity and high

cost-benefit ratio, it was determined that it would not only be unfeasible to complete in a single academic year, but it would also produce a costly product with many possible points of failure.

3.7.3 Collapsible Ring

An additional design that the team considered was a locking mechanism that contains a collapsible, magnetic ring that will act as a clamp. This was conceptualized to remove the pin mechanism of the original design. The downfall of the four pin locations in the original design was that it was simple to maneuver the cap to open it. The idea behind the collapsible ring was that the cap would be secured around the entire circumference instead of only four locations. The group decided to not move forward with this design due to the difficulty of finding a material for this ring concept and that it would have lacked the strength to keep the cap secured.

3.7.4 Calendar Dispense Systems

Aside from the locking mechanisms, it was also important to discuss dispensing mechanisms as well. In the scope of the target audience, it is important to understand that a limiting factor, like Parkinson's-induced tremors, impacts both how the patient opens the bottle as well as their ability to select individual pills from a bottle. Due to this, the team also ideated some designs that could help the patient only access individual pills at a time.

One of the designs the team thought of was a calendar system that would allow the patient to pull a tab, opening a container that housed the dose of medicine for that day. This design would employ physical stops that would prevent more than one dose from being opened at a time, meaning that before the Tuesday dose was taken, the Monday dose must be opened and taken as well. In a similar manner, the team thought through the idea of using a dispensing method similar to a Pez Dispenser, shown in Figure 6, a popular brand of candy whose packaging can dispense a

singular piece at a time. Overall, the team decided to move away from these designs as the calendar design would prove to be less portable than the team wanted, and the Pez dispenser design could lead to an increase in child accessibility due to its potential resemblance to actual Pez dispensers.

Figure 6. Examples of a Pez Dispenser, inspiration for a potential design (Newbold, n.d.).

3.7.5 Additional Alternate Designs

There were several other designs that did not expand past the initial ideation phase. First, a locking mechanism with magnetic teeth was brought up as a way to fasten the cap onto the bottle. This was not explored due to lack of feasibility in the timespan of the project. Next, the group thought of a pressure plate mechanism, meaning that the patient would push the cap onto a pressure plate and turn it slightly to open up the bottle. This was not continued because it did not satisfy the patient accessibility objective to limit strain for the patients. However, the idea of a separate part to open the bottle was used in the creation of the team's final design.

3.8 Design Process

3.8.1 Preliminary Designs

Taking into account the various design objectives and criteria laid out in the previous sections, as well as eliminating potential alternative designs, the team began to narrow down the scope to the use of a magnetic lock. To design for a cognitive difference between children and the target audience, the team had to consider using a method that required logic and critical thinking in order to access the medications. It was also important to understand the knowledge that a typical child would have. After much consideration, the team decided that magnets could be a potential child-proofing method as many children are inexperienced with magnets, if they have any experience at all. This lock would utilize magnets in order for the pill bottle cap to stay in a "locked" state. When the cap was inserted into a slider and moved to a specific point in the slider, a magnet released the magnetic lock inside the cap, allowing the patient to pull the bottle off and access their medication.

This design utilized magnets as the team believed that, in place of a strength requirement, a cognitive leap that children most likely lack could be used. This leap was the thought process behind magnets, as most young children, ages 5 and under, would most likely not recognize the concept behind magnets or know how to use magnets to unlock this design. With this in mind, the team wanted to disguise the "key" magnet needed to open the bottle as to limit the chances that the children being tested would find the magnet and use it to unlock the bottle.

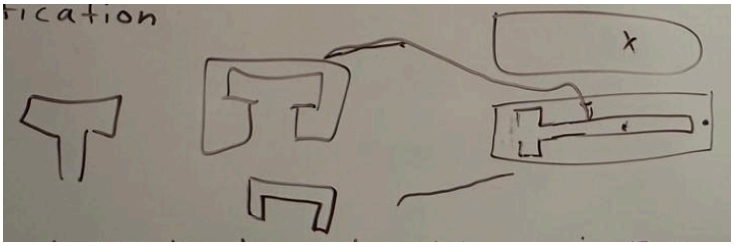


Figure 7. Preliminary design of the magnetic lock and slider, detailing the slider cross section.

By placing the “key” magnet inside a slider at a random location on said slider, the team believed that this would prevent children from accessing the magnet while allowing the target audience the knowledge of its location and how to unlock it. The team hoped that the use of a secondary part to open the bottle would prevent children from connecting the two pieces, and prevent them from opening it. The team wanted the child to fixate on the cap but not be able to open it. This concept was sketched out on a whiteboard as a preliminary idea seen in Figure 7.

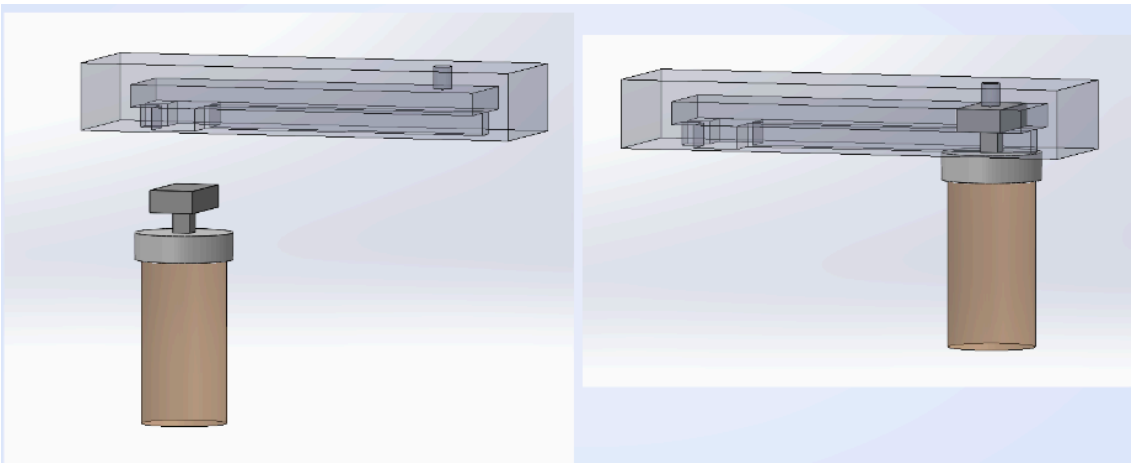


Figure 8. CAD mockup of the magnetic lock/slider design, including a pill bottle with a preliminary cap to demonstrate the sliding mechanism.

The preliminary mockup shown in Figure 8 features a slider, minimalistically designed cap, and a pill bottle based on accurate measurements from a push-twist pill bottle. This CAD

was used to visualize how the slider and cap would interact, including the placement of the “key magnet”, the shape of the cap to ensure that it remains in the slider, as well as the overall shape and dimensions of the device. This initial design did not include any details for the new cap, save for a “T” shaped design that would prevent the cap from being pulled perpendicularly out of the slider, except for at the entry point.

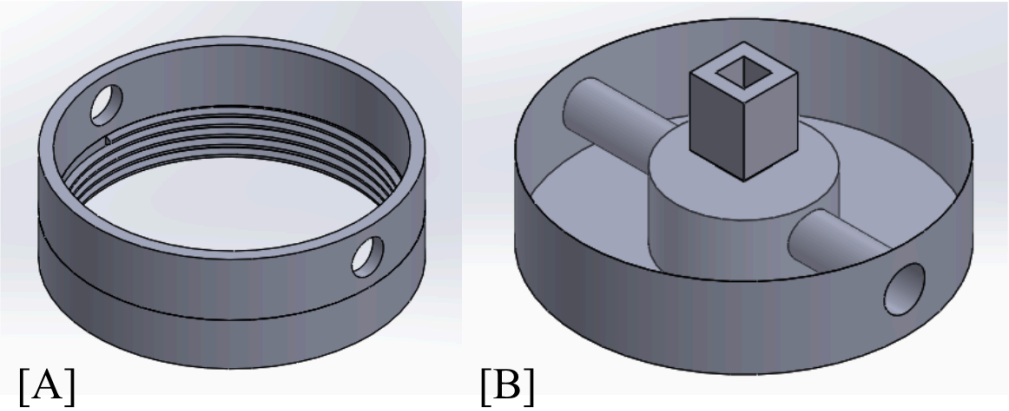


Figure 9. CAD designs for a preliminary magnetic lock. The bottom half (A) included threads to screw onto the bottle, as well as magnet holes. The top half (B) included a top tunnel for the ¨connecting¨ magnet, in addition to magnetic tunnels that would house some more of the magnets.

Once the overall concept was created and detailed enough to start the project, the team moved forward in designing the magnetic lock, as it was far more complex than the slider. The magnetic lock consisted of two separate parts: a bottom half that would be secured to the bottle and remain there, and a top half that would attach itself to the bottom half via magnets, in order to secure the bottle in a ¨closed¨ state.

Moreover, in Figure 9a, there are threads that would screw onto the bottle like a normal cap, however above the threads lie two holes, in line with each other, that would interact with the top half. Aside from that, the middle of the bottom part is empty and so when only the bottom half is on the pill bottle, the bottle is open and the medication is accessible. In the top half, in Figure 9b, the middle is filled in (although the top of the part is transparent in this figure to expose the

magnetic locking mechanism) so that when it is attached to the bottle, it is blocking anyone from accessing the medications.

Inside the cap are two tunnels that extrude into the cap and would line up with the holes on the bottom half. Magnetic rods would then be placed inside these tunnels so that when they are fully pushed into the tunnel, they will not be long enough to reach the holes in the bottom half. However, the magnets would be placed so that they repel each other, allowing them to move from only the magnet tunnels to at least being partially through the holes on the side, which would bridge the top and bottom halves together and prevent anyone from pulling the top half off of the bottle. This would be considered its "locked" state.

In order to unlock the cap, a third magnet would be used in the central tunnel, previously referred to as the "connecting" magnet, shown in Figure 9b, so that its North side is pointing down. This would ideally attract the other magnets, who are currently repelling each other in a South-South position, towards the center of the cap and therefore releasing the bottom and top halves from each other, allowing the patient to open the bottle and access their medication.

Although the main concept of using magnets and their polarity to lock something remained the team's main focus for later iterations, there were some flaws with this design. First, the device lacked anything to prevent the magnets from falling out in either the locked or unlocked state. Second, the fully open hole on the bottom half would bring about the possibility of the target audience accidentally spilling their medication, especially those with Parkinson's or other movement-limiting factors. Last, the exterior of the lock when put together would be a smooth cylinder, and so that would eliminate the goal of having the cap stay in the slider without being able to be pulled out easily.

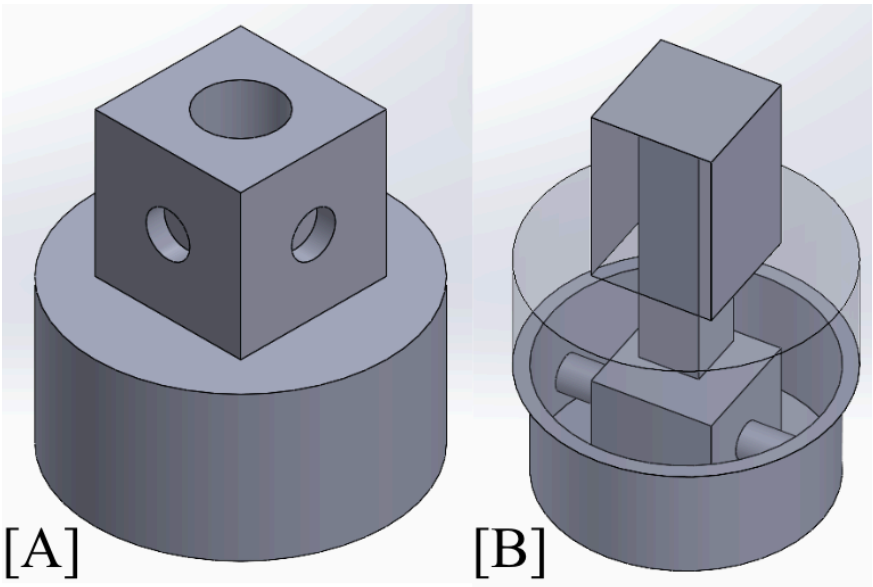


Figure 10. CAD designs of the second version of the device. Featuring redesigned top (A) and bottom (B) half pairing, as well as improved magnet tunnels.

As shown in Figure 10a and b, the overall idea of the design remained the same, however the team modified this version to better fix the limitations of the previous one. The biggest change comes in the form of the locking mechanism itself. To address the issue of the magnets being exposed and prone to falling out, this design closes the system by swapping the orientation of the lock. In the original design, the magnets would naturally sit inside the top half of the lock and push out to bridge the two halves together, creating the “locked” state. In this version, the magnets remain in the top half, however this time, the “locked” state involved the magnets being pulled closer to the middle via a third vertical magnet, bridging the gap to connect the two halves, while preventing the magnet tunnels from being exposed and therefore susceptible to the magnets falling out of the lock.

To unlock the magnet, a similar approach is used, where the vertical magnet is manipulated by a fourth magnet found in the slider, which would pull the vertical magnet up, releasing the attractive forces acting on the side magnets. This would then drive the side magnets

apart from each other and release the lock, allowing the patient to pull the bottle out of the slider while the top half remains magnetically attached to the inside of the slider.

Another limitation that was addressed in this redesign was the narrowing of the hole in the bottom half of the lock. By making this hole smaller, it will limit the amount of medication that can be dispensed at one time. This is an important design feature as many of the target audience members struggle with Parkinson's, tremors, or other movement-limiting factors. For instance, if a patient who experiences tremors tried to use the first design, they could possibly spill out triple what they were intending to dispense, making it a struggle to acquire the correct dosage on the first attempt.

The last feature that was added in this new iteration includes a larger outer diameter of the top cylinder when compared with the other sections of the lock. This would allow for the lock to be put into the slider on a set of rails that would prevent the top cylinder from falling out of the slider. This not only secures the device inside the slider, which is important for patients with limited or imprecise abilities to move, but it also requires the patient to line up the profile of the lock with its counterpart in the slider, adding another layer of cognitive complexity when it comes to opening the container.

While discussing the slider, the final piece to this three piece design, the team designed the slider to inversely match the shape of the pill bottle cap. As seen in Figure 11, this would allow the patient to push the bottle into the slider at a specific entry point, and slide the bottle along the slider until it stopped under a magnet that was at a randomly selected point. This magnet would then unlock the top half from the bottom half of the cap and the patient would then be able to pull the bottle and bottom half of the lock out from the slider, accessing their medication.

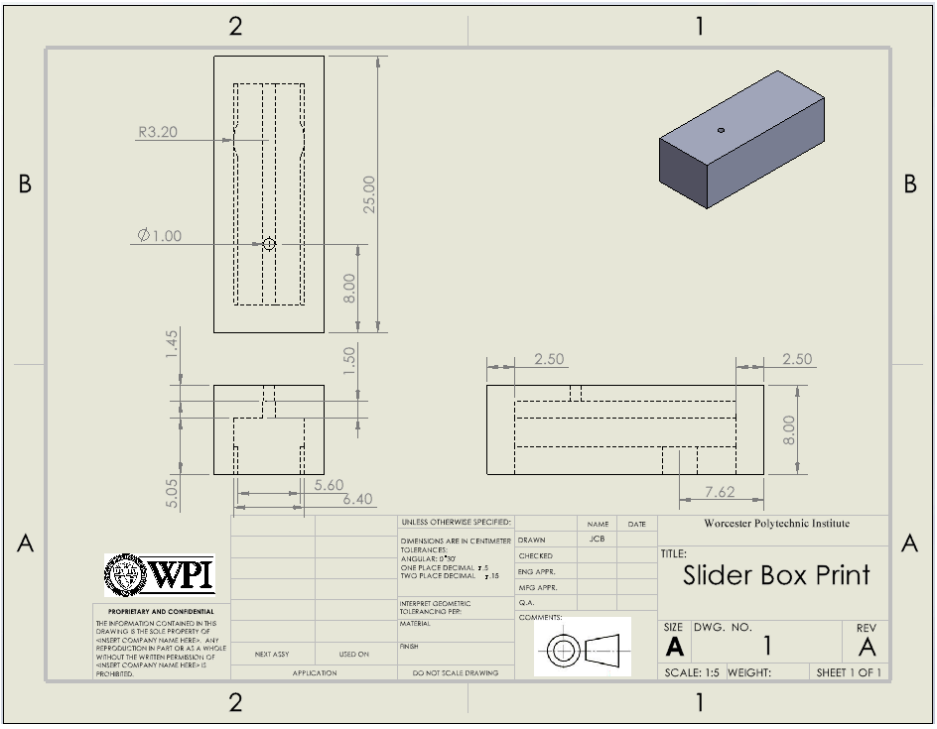


Figure 11. CAD drawing of the slider, showing the cross section of the inside, which lines up with the cap of the pill bottle.

At this point in the design process, there were a few topics to address. First, the overall design lacked realistic measurements and were all done with ratioed dimensions between the parts to at least begin to build the relative shape. Second, the threads on the bottom of the cap were not accurate, and when researched, it was found that pill bottles can vary greatly in their threads and that it would not be easy to design threaded caps to fit any bottle.

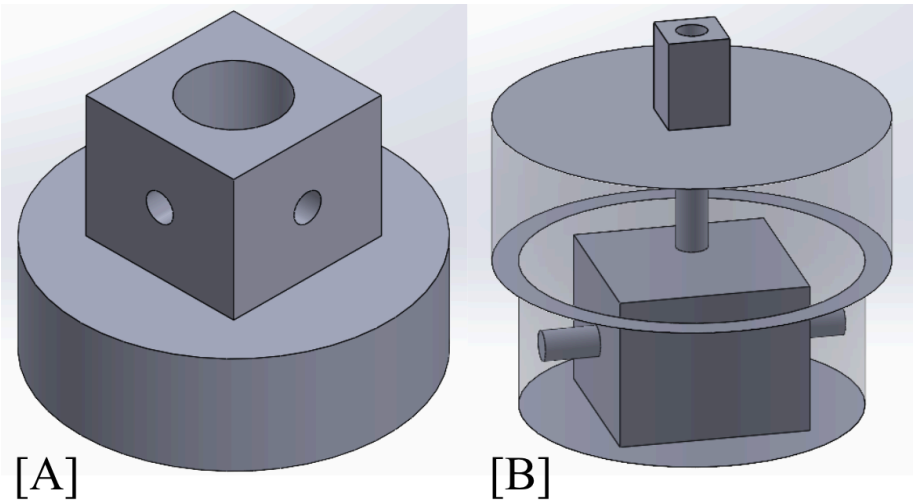


Figure 12. Third iteration of the CAD designs. Notable changes include removal of threads from the bottom half (A) (not shown). Additionally, on the top half (B) the top magnet tunnel was reduced in size, as well as detailed and realistic dimensions for both halves.

As shown in Figures 12a and b, the third version of the team's design included a few addressed issues. Primarily, the threads on the bottom of the lock were removed for universality. By removing the threads on the bottom of the cap, it removed the need to both design and implement different types of threads to match each pill bottle's reciprocative thread. In place of threads, the team opted for a “snap-on” top that would ideally be able to be snapped onto the top of any bottle, circumventing the threads that may already be on them. This would also be ideally designed to prevent anyone from taking the cap off, which would require a one-way snapping mechanism. The team was currently prototyping with PLA, as PLA was believed to be flexible enough to bend enough to allow for a “snap-on” mechanism. This mechanism took the simple form of a snap fit joint, where there is a “hook” design that gets pushed onto the rim of the pill bottle, causing the cap to flex slightly until the end of the hook is overcome and the cap snaps onto the bottle, as shown in Figure 13.

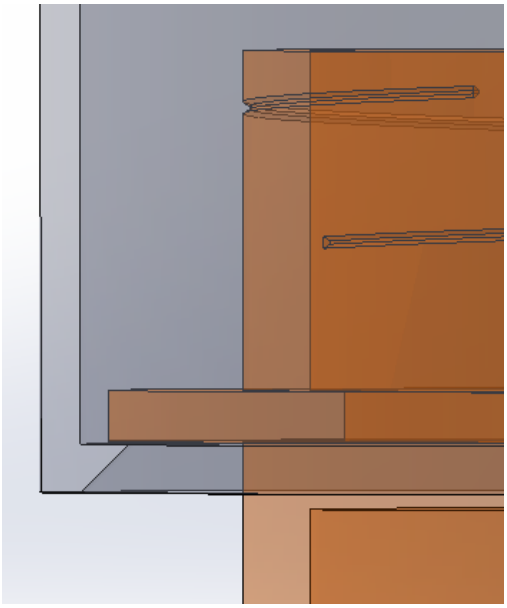


Figure 13. Depiction of the "snap on" mechanism used to attach the cap to the bottle. The dark gray represents empty space while the light gray represents material. The amber color represents the pill bottle.

In addition to the new snap-on cap, actual measurements were taken from a preexisting pill bottle and used to accurately dimension this design. This allowed the printed cap to fit the pill bottle used for dimensioning. As well, using the magnets that the team currently had, all three magnet tunnels, both of the horizontal and the vertical, were dimensioned to ideally fit the magnets during the proof of concept. Once everything had its correct and accurate dimension, the CAD files were sent to the printing lab to be prototyped.

As shown on the right of Figure 14, after printing the second iteration of the CAD designs on a PLA-based 3D printer, some of the initial concepts could be proven. First, the snap-on cap concept was proven successful as it attached fairly easily to the bottle, and was much more difficult to pull off than it was to put on. Secondly, the pill bottle cap fit inside the slider and was able to be moved around, without much difficulty. One difficult part about sliding the bottle was that the size of the cap and the slider were too close together which created areas of difficulty due to the inaccuracies and tolerances of the 3D printer. Another challenge was that the top of the cap,

which housed the vertical magnet, was square and therefore would have to be oriented in just the correct manner in order to fit inside the slider. After reviewing this detail, the team decided that it could prove to be overly difficult for the target audience and so it was later changed to a cylinder for ease of entry. To address the first problem, the size of the slider was slightly increased to avoid any interferences in the sliding and unlocking process.

There were also two flaws in the overall design. First, the design itself was too large to be considered portable. This was mostly due to it being the first prototype, as it was easier to start at a larger scale and cut down from there, rather than starting small and having to add more. Additionally, although all the dimensions were known prior to printing, the scope of how large it would be in terms of the target audiences' limited mobility, dexterity, and strength did not come to mind. To address this, the team cut down on the unnecessary material in the print, such as cutting the slider wall thickness in half, and removing some unnecessary space in the cap. This led to a smaller and more efficient design.

The second overall problem dealt with the magnetic locking aspect of the design. In short, the tunnels were too small to house the magnets in and to efficiently slide along the tunnels to allow for the unlocking and locking aspect. To correct this, all magnet tunnels were made larger in the second print.

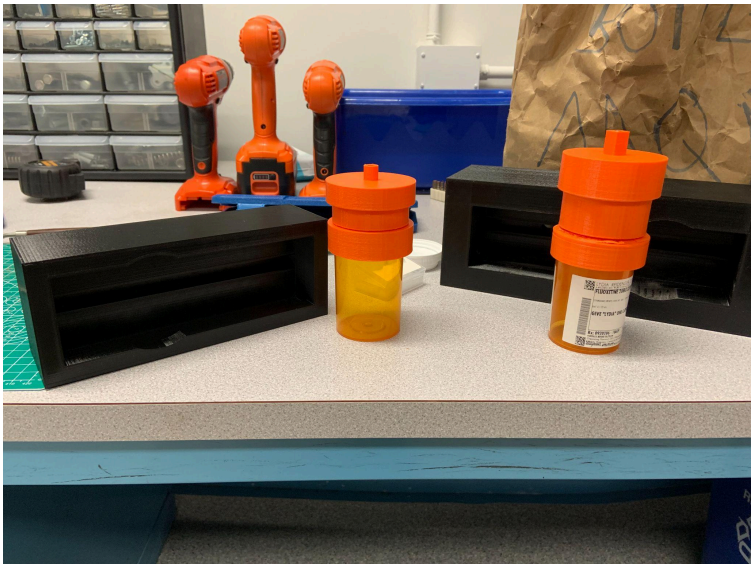


Figure 14. The second printed prototype (left) compared to the first version (right). Improvements include smaller design and improved magnet tunnels.

In Figure 14, it can be seen that the second printed prototype has a smaller design, with the cap being almost half the height of its previous counterpart. Aside from the size of the cap and slider, the magnet tunnels were also improved. Due to their size increase to accurately accommodate the magnets, these tunnels allowed for them to slide back and forth. However, the overall locking mechanism still ran into an issue. This issue was that the holes did not correctly align inside the cap, most likely due to inaccuracies in the 3D printing process.

In order to compensate for these errors, the cap was redesigned to feature a top piece that fits into the bottom piece, but with enough tolerance that the magnet tunnels on the top piece could vary in height in order to accurately line up with the magnet tunnels in the bottom piece when joined together. This redesign also featured minimizing the overall height of the cap, as it was still ineffectively bulky. By changing the orientation of the top and bottom pieces, so that the top half extruded into the bottom half instead of vice versa, it allowed the top half to only contain a larger lip. This lip acted as a guide for the rails inside of the slider, while eliminating the need to

have a large empty space inside the top half, thus effectively reducing the additional height from the top half to a few millimeters.

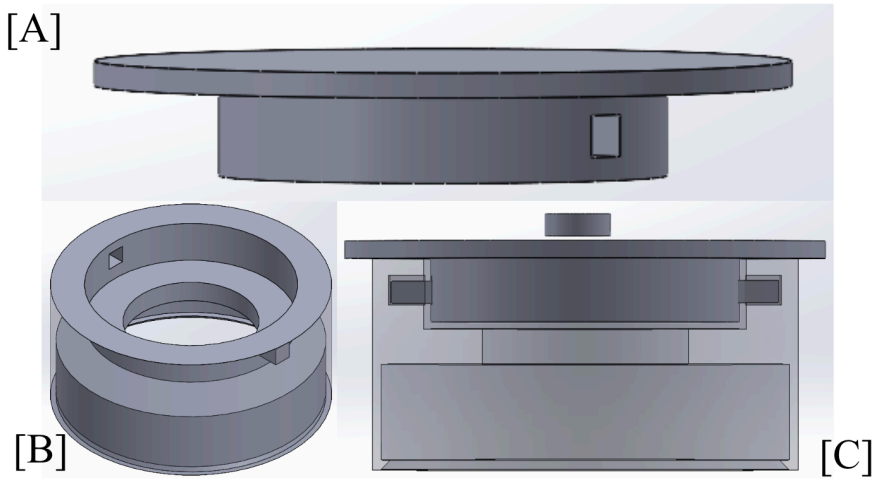


Figure 15. CAD designs for the top (A) and bottom (B) half, as well as a subassembly design (C) showing the joining of the two pieces via magnets. This new design features the same snap-on mechanism, a hole for medication, and new square magnet tunnels to fit the stronger magnets.

In Figure 15a and 15b, it can be seen that this updated design features an overall reduction in height, while maintaining other important mechanisms already established, such as the access hole for medication to go through, the snap-on mechanism that allows for greater bottle universality, and a lip that can be used to guide the cap through the slider to unlock the top. Another issue that was present in previous versions was the use of a middle third magnet that would effectively repel both the side magnets, until this third magnet was attracted upwards by a fourth magnet, which would then allow the side magnets to attract to each other, unlocking the cap. In this new design, the middle magnet could be removed due to the low thickness of the top half, allowing the magnet in the slider to now act as the third magnet instead. The magnet in the slider, shown in Figure 15c, would then attract the side magnets, allowing the cap to be unlocked.

Now that the overall design had been simplified, the only persisting problems dealt with the magnets themselves. The main issue was finding the correct ratio between the side magnet

strength, and the top magnet strength. If the magnets on the side were too weak, then they would not be able to strongly repel each other enough to keep the top and bottom halves secured together. However, if the magnets were too strong, then the top magnet would not be able to overcome the repelling forces of the side magnets, and therefore would not be able to open the cap. Through trial and error, the team found the correct ratio of magnet pull force ratings in order to create a smooth and reliable magnetic locking mechanism. This was shown to be around 2:1 between the top magnet and each of the side magnets.

With the design of the cap finalized, the team returned to the design of the slider to ensure that it would fit over the cross-sectional area of the cap. This made sure that the cap was able to slide smoothly along the rails to the specific point that housed the top magnet, allowing the cap to unlock and the bottle to be effectively pulled off.

After discussing potential design specifications amongst the team and the MQP advisor, one additional change was made to allow for better accessibility for patients with disabilities that might limit the accuracy or range of their motion when using the device. To accommodate this, a flared entrance was implemented into the design to allow for an easier point of entry when sliding the pill bottle into the slider, as shown in Figure 16.

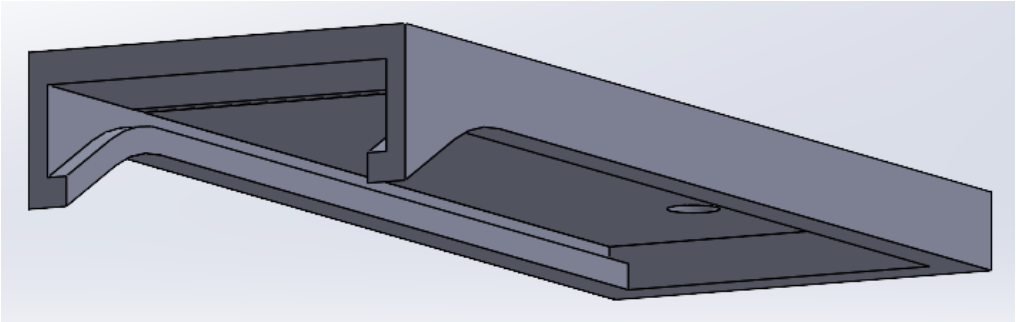


Figure 16. A CAD mockup of the updated slider, featuring a flared opening, with complementary slider rails. Also visible is the hole for the third, top, magnet which will be used to unlock the cap.

After printing the flared model, and pairing it with the updated cap, a functionality test was done to determine the effectiveness of this design, including ease of inserting the cap into the slider and unlocking and relocking the bottle. After this evaluation, it was found that when relocking the cap, it needed to be rotated in order to realign the magnet tunnels between the bottom and top half, or else the cap would not be able to lock and run the risk of the magnets falling out and becoming lost. As for the slider, the flared design proved to be slightly awkward and not entirely effective at reducing any difficulties in inserting the cap. It only slightly added to the vertical range of insertion and did nothing to mitigate the horizontal range.

In order to compensate for this, the flared design was changed to a "tapered" design, which included a slightly wider base, and used tapered rails in order to more effectively guide the cap towards the end of the slider, shown in Figure 17b. The cap redesign involved removing the magnet tunnels in the bottom half of the lock and replacing them with an extruded cut ring that would allow universality when it comes to the orientation of the top half locking into the bottom half, seen in Figure 17a.

Figure 17. CAD designs of the updated bottom half of the cap (A), and the tapered slider (B). The updated cap includes the change from two magnet tunnels to a continuous ring to house half of each magnet in the locked state. The tapered slider, shown from the insertion site, features rails that taper down to a point to allow for better cap guidance when inserting the bottle.

After reviewing the current designs, the team decided to change the top part of the cap to include a conic end in order to help guide the patients in putting the cap back onto the bottle

during the relocking phase, shown in Figure 18a. This simple change would hopefully assist those with accuracy-limiting disabilities such as Parkinson's, while not disrupting or damaging the medicine inside. The bottom half, seen in Figure 18b, was redesigned to accommodate this new sloped section.

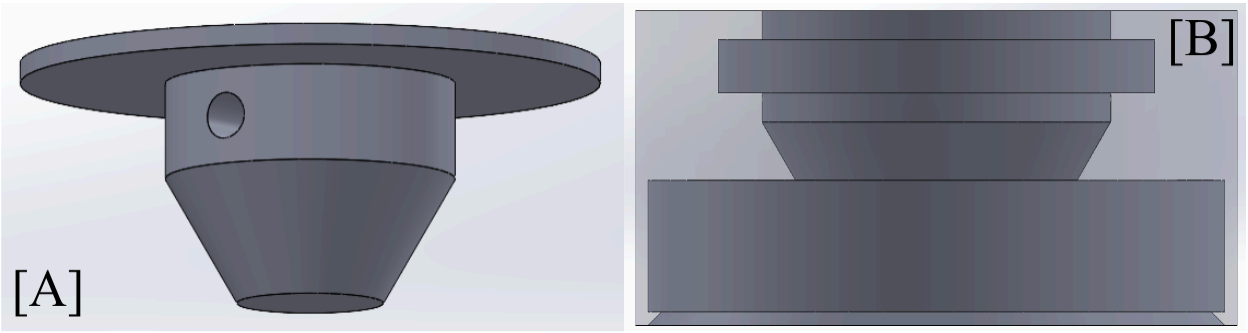


Figure 18. Redesigned top half (A) to incorporate a tapered end, allowing the cap to be "guided" back onto the bottle. The bottom half (B) was redesigned to incorporate the slope of the top half, leading to a tapered hole. This design was used in all of the mechanical testing and the majority of human testing.

3.8.2 Final Design Modifications

Once the team received IRB approval (24-0236) for human testing and printed the design, they proceeded to source subjects to test the design shown in Figure 18. After the initial round of testing, it became apparent that the design needed to be modified to prevent the side magnets from repelling away from each other and out of the device. In order to prevent this, a preliminary design was drafted to include "magnet shields," which would add a barricade to prevent the magnets from falling out of the design when the top and bottom halves are separated. A preliminary mockup of this idea was drafted, and shown in Figure 19.

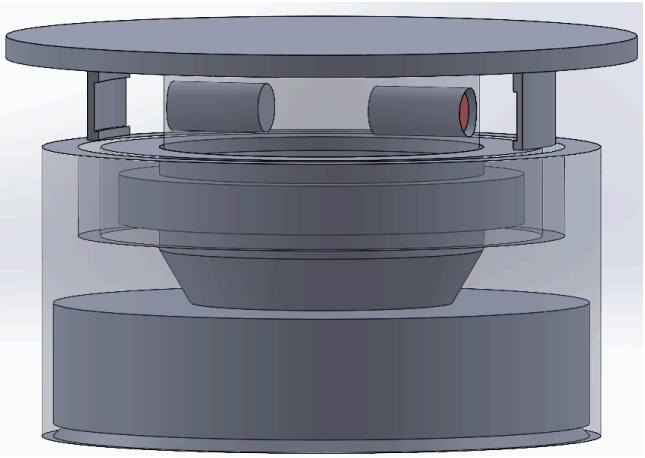


Figure 19. Preliminary design incorporating magnet shields, which would require them to be nested inside a ring on the bottom half of the lock.

After printing the shields, there were difficulties in attaching them to the underside of the top half of the cap. The shields lacked stability and the ability to maintain uprightness when drying. To compensate for this, the shields were increased in overall height so that they could be put through the magnet top, and glued in place. The team believed that this design would not only increase the stability of the magnet shields, but also reduce the risk of them being snapped off during trials. However, before the shields were even printed, the team realized that the patient would not be able to bring together the two halves of the lock unless they were completely in line with each other, which would put patients with accuracy-limiting disabilities such as Parkinson's at a disadvantage.

At this point, the group was struggling to find a solution that would prevent the magnets from falling out of the cap while not affecting the ease of use and accessibility for the patients. The simplest idea was to introduce a "stopper" that would allow the magnet to slide out, but not all the way. This idea held promise and ideally would not complicate the design or use of it. As shown in Figure 20, the new design used a mirrored empty space inside of the cap that would allow the movement of a slider to act as a rail that restricts the magnet to stay inside of the cap.

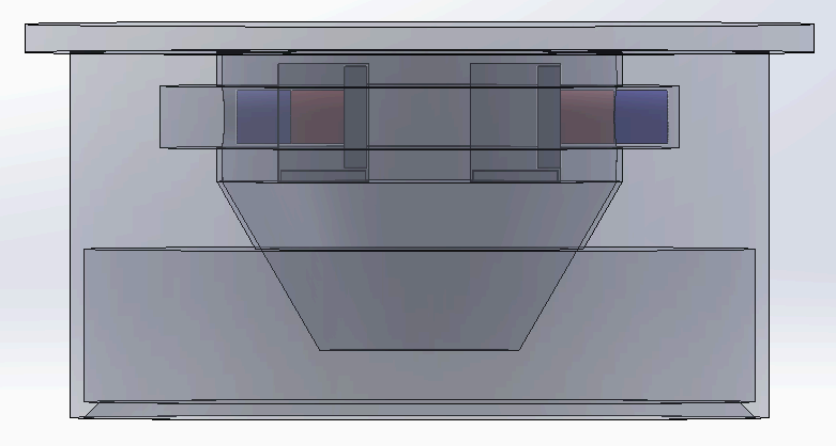


Figure 20. Preliminary stopper concept, attached to the magnets, and their corresponding stopper "rails".

When printed, the design failed at the intersection between the stopper and the magnet, which was held together using superglue. This problem occurred as the force of the magnet repeatedly locking and unlocking cyclically weakened the glue to the point of failure. However, before the point of failure, the mechanism appeared to work well as it prevented the magnets from leaving the device. Through the limited time before failure, the new stopper mechanism seemed to not affect the use of the device.

In order to correct this problem, the team wanted to redesign the stoppers to mitigate and distribute the force acting on this mechanism. By changing the stoppers to not only attach to the magnets but to house them, and adding a flared end, the magnets would be able to be contained inside the stoppers, that will run along the empty space inside the cap until it hits a countersunk hole that would catch the stopper before it falls out, shown in Figure 21.

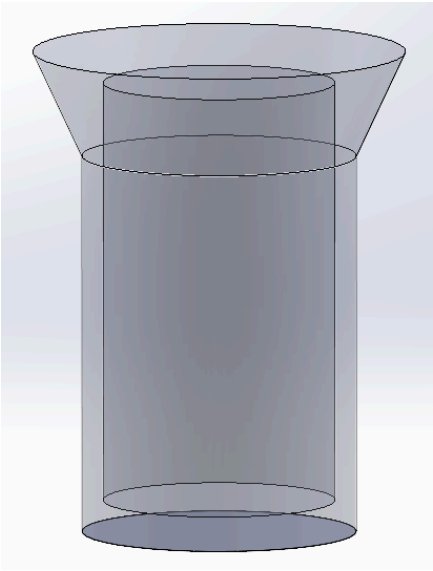


Figure 21. CAD mockup of proposed capsules to contain the magnets, including the flared end.

By pausing the 3D print midway through its process, the magnets could be inserted into the print before continuing, covering the magnet in the flared end of the 3D print, and sealing it inside. By encasing the magnet in one piece, it was now possible to create a cap that would prevent the magnets from falling out, while giving the magnets the adequate mobility to function in the locking mechanism.

After this capsule was printed it was shown that by printing in PLA, even though it was created as one piece, it lacked the mechanical strength required to endure the repetitive forces of unlocking and relocking. Due to this, new capsules were printed in resin, and in two parts. By using superglue while assembling the magnets into the capsules, they were effectively sealed and were tested on their ability to withstand the forces of the locking mechanism. After the capsules were seemingly proven to work, the cap was redesigned to accommodate not only the larger size of the capsules, but also the flared end that would act as the stopper for the magnets.

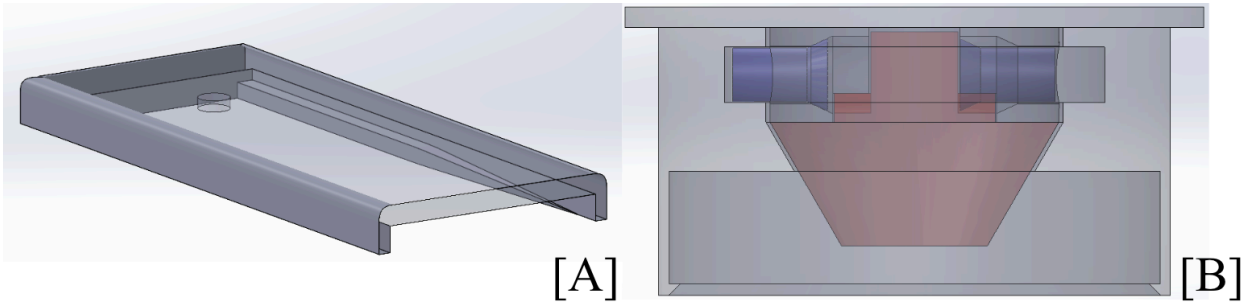


Figure 22. Final CAD design for slider (A) and cap (B) featuring magnet capsules, the flared ends, and corresponding countersunk holes and rails to guide the capsules between "locked" and "unlocked" state.

This was the final iteration that would be completed during the time available in the academic year. The slider, shown in Figure 22a, had a cap-matching shape, tapered guide rails that now extended all the way to the end of the slider, and ergonomic edges to better assist the patients in unlocking the slider. This cap, shown in Figure 22b, featured a magnetic locking mechanism, held in place by magnetic capsules (blue) inside countersunk holes, as well as a snap-on mechanism to allow it to be attached over pill bottles, to bypass any variations in threads. Detailed schematics of all final parts of this design can be found in Appendix A, Figures 34-39.

For material selection, preventing interactions between the device and the medicine is important. Due to the team's research, the team decided to move forward with polyethylene for the cap (*Amber Pharmacy Vials, Child Resistant Caps, 6 Dram (22mL), Case/600*, n.d.). Polyethylene is more cost effective than PLA, and can offer greater strength and a higher flexural modulus (*HDPE vs. PLA :: MakeItFrom.Com*, n.d.). However for prototyping purposes, the team utilized polylactic acid (PLA) and resin when 3D printing in order to rapidly manufacture and test the designs. PLA was overall not the best material for this application as it was shown through testing to have a lower than ideal fatigue resistance, and a higher permeability to water (Sonchaeng et al., 2018).

3.9 Ethics & Regulations

When designing a new product, some ethical issues may arise. For this design process, some of those issues were accessibility, user involvement, financials, and sustainability. Additionally, on the larger scale, some issues such as sustainability could pose an issue if the design is mass produced. The team does not foresee any global or cultural issues.

3.9.1 Social Impact

One issue that the team's design hoped to address was accessibility. In many cases, products are designed with a specific audience in mind, or for what the designer may think is the general public. By doing this, designers do not consider users who may not be able to access the design in the same way as the general public, or even access the design at all. By catering this design to a population that needs help opening pill bottles, it allowed both that population as well as the general public to be able to use the product as designed. Although the design was created with intentions of a wide variety of people being able to use it, testing on the device was only able to be conducted on college students, young children, and elderly adults. In the future, it would be important to have populations that have other disabilities or conditions test the device in order to be sure that the design is completely accessible. Other groups, such as those with cognitive impairments, might struggle to understand or forget how the device's mechanism works.

User involvement is important during the design process because without it, researchers will not have the same amount of insight on issues that a certain population may have. In this design process, the team created surveys for several different stakeholders in order to receive feedback from the populations that will interact with the design, as well as asked individuals who tested the design for feedback on how it could be improved.

3.9.2 Financial Impact

By modifying the pill bottle cap instead of the whole bottle, it allowed the redesigned cap to be used on current pill bottle bases. This creates a better financially ethical situation, as it does not require the consumer to buy an entirely new pill container. If an entire new container needed to be purchased in addition to the cost of the medication, it would exclude a larger population that either does not have the funds to purchase a separate container, or the means to transfer the medication to a new container. Allowing pharmacies to offer this pill bottle cap as an option for consumers who want it would allow the caps to be swapped and installed before the consumer receives the medication. Despite the slight increase in cost due to the manufacturing of the cap, it offers a cost-effective alternative when compared with some of the other pre-existing designs.

3.9.3 Environmental and Sustainability Impacts

The future manufacturing of the design could pose a sustainability issue, depending on what the caps are made out of. Current prototypes use PLA-based 3D printing to manufacture the prototypes, while also using neodymium magnets inside for the magnetic locking mechanism. PLA is known to be biodegradable and recyclable and therefore the printed parts would not pose a sustainability issue. The neodymium magnets however, do not break down naturally, and therefore are not as sustainable. On a mass production scale, if this design was manufactured for the commercial market, it would most likely be made out of a different plastic that is commonly used for medicine bottle caps, such as polypropylene or polyethylene (most likely polyethylene for the cap due to its balance of strength and flexibility), both of which are recyclable and therefore pose a smaller impact on the environment (*Two Common Materials for Medicinal Bottle Cap-Xinfuda*, n.d.). However the issue of the unsustainability of the neodymium magnets persists.

One possible solution would be to incentivise the reusing of the caps. Where, if possible, a certain discount would be applied to the patient's medications at the pharmacy provided they return the magnetic cap to be taken off the old pill bottle and attached to the new pill bottle, thus eliminating the need to dispose of the cap after all the medication inside the bottle has been taken.

3.9.4 Standards

Industry standards and government regulations needed to be considered and adhered to during the design process. The standards that were referenced throughout the design process were Title 16 Code of Federal Regulations 1700.15 Poison Prevention Packaging, ASTM D5276, and ASTM D3481-06. Title 16 of the Code of Federal Regulations outlines commercial packaging practices and poison prevention. Section 1700.15 of the Code describes the necessary requirements that packaging of substances must adhere to be child-proof, such as proper labeling and human testing for different age groups. ASTM D5276 standard details a drop test that can be used on many different products and packaging like boxes, cylindrical containers, and bags. This test simulates accidental droppings, and shipping and distribution environments. ASTM D3481-06 outlined a force test method that simulates children's attempt to open different bottles such as snap-fitted outer caps and thread closures. This can be used as an additional test in conjunction with pediatric testing outlined in the Code of Federal Regulations or in the event pediatric testing cannot be done.

4.0 Methods

The team wanted to evaluate current issues with pill bottles in regards to accessibility, child resistance, drug interactions, cost, and portability. To effectively test if the design meets the criteria for these objectives, the team performed preliminary research through Qualtrics surveys, and conducted human and mechanical testing.

4.1 Surveys

To further understand the issues that the target audience faces with current pill dispense systems, the team created different anonymous surveys. These surveys assisted the team to go beyond primary research. The application Qualtrics was used to create four surveys for different groups: pharmacists, caregivers, patients, and parents.

The pharmacist survey was created to understand how pharmacists interact with pill bottles on a daily basis, as well as to learn their perspective on patient experience (See Appendix B). In the survey, there were questions that asked the participant to rate ease of use and filling of different medication containers on a scale from 1-10, as well as their reasoning behind why they chose those answers. Other questions in the survey asked about alternative storage options, novel pill packaging, and ideal features for a new pill container that may fix the limitations of current designs.

The survey designed for caregivers had the same ‘scale-type’ questions as the pharmacist survey, but the team removed the question about filling prescription containers (See Appendix C). Other questions on the survey asked about their experience with alternative storage containers and the limitations that they face with current designs.

The general patient survey focused on the general population of people who have interacted with prescription containers. Similar questions that were asked in the caregivers survey were used for the patient survey (See Appendix D). In addition to those questions, patients were asked about how regularly they use their medication, which prescription containers they use the most, health conditions that may impact their ability to use the container, difficulties with their containers, and alternative methods of accessing prescriptions.

The final survey was created for parents. Scale questions were used just like the other surveys, and the parents were also asked about their child's age, methods they use to keep medication away from their child, and instances of their child accessing medication when they should not be (See Appendix E). Once the surveys received IRB approval (24-0236)(See Appendix F), the team sent the respective survey to family members and friends that corresponded to each group. After receiving sufficient responses, data was extracted and the feedback was used to alter the team's design.

4.2 Human Testing

4.2.1 Pediatric

According to the Code of Federal Regulations, Title 16, under section § 1700.15, a child-resistant package must remain unopened by no less than "...85% of the children without a demonstration and not less than 80% after a demonstration of the proper means of opening…" (*Code of Federal Regulations*, n.d.) after a 10-minute opportunity to open the package. The Code of Federal Regulations states that a panel of at least 50 volunteer children between the ages of 42-51 months should be given 10 minutes to open the pill bottle without instruction. The trial time

must be recorded for each participant. If the child were to open the packaging before the end of the 10 minutes, it would be considered a failure (See Appendix G for full pediatric protocol).

Due to time constraints, the team decided to expand the group age to 2 - 7 years old to get a larger sample size and to further understand children's ability to open pill bottles. During testing, the participant's hands were videotaped; this recording was used to further study the behaviors around pill bottles. The team, advisor, and the Biomedical Engineering department had access to the recordings. Before testing, IRB approval (24-0236)(See Appendix F) was given and the team asked parents or guardians to sign a consent form (See Appendix H). Once the consent form was received, the team commenced the first trial of testing by giving the child the cap without the slider to try to unlock the pill bottle within 10 minutes without instruction. If the child became disinterested, frustrated, or did not want to continue with the task, the test stopped. This trial aimed to see if the child was able to open the pill bottle, testing the child proof objective of this design. The trial time was recorded for each participant and notes on their behavior were recorded. If they were able to open the bottle within the time provided, it was considered a failure.

The next trial required them to use the slider and the pill bottle; the child was given 10 minutes to open it again. After approximately two to five minutes, if the child was not able to open the bottle with the slider, a demonstration was given. If the child became disinterested, frustrated, or did not want to continue with the task, the test stopped. For both trials, the time and notes on the subjects' behavior were recorded for each participant. The purpose of this trial was to understand the amount of time it would take for children to understand how the locking mechanism worked. This also aimed to find out if children can replicate the actions of their parents or guardians while they are in the room.

Additionally, the parent or guardian was asked follow-up questions to gain insight into how they keep medications at home with a young child, in addition to their overall thoughts on the design. The parents were asked if they have run into issues with their child gaining access to their medication, how comfortable the design makes them, if they have any difficulties or comments on the design, and if they would implement it into their everyday life.

4.2.2 Young Adult and Elderly Adult

Patient testing was based on the Code of Federal Regulations, Title 16, section § 1700.15. Under this section, it is detailed that of a panel of elderly adults (ages 50-70), "no less than 90%" (*Code of Federal Regulations*, n.d.) must be able to open the package. The separate younger adult sample group should also "have an effectiveness of not less than 90%" (*Code of Federal Regulations*, n.d.); "effectiveness" means the ability to open the bottle. For the purposes of the study, senior adults and younger adults were grouped together. The team asked for volunteers ages 18 and older to participate in the experiment, especially adults in the 50 to 70-year-old range. Other than age, the team also asked for volunteers who were considered disabled (refer to Section 2.4 for more detail). Both of these requirements allowed for a diverse group to serve as a control group to compare against the children. During testing, the participant's hands were videotaped; this recording was used to further study the behaviors around pill bottles. Only the team, advisor, and the BME department had access to the recordings. Before testing, IRB approval (24-0236) (See Appendix F) was given and each participant signed a consent form, shown in Appendix I.

For this test, the participant was given the team's child-resistant cap as well as the slider. Team members gave each participant 5 minutes to open and close the prototype. If the participant was able to open the bottle, they were then given 1 minute to reproduce the action. No other instruction was given other than to open and close it in the given time interval. Time and notes on

their behavior was recorded for each participant. If the participant exceeded the time, it was considered a failure. Feedback on the pill bottle design was also taken from each participant. The participants were asked questions about how comfortable it was to use, any difficulties they faced with the design, the features they liked about the design, and whether or not they would consider using it in day-to-day life. These tests assessed whether the device was patient-accessible.

A follow-up trial was done for elderly adult participants where they were asked to open a standard child-safe pill bottle. This trial was used as the control group and participant opened and closed the bottle three times to open these pill bottles (See Appendix J for full protocol).

Figure 23. Wooden frame used in elderly adult human testing to simulate the slider being adhered to the bottom of a cabinet.

For elderly adult testing, a wooden frame was constructed to simulate the underside of a cabinet, the intended set-up of the device, shown in Figure 23. This was a direct result of the feedback the team received during young adult testing, as those participants were confused on the purpose of the slider. The frame was only used for three out of the five subjects testing, due to a testing location change.

4.3 Mechanical Testing

4.3.1 Drop Test

Mechanical testing is frequently used to assess child-resistant packages such as pill bottles. Free fall testing helps ensure the safety of the product and the package itself ("ASTM D5276," n.d.). This standard discussed the use of angle measurements for the procedure. According to the standard, if the container were to be dropped flat on its face, the container must be positioned so that the impact will be no more than a 2° angle between the palen of the face and the testing impact surface. Then, specifically for cylindrical containers, when it is "dropped on either a chime or a circumferential edge, position it so that, upon impact, a plane contains this edge and the center of gravity of the container makes no more than a 5° angle with the vertical plane perpendicular to the drop surface" ("ASTM D5276," n.d.). Neither of these scenarios seemed to be practical nor include variability so they were not included in this test.

The team did two different variants of the drop test: one test with the bottle empty and one test with "pills". Before starting the test, the team put approximately 20 pieces of candy in one bottle to simulate normal use. The team dropped the bottle on different floor types: carpet, wood, and linoleum. These floorings were chosen because they can be found in hospitals, homes, and several other locations that medications could be taken in. The prototype was dropped from what is considered to be a table height (approximately 30 inches) and a shelf height (approximately 60 inches). This was to see if the change in kinetic energy would affect the locking mechanism. Then, team members did a visual inspection to check if there were any signs of bottle cap deformation. Also, the candy pieces were inspected to verify their integrity. When signs of substantial deformation were found or the candy was broken, the bottle was readjusted and

updated to reduce the likelihood of damage. The ASTM standard specifies that failure criteria must be made before testing. For this test, the failure state was if there was significant visual damage on the cap, if the cap fell off the bottle, and if any of the pills fell out of the bottle or were damaged. This helped to assess if the device was portable and child resistant.

4.3.2 Jostle Test

Patients may need their medications and prescriptions outside of the home. In the event that they need to put it in a bag with other items, it is important that the cap stays locked so pills do not fall out or become damaged. At the time of this report, there were no standards that outlined how to test pill bottles this way.

Figure 24. Setup of jostle test.

To assess the pill bottle's portability, the team used an orbital shaker to simulate an environment where the pill bottle interacts with other objects in a bag, backpack, or purse. The pill bottle was placed in a large aluminum tray with the following items: three markers, two pairs

of scissors, two cans of play-doh, two rolls of tape, and a protractor, seen in Figure 24. The aluminum tray was taped onto the orbital shaker and was left on maximum speed, 210 rotations per minute, for approximately three days. After three days, the orbital shaker was turned off and the pill bottle was inspected. It was checked for damage and if the lock was intact.

4.3.3 Force Test

The tensile strength of the design needed to be tested to determine if the cap could be removed using brute force. For this type of testing, standard ASTM D3481-06 was used as only a reference. This standard tests three types of child-resistant closures: Type 1A, Type 1B, and Type 1C. All types use two-piece continuous thread closures and require different types of forces (push, squeeze, etc.) to open the bottle. However, the team's prototype did not use threads, so it did not meet the standards' design requirements. But, the results of this test were useful for understanding failure points in the prototype. Due to time and resources, Instron testing could not be done but a protocol was made (see Appendix K). Since the device solely depends on magnetic attraction and repulsion, the Instron was not a compatible machine to test the locking mechanism due to its high metal composition. Instead of using an Instron machine, a handheld force meter was used to conduct this testing.

Figure 25. Setup of force test.

As seen in Figure 25, a small hole was drilled through the center of the cap and reinforced with a small piece of wood. A string was threaded through the hole and tied on a spring scale force meter. The bottle was held down while a team member pulled the force meter up. The team member exerted 25 newtons then 50 newtons of pull force based on the average child hand grip strength which is 45.11 - 52.95 newtons (Bohannon et al., 2017). This test was done five times.

5.0 Results and Discussion

To meet the design objectives of the project, several different types of testing were completed on the prototypes, along with data and feedback collection from participants. First, anonymous online surveys were conducted on patients, caregivers, parents, and pharmacists to act as preliminary research. The responses were considered in the process, but due to the amount of responses, the patient survey was the largest component of the team's data collection and analysis. The types of testing completed were human testing (children, young adult, and elderly adult) and mechanical testing (drop, jostle, and force). These tests were extremely valuable as the group was able to receive feedback from human subjects, in addition to analyzing the performance of the prototype when put under different mechanical stresses.

5.1 Surveys

In order to gauge the target population's opinions on the usability of different prescription containers, the team created several surveys using Qualtrics (Refer to Section 4.1). The four different surveys that were created were for patients, pharmacists, caregivers, and parents (See Appendices B-E). The team received 56 responses for the patient survey, 15 from the parent survey, one for the pharmacist survey, and zero for caregiver surveys. Due to this, results were analyzed from predominantly the patient and parent surveys.

From the surveys, the data that was most impactful were the responses as to why pill bottles were difficult to open and additional limitations to current prescription container systems. Many responses simply stated that "child proof containers are hard to open," while others elaborated on reasoning behind why they thought it was hard: "pushing down is sometimes

difficult", "the child lock can be confusing", "you have to put in a good amount of effort to open it and sometimes do not get it first try". These results mostly showed that survey participants struggled with the combined motion of pushing down on the pill bottle cap and twisting, which aligned with the team's background research about sentiments behind using pill bottles.

There were also many survey responses that related to disabilities or dexterity issues causing problems with opening containers. Some example responses of this were "having arthritis makes it difficult", "all [containers] need two hands", "sometimes if I am weak, it is hard to put more force". Some disabilities that were shared that impact the ability to open pill bottles included arthritis, Ehlers Danlos Syndrome, basal thumb, tendonitis, and joint inflammation. These results showed that many people who struggle with pill bottles additionally have some sort of condition that may also impact their dexterity.

5.2 Human Testing

5.2.1 Young Adult

The young adult portion of the in-person human testing yielded the most impactful results that the group collected throughout the process. 33 college-aged subjects participated in this segment of testing. Following the minimal instructions that the team provided, each subject had a unique approach and interaction with the prototype. Figure 26 shows the average time across all subjects to open the pill bottle in Trial 1 and Trial 2. The average time for Trial 1 was 21.39 seconds while the Trial 2 average was 6.96 seconds. In addition to the team's observations of the testing, these timings showed that it took longer for each subject in Trial 1 to open the device because they took time to understand it and become familiar with it. For 97% of subjects, once they learned how to open the device in Trial 1, they were able to quickly adapt this method in

Trial 2 and shorten their time. This can be seen in Figure 27, which shows each individual subject's time for Trial 1 and Trial 2. The team also believes that, with repeated use by the subject beyond the two trials, these times would lessen even more.

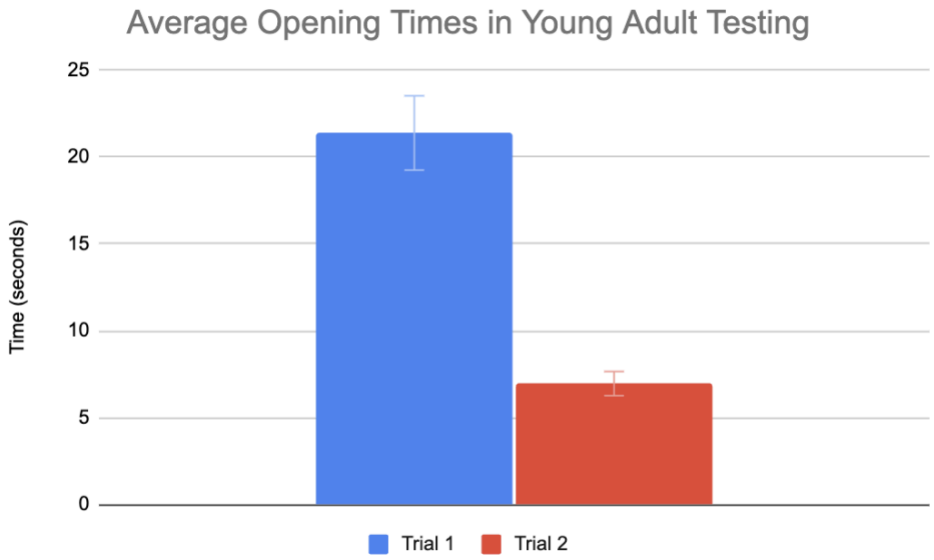


Figure 26. Graph displaying the average time the subjects took to open the pill bottle in Trial 1 and Trial 2.

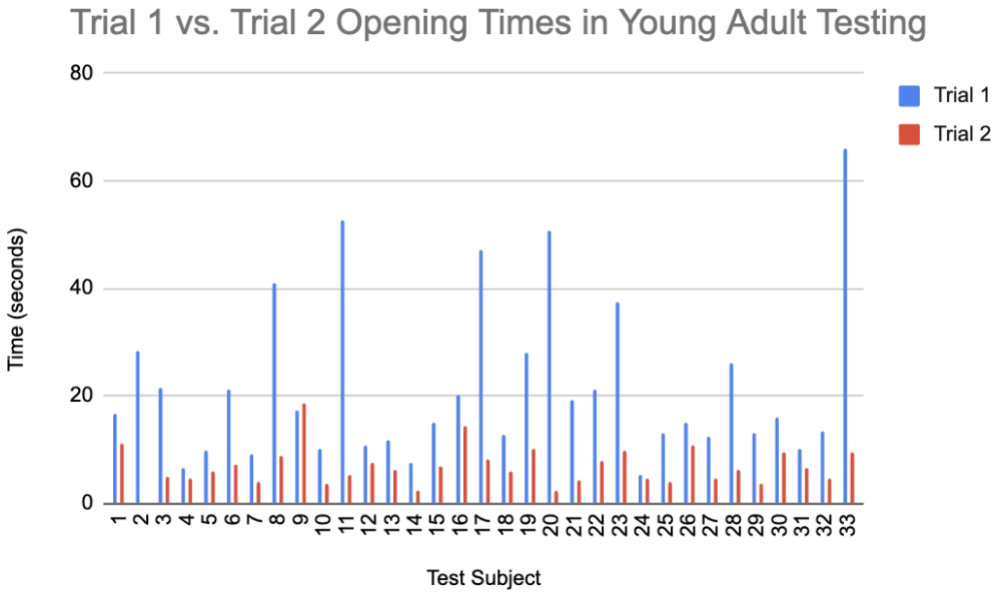


Figure 27. Graph showing breakdown of Trial 1 and 2 times to open pill bottle by subject.

This test was instrumental in a redesign of the prototype due to the large number of failing trials. According to Figure 28, 13 out of 33 trials, equating to 38.9%, resulted in the magnetic pins falling out. A notable point of failure in one of the team's prior designs, shown in Figure 18 (page 48), was that the magnetic pins were exposed. More specifically, the locking mechanism of the cap depends on the repulsion of the magnetic pins into the bottle. When there is no bottle present for the magnetic pins to eject into and the cap is removed from the slider magnet, these pins become dislodged and the device fails. During testing, several subjects did not realize that this would happen and would remove the cap from the slider magnet without using the bottle and the magnetic pins would fall out. This data analysis was a stepping stone for the group to make further analysis of the design and make improvements.

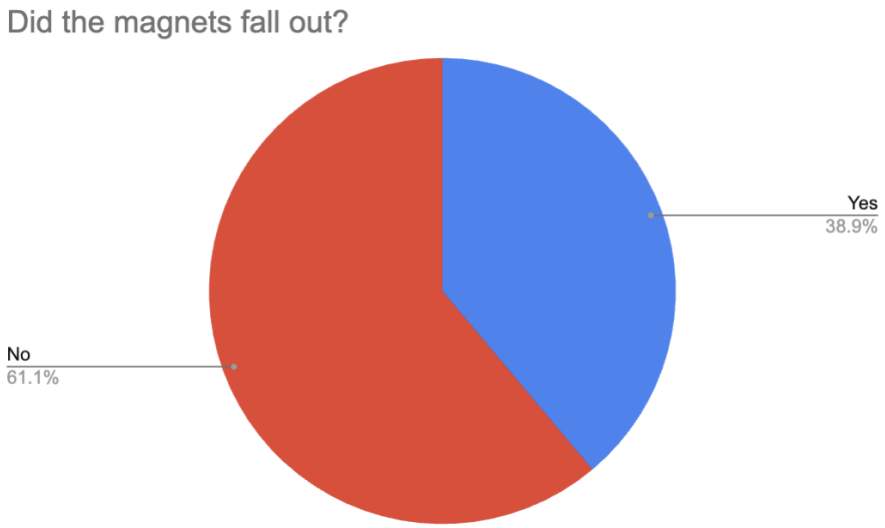


Figure 28. Graph depicting the percentage of failures during adult testing.

The feedback from the subjects was valuable, and it was also helpful to see subjects interact with the device for the very first time. Due to an error made by the team, only 28 subjects were asked post-testing feedback questions. Out of these 28 people, 20 said that the device was comfortable and did not have any critiques to make it more comfortable. 12 out of the 28 subjects

did not have any difficulties at all with the design. The remaining participants' main point of difficulty was with the lack of instructions in the testing, not with the design itself. When the subjects were asked what they liked about the design, the vast majority said that it was satisfying to use, simple, and lightweight. Nine subjects said that they would implement the device into their everyday life while 11 said that if they had the use for it, they would. The remaining subjects did not see a need for the device because they either do not normally experience difficulty opening medication or they do not take prescription medication regularly.

The test was able to simulate how a patient would operate the device if it were to be manufactured and put on the market. One interesting observation the group made while watching each subject was that several people's first instinct was to screw the cap off or use brute force to pull it off. Even though the team explained at the beginning of the test that there were two materials to use, several people still only used the cap alone. Many subjects found the lack of instructions frustrating because they were confused on how to work the device at first. With these results collected, the group adapted a new design that focused on encapsulating the magnetic pins, preventing the pins from dislodging.

5.2.2 Pediatric

Five children, with ages ranging from 2-7 years, performed testing for the device over the course of two weeks whenever the families were available. One of the most prevalent themes in these observations was the lack of prolonged attention that the children had for the design. After a preliminary examination of the pill bottle, and the childrens' attempts to open the bottle, they seemed to lose interest in it quickly, despite attempts from either the team, the parents, or the attention-grabbing modifications implemented by the team such as stickers, drawings, and a

makeshift rattle. This was a solid indication that the design was complicated enough to deter children from accessing the medication inside the bottle, despite efforts to incentivise just that.

During the tests, qualitative assessments proved to be more useful in understanding the pediatric-device interaction than any quantitative assessment, such as the time it took to open the device or how long it took for the child to become distracted. Through qualitative observations, it could be seen that, although the children understood that they wanted to unlock the bottle, they did not quite comprehend the magnetic locking mechanism and what is required to do so. This means that they tried to unscrew the cap, pull it off, disregard or misuse the slider, and put the bottle in the slider in the wrong orientation, all to no avail. Five out of nine trials (five initial trials in addition to four of the repeated trials; one pediatric test did not have a repeat trial as the pediatric patient wanted to leave early) ended before the 1 minute and 30 second mark of testing because the child became disinterested in the test and easily distracted by other objects in the room. Once the child stopped trying to access the inside of the bottle, they turned to more interesting and familiar objects. At this point, the test was concluded by the team due to the child's disinterest. Average times between the first and repeat trials, being 102.82 and 71.84 seconds respectively, were compiled and can be seen in Figure 29. As it can be seen, during the repeat trial the child became disinterested in a shorter time, a positive indication towards the child-resistance of the device and the deterrent that the cap presents.

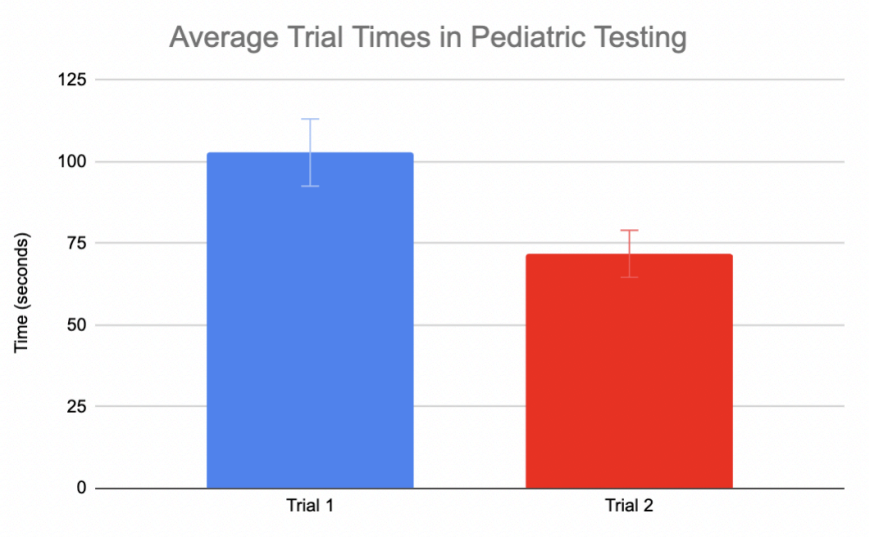


Figure 29. Graph displaying the average trial times in Trial 1 and Trial 2 of pediatric testing. The trials were concluded by the team if the child became overly distracted or disinterested in the device.

After the test was concluded, the parents or guardians were surveyed for their perspective on the design. These questions included their experiences related to their child's potential attempts to access medication at home, how this design made the parent feel in terms of safety and efficacy, as well as if they would use this design in their everyday life, either due to its child resistance or ease of use for patients. Although it varied whether their child had previously tried to access medication, parents commonly felt safe with and would use the design, especially if the slider needed to unlock the bottle was kept out of reach. There was some concern over the idea that children like to replicate their parents' actions, which could lead to them replicating the opening of the pill bottle. After reiterating the intended placement of the slider, the parents felt less concerned about children's tendency to mimic and replicate parents' actions.

5.2.3 Elderly Adult

Five elderly adult subjects ranging from 50 to 70 years of age participated in testing. This test ran similarly to the young adult testing in terms of protocol. However, during this testing

phase, the team adapted the design into the final version which included the capsules for the magnetic pins. Only two elderly adult subjects used the testing prototype that had the magnetic pins exposed. However, the team thought that this split in the data would not cause an issue because the locking mechanism itself did not change, so these trials were analyzed similarly to the rest of the elderly adult testing pool. In addition, these two subjects did not have failing trials because the magnets did not become dislodged like they did in the young adult testing. The team concluded that the addition of the capsules was a successful redesign, as all three of the elderly subject trials did not result in failure. The most important outcomes were the observations and feedback from each subject. Since elderly adults are a vast majority of the target audience of this project, it was crucial to gain insight from this portion of the testing.

In terms of average times, the control trial was 3.826 seconds, Trial 1 was 30.32 seconds, and Trial 2 was 12.312 seconds, shown in Figure 30. Additionally, Figure 31 breaks down the times of each trial per subject. These results were satisfactory because the majority of the time that participants took in Trial 1 and Trial 2 was spent trying to become familiar with the prototype. Once each subject learned how to open the bottle using the slider, they found it much easier. Similar to the young adult testing, several subjects found the lack of instructions frustrating because they did not understand how the device worked at first.

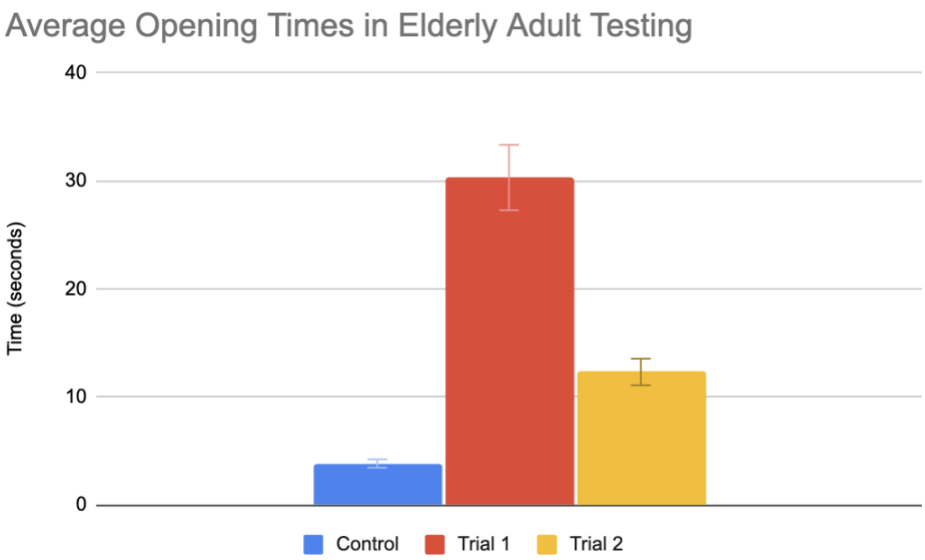


Figure 30. Graph showing breakdown of average Control, Trial 1, and Trial 2 times across all subjects.

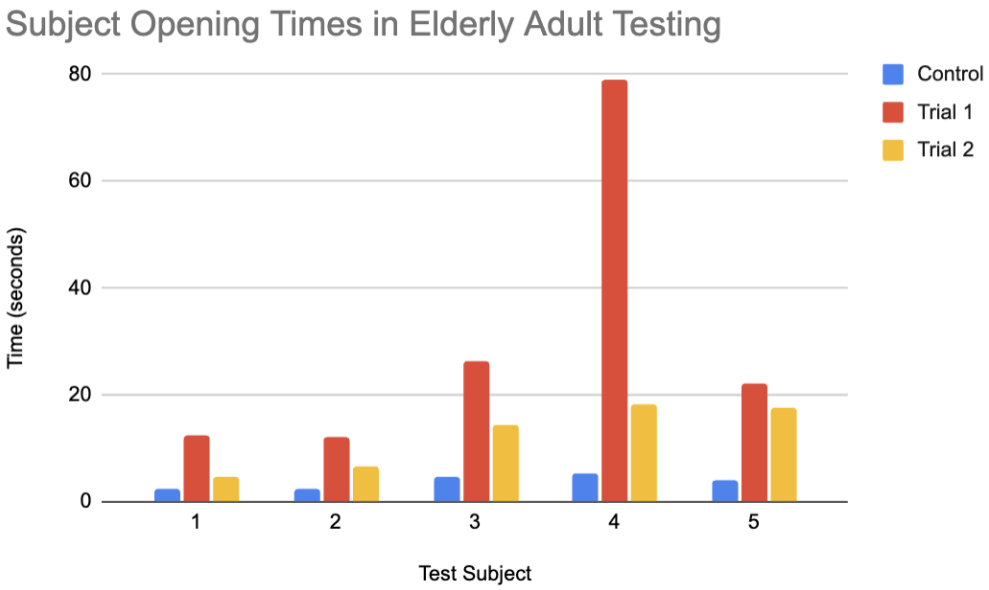


Figure 31. Graph displaying the average time the subjects took to open the pill bottle in the Control, Trial 1, and Trial 2.

Like in both the young adult and pediatric testing, post-test feedback questions were asked of the subjects. All five subjects found the device very comfortable to use and did not have any difficulties with it. For features that they liked about the design, four people said that it was simple and easy to operate to open the pill bottle. The remaining subject noted that it did not require any hand strength and said that, as long as the person has the strength to pick up the bottle, they would be able to open it using the slider. Another interesting note from a subject that the team had not considered was the fact that several people use pill organizers for their day-to-day routine schedule. This individual liked the design, but thought that it may interfere with their current medication regimen because they may not know if they have taken the correct medications for that day. Overall, the team found the elderly adult portion of the human testing to be very successful, as they were able to gain helpful feedback and observations about the project.

5.3 Mechanical Testing

5.3.1 Drop Test

To simulate a patient implementing this design into their everyday life, drop tests were performed. There were several different iterations of this test, including different floor types, two different heights, and filling the bottle with candy to simulate medication (Refer to Section 4.4.1). Observations from two testing iterations on the same flooring but different heights are shown in Tables 3 and 4.

Table 3.

Drop test results on wooden floor from table height (32.25 inches).

Drop 1	No visual damage Lock intact
Drop 2	No visual damage Lock intact
Drop 3	No visual damage Lock intact, one side raised but still “closed”
Drop 4	No visual damage Lock intact
Drop 5	No visual damage Lock intact

Table 4.

Drop test results on wooden floor from shelf height (59.5 inches).

Drop 1	No visual damage Lock intact
Drop 2	No visual damage Lock intact, cap came over lip on one side, effectively allowing the cap to be taken off
Drop 3	No visual damage Lock intact
Drop 4	No visual damage Lock intact, edge was raised to a point of resistance on the bottle, close to coming off
Drop 5	No visual damage Lock intact

Out of the 30 total trials in which the bottle was empty, there were three failures, yielding a 10% failure rate. All of these failures were on the linoleum floor, two of them being from the shelf height. One shelf height trial consisted of one of the pins becoming loose and either flew out

of the cap or switched positions, causing a change in the polarity. This would cause the cap to be locked on one side and open on the other. The other shelf height trial involved the top part of the cap completely coming off. The table height failure was minor as the lock only loosened briefly but remained closed.

When the bottle was filled with candy pieces, there was a higher failure percentage. There were 34 total trials completed with a total of 6 failures, yielding a 17% failure rate. The main iteration that encompassed the failing trials was the table height on the linoleum floor. There were 7 trials, 4 of which failed due to the entire cap coming off, leaving the bottle completely open and exposing the contents inside, shown in Figure 32.

Figure 32. Result of drop test trial on linoleum floor at shelf height (30.5 inches).

The main conclusion the group took from this test is that PLA is not a sufficient material for the design to be made out of. Due to the nature of the drop test, the device experienced impact forces that caused the PLA to wear down and become weaker. Throughout the project, the team used PLA to 3D print the cap due to its low cost and it being easy to obtain. These two factors were very important during the design process because of the high number of redesigns that

occurred throughout the design process. The vast majority of the failures were due to the cap being worn out after repeated uses, not due to the locking mechanism. This test affirmed the team's thought that the cap would need to be made out of a stronger material that would not wear down over time if it were to be manufactured. The main concern was the weight distribution of the candy and its effect on the cap. Candy integrity was not the main concern during testing but candy was damaged during this test.

5.3.2 Jostle Test

A jostle test was performed on the prototype to learn if constant shaking would cause the lock to break. This test was successful because the lock was intact at the conclusion of these three days. The primary takeaway from this test was that the device is able to be shaken and moved around constantly without the locking mechanism breaking. The group concluded that the force of magnets was stronger than the external forces on the bottle such as the collisions and shaking.

5.3.3 Force Test

According to the measurement read on the force meter, the group member was able to apply 50 newtons of force to the cap in each of the five trials. The prototype sustained no breaks or failures, resulting in successful force testing.

The group had to make several adjustments and direction changes when trying to conduct force testing. Due to material and time constraints, the team had to change the force testing from the Instron machine to a hand held force meter. The original Instron test protocol can be reviewed in Appendix J. The handheld force meter was able to provide the team with sufficient tensile strength data. After exerting 25 newtons then 50 newtons five times, it proved that a three year old child could not break into the bottle.

6.0 Conclusion

Throughout this project, the group was able to create a proof of concept model of a modified pill bottle cap and slider in order to demonstrate an easier locking mechanism that allows patients to take medication independently. Human testing showed that the target audience was able to understand, open, and close the device while maintaining child-resistance. Although design flaws were brought to the team's attention through human and mechanical trials, the design concept was proven successful. However, the team recognized limitations throughout the process, and proposed future solutions in order to address them.

6.1 Limitations

While working through testing, there were a few limitations. Firstly, the team originally planned on using the Instron machine to test how much pull force that the cap could withstand before failing. Unfortunately, the magnets in the cap design did not allow for the locking mechanism to work correctly due to the Instron being made of metal that the magnets were attracted to. As seen in Section 4.4.3, the team made a shift to handheld force testing to replace this.

Another limitation of the project was the materials that the team feasibly had access to. All of the team's prototypes and design iterations were 3D printed out of PLA and resin, which proved to work well for the scope of the project. These materials were not sustainable as seen through the various testing results. The PLA proved to work for some time, but would eventually wear down, blunt, or fracture. This would lead to either a failure of the prototype, or a decrease in the ease of use of the designs.

During human testing, the participant criteria (such as age range, number of participants, and dexterity) were changed to accept a wider audience. Specific age ranges, number of participants and patient's hand dexterity are outlined in the Code of Federal Regulations. The team acquired dozens of test subjects and extracted data from them, but the sample size did not adhere to the Code. The team tested 33 college aged subjects, 5 child subjects ranging in age from 2 – 7 years, and 5 elderly adult subjects who ranged between 50 – 70 years who suffered from a disability that made it difficult to open conventional pill bottles. The team was not able to accumulate the required number, age range, or distribution that is outlined in the Code. Despite this, the data proved useful in determining the efficacy of the design and potential interactions with patients of all ages.

When creating the testing protocols, the team found a standard discussing pressure leak testing for pharmaceutical packaging. This test would have helped the team understand the leakage rate of the cap design and ensure no drug interactions and security of the design. This test would be based on ASTM standard F2095-07 and F2338-09 which outlines a comprehensive destructive and non-destructive method to find the leakage rates of various packaging that are used to store liquid and powder medications. The team was not able to access a machine that could perform a pressure decay leak test, and there were no replacement tests that could be done.

6.2 Future Considerations

In order to overcome the previously listed limitations, there are directions that the project can continue in the future. To circumvent the magnetic properties of an Instron machine, a non-magnetic attachment could be manufactured and attached to the machine. This would allow for a force test while maintaining the "locked" state of the device to ensure a realistic force test.

Additionally, using non-magnetic pins, somehow held in place to create the “locked” state, could be used to bypass this issue.

Another consideration is in the materials and methods of the production of the prototypes. The prototypes were done mainly in PLA as it proved to be an inexpensive, easy, and fast prototyping method, allowing the team to make alterations to the design without costing too much time or money. However, due to the drawbacks such as a low strength, fatigue resistance, inaccuracies in printing, and potential interactions with the medications, the team believes that using a method and material more suitable for mass production, such as injection molding and polyethylene, would lower the rate of failure, associated costs, and chance of inaccuracies in the prototypes.

Other future considerations are additional modifications that could be made to the design. If given more time, there were a few smaller issues that the team wanted to correct. If given more time, smaller flaws with the design can be corrected. The magnet in the slider key was flush with the inner surface of the slider, meaning it could be seen by the user if flipped over. Through testing, this proved to be a potential issue as children frequently get distracted by shiny objects. Having an exposed metallic surface could possibly focus the child’s attention on the main component of the unlocking mechanism. In addition, exposure of the magnet in the slider can prove to be a choking hazard if it falls out.

Another future consideration for the design is that through the elderly patients that were tested, there was interest in making the slider smaller, or potentially creating a “travel sized” slider in addition to the normal one. This would allow patients to take a smaller version with them if they happened to be traveling, or otherwise away from home and still need to access

medication. This could pose issues as by making it smaller, it is then easier for a child to grasp and use the slider, however further testing would be needed to confirm this possibility.

Another issue was in the interaction between the magnet capsules and the bottom half of the lock. Inside the cap, the magnet capsules were occasionally prevented from moving to the "unlocked" position, and this typically occurred when someone put the cap into the slider, and kept pulling down the bottle as it slid to the slider magnet. The cap would not unlock until the user pushed up on the bottle, where the capsules would unlock and the top half would come off. Due to this observation, the team believed it came from either the capsule catching the edge of the ring inside the bottom half, or there was enough friction in the same region to prevent the magnet from moving to the unlocked state. As seen in Figure 33, there is a region, highlighted in red, where the capsule and the bottom half of the cap overlap. This issue could be solved by redesigning the cap, however due to time constraints it was left for future considerations.

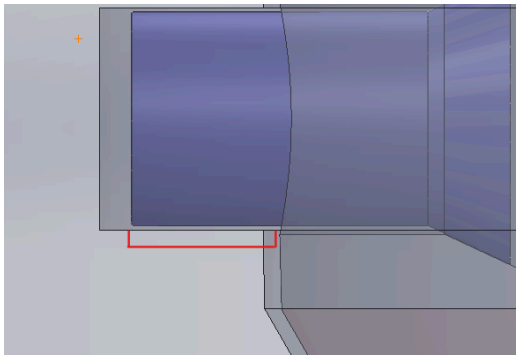


Figure 33. Close up CAD of the magnet capsule/bottom half interaction, with the potential region of this issue shown in red.

In the event that this design is considered for commercial availability, it would need to be retested under the specific conditions for age and size of trial groups outlined in ASTM standards and in accordance with the Code of Federal Regulations. Most notably, the trials should be completed with larger groups of both pediatric subjects as well as elderly patients, to ensure that

no more than 20% of the children are able to open the cap, and no less than 90% of the elderly patients are able to access their medications (*Code of Federal Regulations*, n.d.).

To continue studying the cap's security, a pressure decay leak test should be done. The team would use the non-destructive method, using ASTM F2338-09 as a reference. The team's cap and bottle would be placed in a testing chamber and vacuum would be applied. The chamber is isolated from the vacuum source and pressure transducers. These transducers will help find the change in the vacuum over time and the level of vacuum. When the pressure in the test chamber rises, that means that gas is being drawn out of the package. Ideally, the team's design would go through multiple tests to ensure that the medication is secured in the bottle. Necessary equipment for this test would be a vacuum decay leak detection apparatus, a testing chamber, a vacuum source, pressure transducers (absolute and gauge), a volumetric airflow meter, and an upper and lower tooling.

6.3 Overview

In conclusion, the team was able to successfully create a working model of a redesigned pill bottle cap using a magnetic locking mechanism and slider key system. Through mechanical and human testing, the team received feedback to improve initial designs, ending with a final product that catered towards the target audience and maintained child-resistance. The team believes that with further testing and manufacturing, the design will be able to improve the quality of life of patients struggling with pill bottles.

Appendices

Appendix A: CAD Schematics

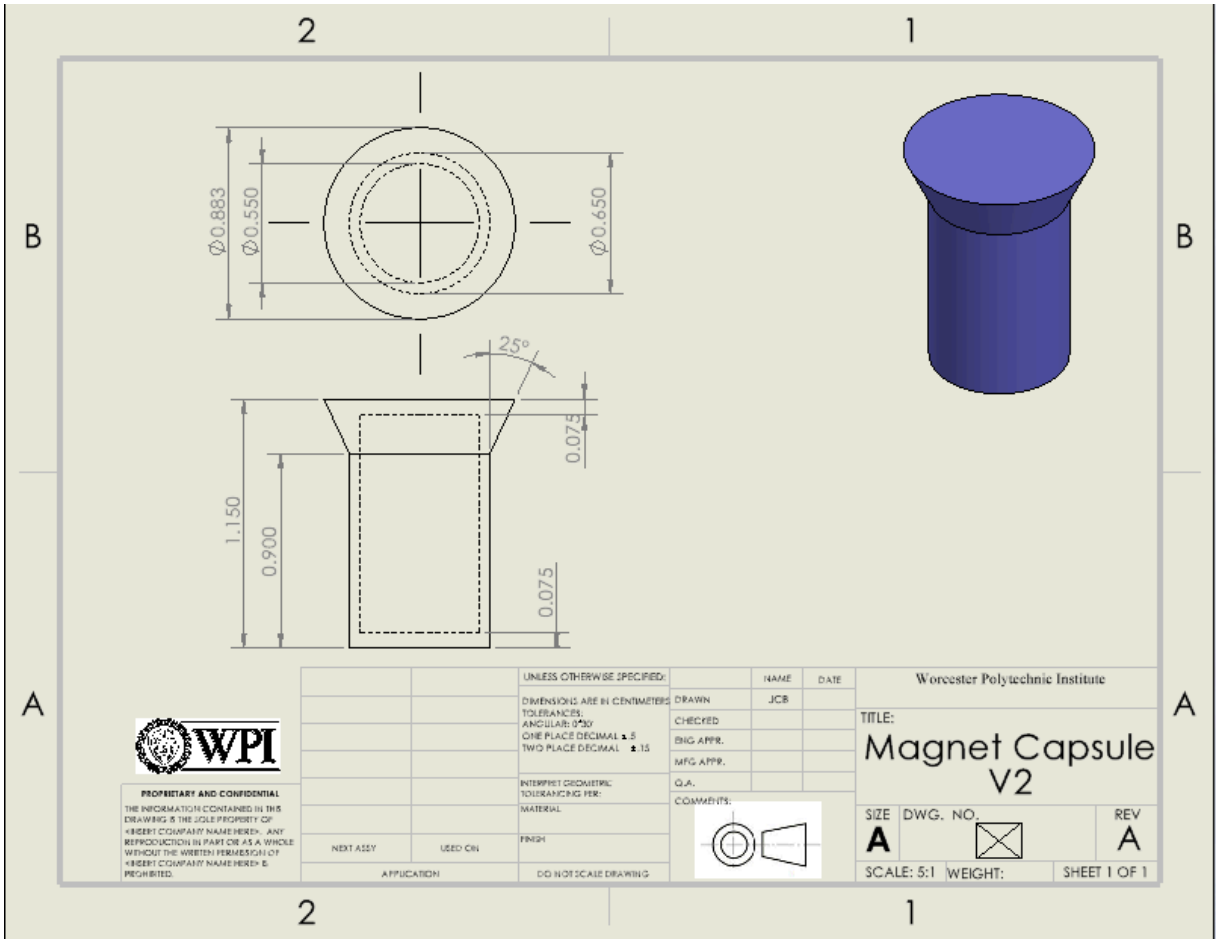


Figure 34. CAD Drawing schematic for the final design of the magnet capsules.

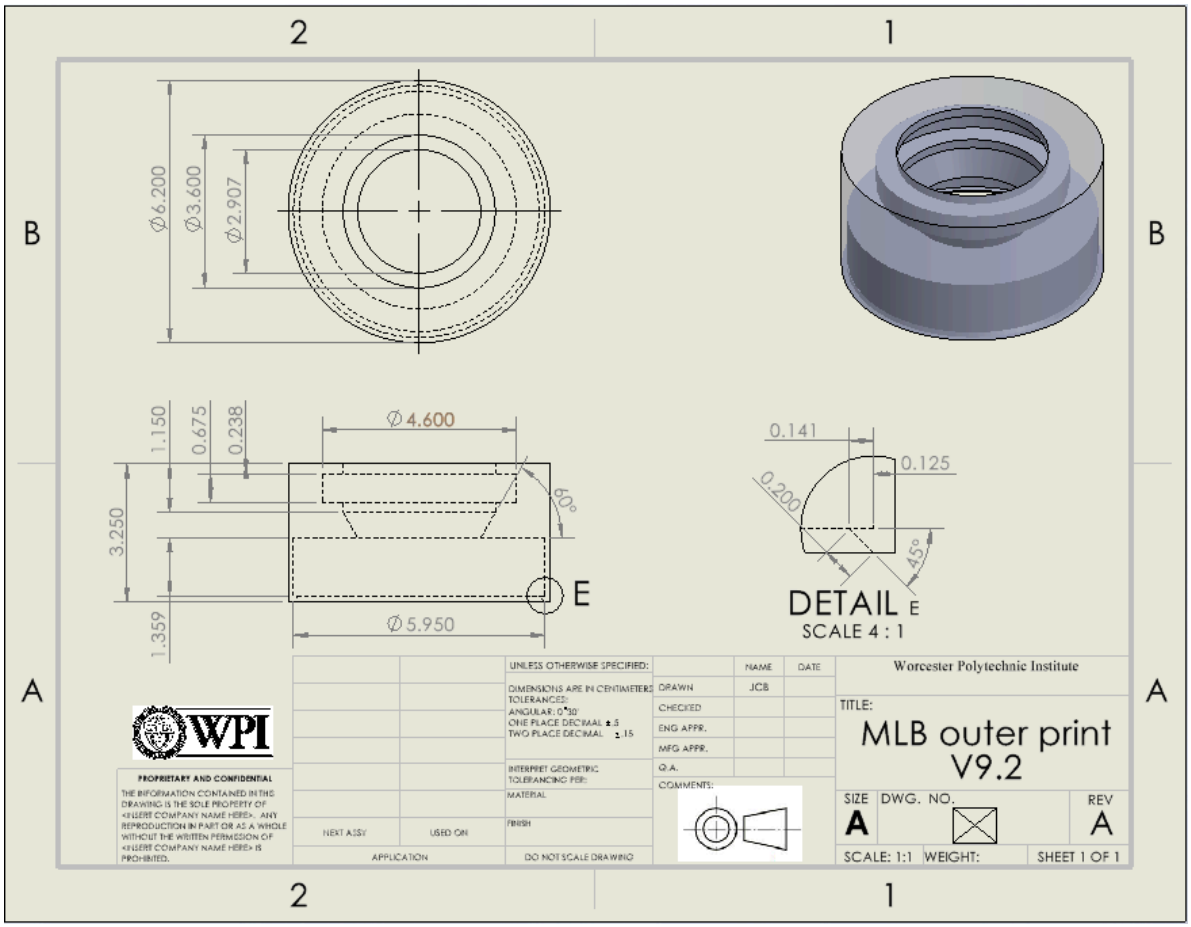


Figure 35. CAD Drawing schematic for the final design of the bottom half of the cap.

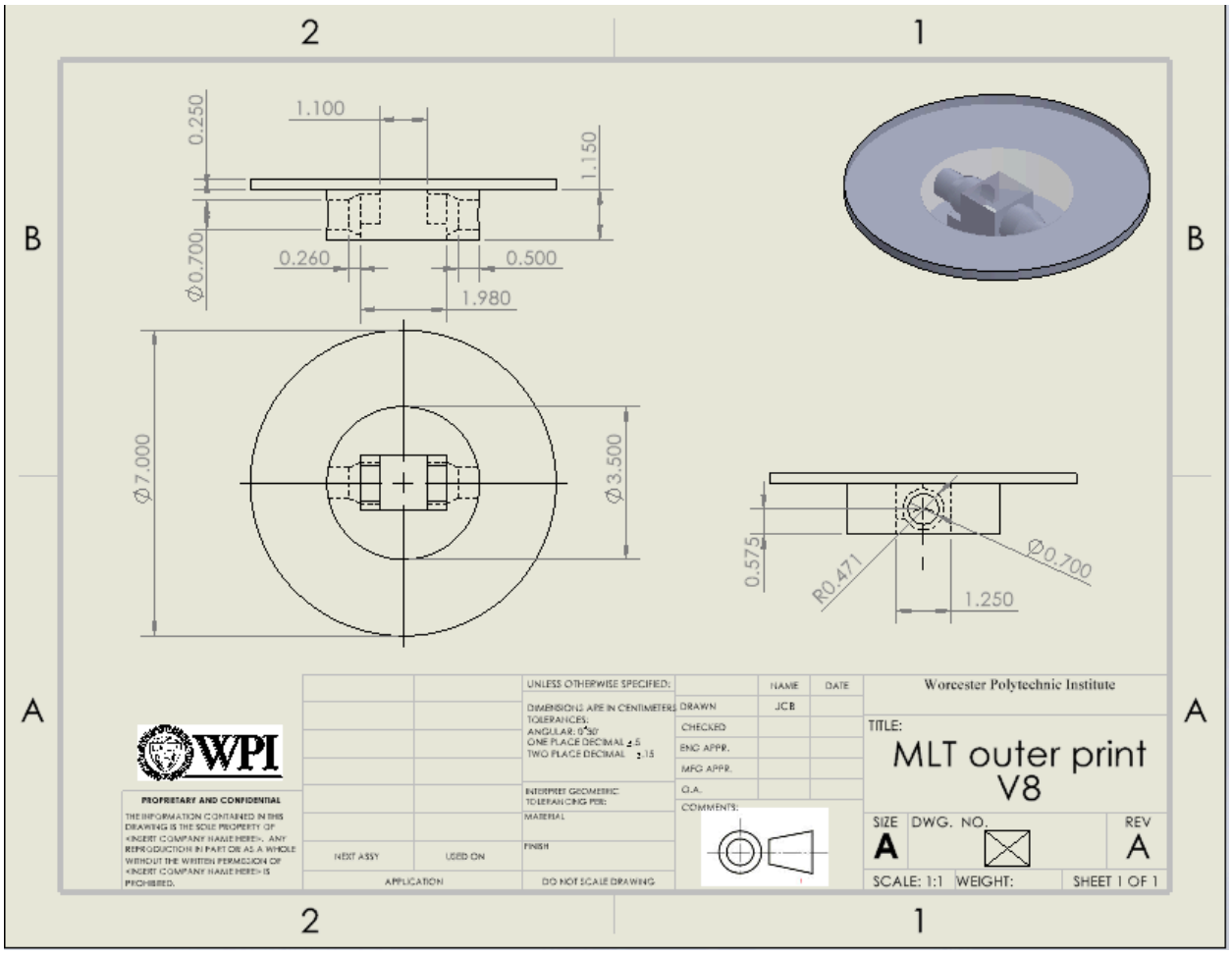


Figure 36. CAD Drawing schematic for the final design of the top half of the cap.

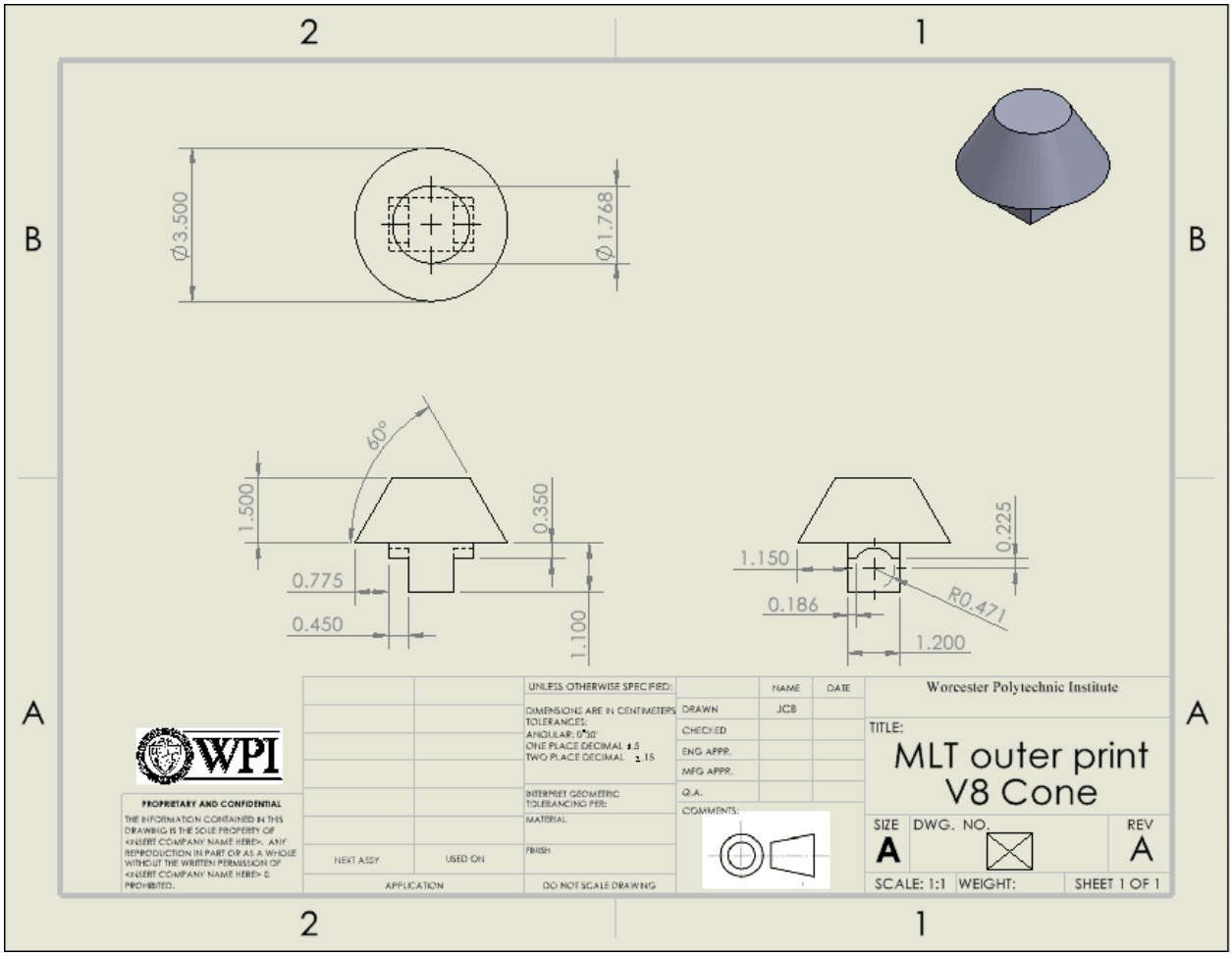


Figure 37. CAD Drawing schematic for the final design of the conic section of the top half of the cap.

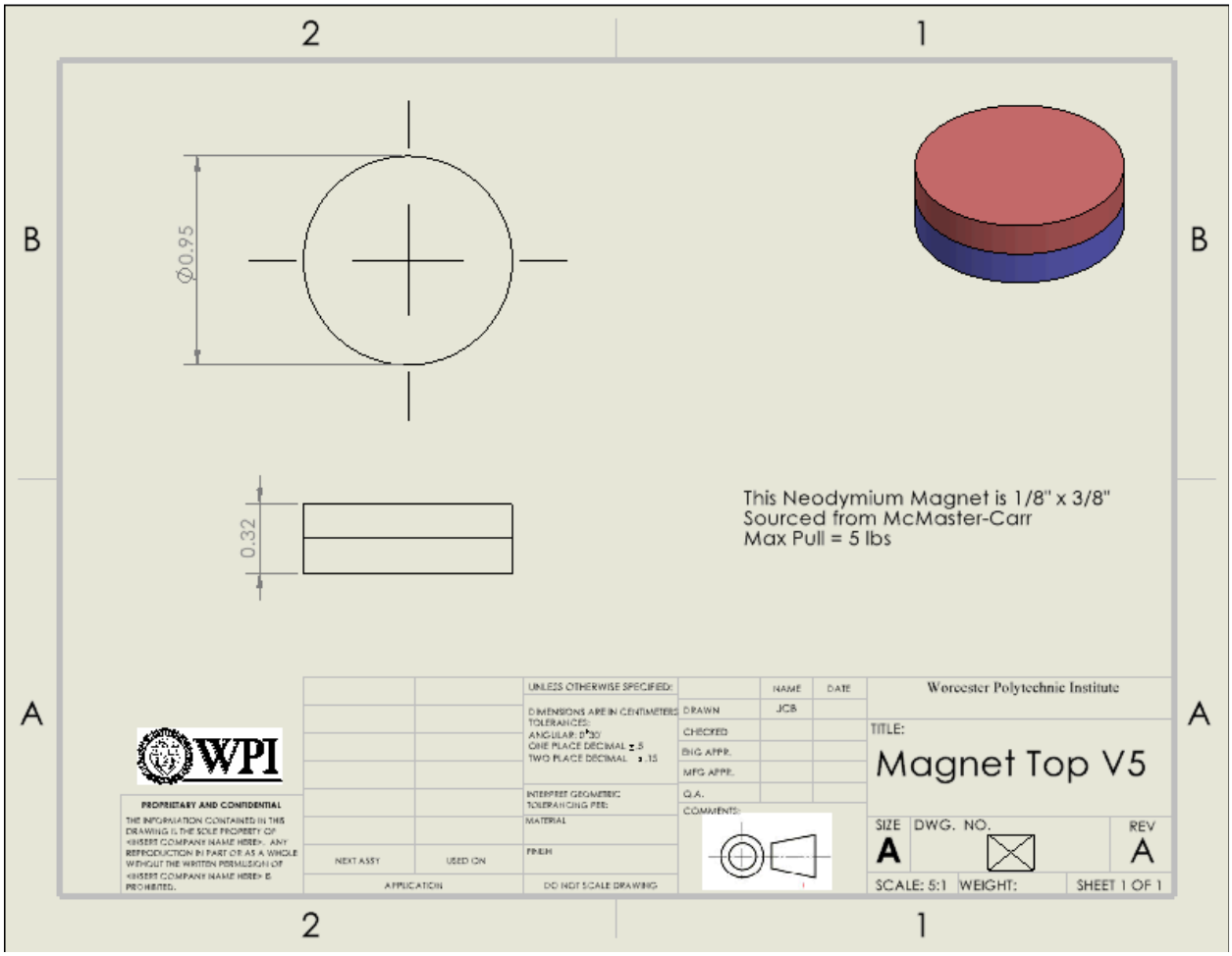


Figure 38. CAD Drawing schematic for top magnet, which was inserted in the slider, which was used in the final design.

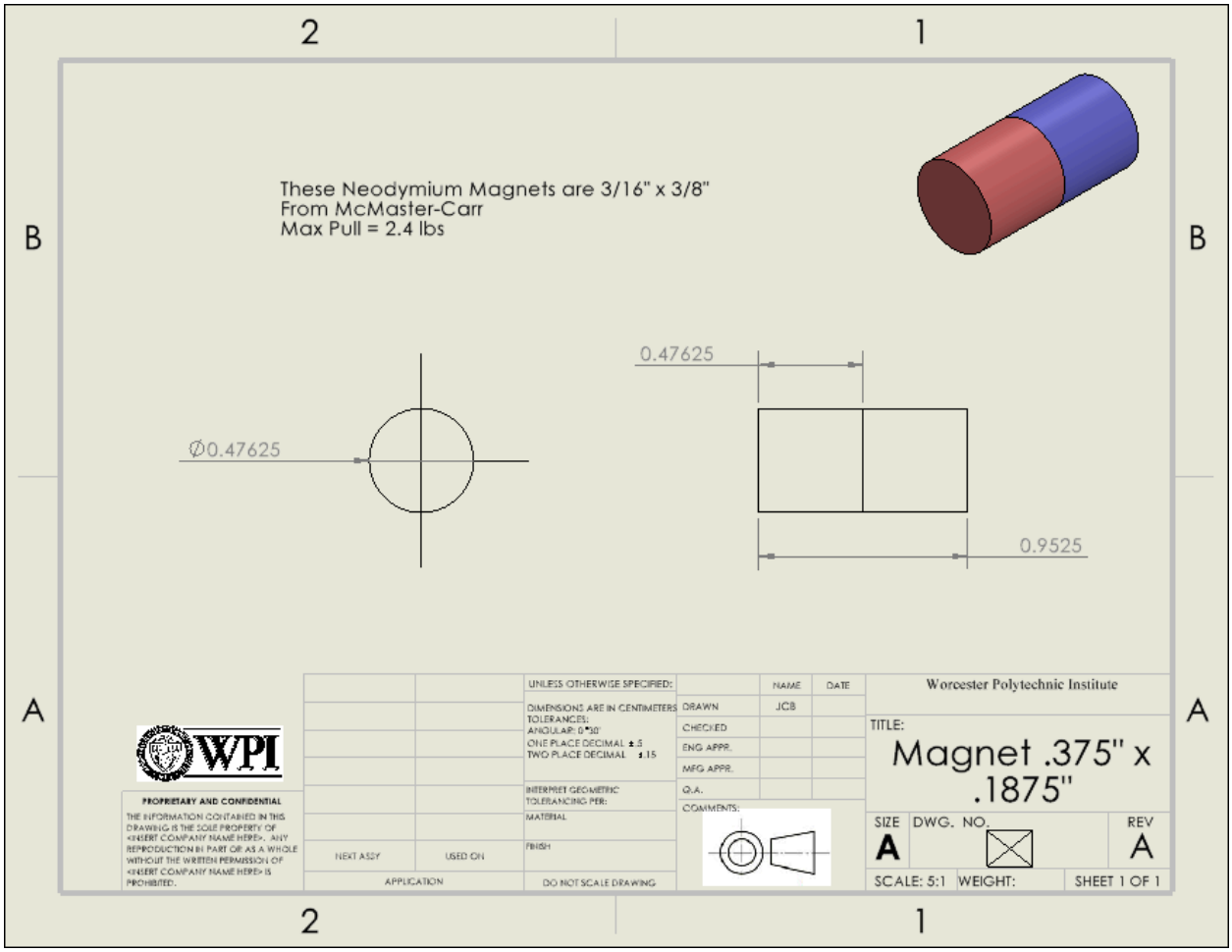


Figure 39. CAD Drawing schematic for the side magnets which were used in the final prototype of the cap.

Appendix B: Pharmacist Survey

A survey created for the target audience of pharmacists.

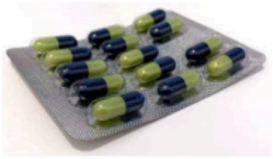
WPI

We are a team from Worcester Polytechnic Institute (WPI). We are currently working on a project that aims to redesign the current pill bottle cap in order to allow greater accessibility for taking medication independently. In this survey, we hope to gain insight on the usability of specific prescription containers. During this survey, you will be asked questions about your experiences with pill bottles, and potential improvements that could be made. Your participation in this survey is completely voluntary, and you may choose to not answer questions or withdraw at any time. Your responses will remain anonymous. If you have any questions, please contact gr-pillbottlemqp@wpi.edu.

→

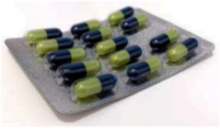
What prescription container do you interact with the most?

○ 

○ 

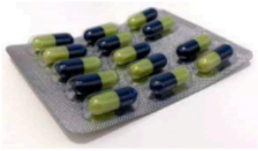
○ 

How easy is it to use these prescription containers?

	Extremely difficult	Somewhat difficult	Neither easy nor difficult	Somewhat easy	Extremely easy
	○	○	○	○	○
	○	○	○	○	○
	○	○	○	○	○

What is your reasoning behind choosing these answers?

How easy is it to fill these prescription containers?

	Extremely difficult	Somewhat difficult	Neither easy nor difficult	Somewhat easy	Extremely easy
	○	○	○	○	○
	○	○	○	○	○
	○	○	○	○	○

What is your reasoning behind choosing these answers?

What are the most common alternative storage options for pills that consumers use?

Do you know of any novel pill packaging designs that could aid with accessibility?

Are there any ideal features you would like to see in a new pill storage system?

Are there any other limitations to current designs you feel the need to share with us?

Appendix C: Caregiver Survey

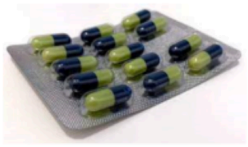
A survey created for the target audience of caregivers who daily assist older patients..

WPI

We are a team from Worcester Polytechnic Institute (WPI). We are currently working on a project that aims to redesign the current pill bottle cap in order to allow greater accessibility for taking medication independently. In this survey, we hope to gain insight on the usability of specific prescription containers. During this survey, you will be asked questions about your experiences with pill bottles, and potential improvements that could be made. Your participation in this survey is completely voluntary, and you may choose to not answer questions or withdraw at any time. Your responses will remain anonymous. If you have any questions, please contact gr-pillbottlemqp@wpi.edu.

→

What prescription container do you interact with the most?

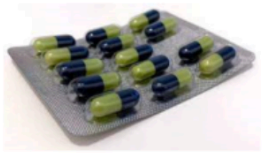


What inhibits your patient from taking medication on their own?

Do you encounter any difficulties with opening or using current pill container designs? If so, what difficulties do you have?

- ○ Yes
- ○ No
- ○ Sometimes

How easy is it to use these prescription containers?

	Extremely difficult	Somewhat difficult	Neither easy nor difficult	Somewhat easy	Extremely easy
	○	○	○	○	○
	○	○	○	○	○
	○	○	○	○	○

What is your reasoning behind choosing these answers?

Have you used alternative storage containers for pills/medication before? If so, what were your experiences like?

- ○ Yes
- ○ No

Are there any other limitations to current designs you feel the need to share with us?

Appendix D: Patient Survey

A survey created for the target audience of patients who interact with pill bottles.

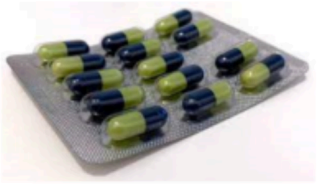
We are a team from Worcester Polytechnic Institute (WPI). We are currently working on a project that aims to redesign the current pill bottle cap in order to allow greater accessibility for taking medication independently. In this survey, we hope to gain insight on the usability of specific prescription containers. During this survey, you will be asked questions about your experiences with pill bottles, and potential improvements that could be made. Your participation in this survey is completely voluntary, and you may choose to not answer questions or withdraw at any time. Your responses will remain anonymous. If you have any questions, please contact gr-pillbottlemqp@wpi.edu.

→

Do you regularly take prescription medication?

- ○ Yes
- ○ No
- ○ Sometimes

What prescription container do you interact with the most?

- ○ 
- ○ 
- ○ 

Do you have any health conditions that may impact your ability to open a prescription container?

- ○ Yes
- ○ No

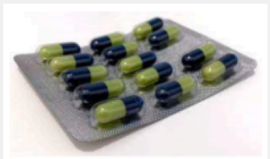
Do you encounter any difficulties with opening or using current pill container designs? If so, what difficulties do you have?

- ○ Yes
- ○ No
- ○ Sometimes

Do you have an alternative method that you use to adhere to your prescription

- ○ Yes
- ○ No

How easy is it to use these prescription containers?

	Extremely difficult	Somewhat difficult	Neither easy nor difficult	Somewhat easy	Extremely easy
	○	○	○	○	○
	○	○	○	○	○
	○	○	○	○	○

What is your reasoning behind choosing these answers?

Have you used alternative storage containers for pills/medication before? If so, what were your experiences like?

- Yes
- No

Are there any other limitations to current designs you feel the need to share with us?

Appendix E: Parent Survey

A survey created for the target audience of parents of young children.

We are a team from Worcester Polytechnic Institute (WPI). We are currently working on a project that aims to redesign the current pill bottle cap in order to allow greater accessibility for taking medication independently. In this survey, we hope to gain insight on the usability of specific prescription containers. During this survey, you will be asked questions about your experiences with pill bottles, and potential improvements that could be made. Your participation in this survey is completely voluntary, and you may choose to not answer questions or withdraw at any time. Your responses will remain anonymous. If you have any questions, please contact gr-pillbottlemqp@wpi.edu.

→

How old are your children?

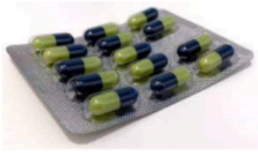
What methods do you use to keep medication away from your children?

Have there been instances when your child has obtained medications that they were not supposed to? Explain.

Do you encounter any difficulties with opening or using current pill container designs? If so, what difficulties do you have?

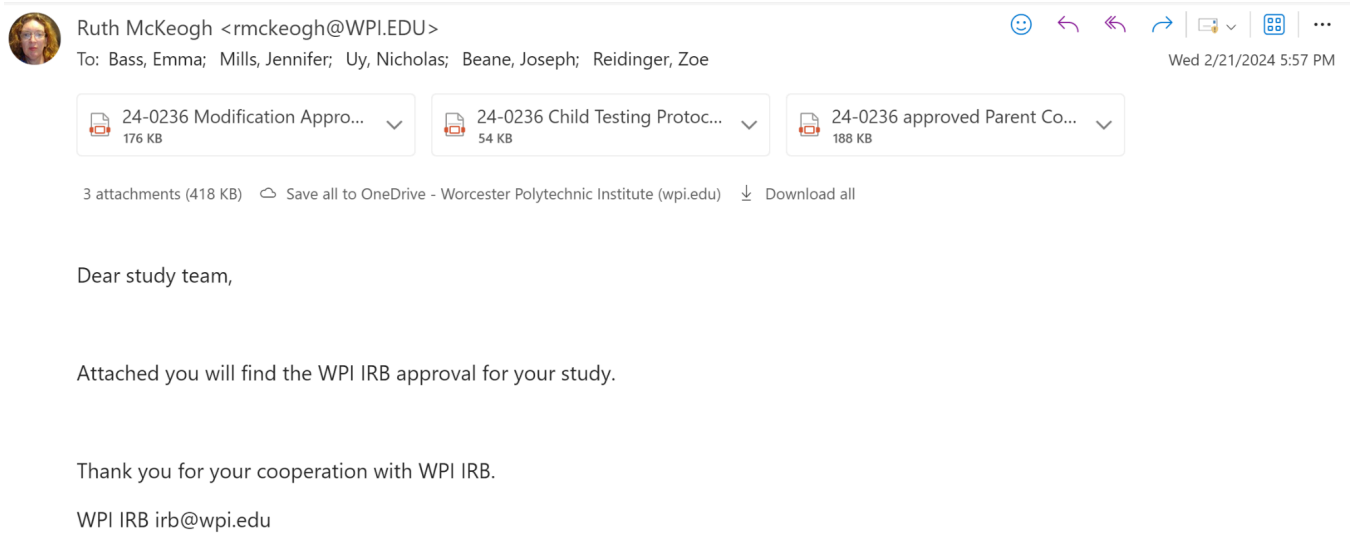
- ○ Yes
- ○ No
- ○ Sometimes

How easy is it to use these prescription containers?

	Extremely difficult	Somewhat difficult	Neither easy nor difficult	Somewhat easy	Extremely easy
	○	○	○	○	○
	○	○	○	○	○
	○	○	○	○	○

What is your reasoning behind choosing these answers?

Appendix F: IRB Approval



Ruth McKeogh <rmckeogh@WPI.EDU>
To: Bass, Emma; Mills, Jennifer; Uy, Nicholas; Beane, Joseph; Reidinger, Zoe
Wed 2/21/2024 5:57 PM

24-0236 Modification Appro... 176 KB
24-0236 Child Testing Protoc... 54 KB
24-0236 approved Parent Co... 188 KB

3 attachments (418 KB) Save all to OneDrive - Worcester Polytechnic Institute (wpi.edu) Download all

Dear study team,

Attached you will find the WPI IRB approval for your study.

Thank you for your cooperation with WPI IRB.

WPI IRB irb@wpi.edu

Appendix G: Pediatric Testing Protocol

Child Testing Protocol:

Where/how will we be recruiting? We will be recruiting by word of mouth and email asking professors that have young children (ages 2-7) if they would be willing to participate.

Where will the research take place? The research will take place on campus.

What age of children will be used in this study? Children aged 24-84 months.

At the beginning of the study, the parent will be asked to sign a parental consent form. The parents will stay to watch the study to make sure that they are comfortable for the entirety of the study. This will allow them to have the ability to withdraw consent at any time.

During the study, the child will be given a pill bottle that has our newly designed cap attached to it. They will be given no further instructions. We will set a timer for 10 minutes and allow the child to use the 10 minutes to try to open the pill bottle. If the child becomes bored, frustrated, or does not want to continue with the task, the task will stop and the timer will stop as well. During testing, the child's hands will be videotaped and the recording will be used to further study the behaviors that children have around pill bottles. If the child's face ever comes into view, we will crop the video or blur out any identifying features. Only the team, advisor, and the BME department will have access to the recordings. If the child does not open the pill bottle within the 10 minutes, or gives up before the 10 minutes is over, the test will be considered a success.

Next, the child will be given the same pill bottle as well as our slide key. They will be given no further instructions. We will set a timer for 10 minutes and allow the child to use the 10 minutes to try to open the pill bottle. If the child becomes bored, frustrated, or does not want to continue with the task, the task will stop and the timer will stop as well. During testing, the child's hands will be videotaped and the recording will be used to further study the behaviors that children have around pill bottles. If the child's face ever comes into view, we will crop the video or blur out any identifying features. Only the team, advisor, and the BME department will have access to the recordings. If the child does not open the pill bottle within the 10 minutes, or gives up before the 10 minutes is over, the test will be considered a success.

Appendix H: Pediatric Testing Consent Form

Consent Form:

Informed Consent Agreement for Participation in a Research Study

Investigators: Emma Bass, Connor Beane, Jen Mills, Nico Uy

Contact Information: gr-pillbottlemqp@wpi.edu

Title of Research Study: Redesign of a Pill Bottle Cap

Sponsor: WPI

You are being asked to allow your child to participate in a research study. Before you agree, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks or discomfort that you or your child may experience as a result of your child's participation. This form presents information about the study so that you may make a fully informed decision regarding your child's participation.

Purpose of the study: This study will be used to evaluate if children are able to open our new pill bottle cap design. The results will be used to determine how child-proof the cap is as well as what changes can be made in order for the children to not be able to open the cap.

Procedures to be followed: In this study, your child will be given a pill bottle with our new cap design. Your child will be given 10 minutes to try to open the pill bottle. Then, your child will be given 10 minutes to try to open the pill bottle with the assistance of the slide key. If at any point in either trial your child becomes bored, frustrated, or does not want to finish the task, you are allowed to stop the task before the timer is complete.

Risks to study participants: You as a parent may feel uncomfortable with your child trying to open a pill bottle.

Benefits to research participants and others: Allowing your child to participate in this study will allow our team to continue making improvements to the pill bottle cap in order to make it more child-proof.

Record keeping and confidentiality: Your child's hands will be recorded. If the child's face ever comes into view, we will crop the video or blur out any identifying features. Any and all video recordings and records of your participation in this study will be held confidential so far as

permitted by law. However, the study investigators, the sponsor or its designee and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name. Any publication or presentation of the data will not identify you.

Compensation or treatment in the event of injury: You do not give up any of your legal rights by signing this statement.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact:
Pill Bottle MQP Team - gr-pillbottlemqp@wpi.edu
IRB Manager (Ruth McKeogh, Tel. 508 831- 6699, Email: irb@wpi.edu)
Human Protection Administrator (Gabriel Johnson, Tel. 508-831-4989, Email: gjohnson@wpi.edu).

Your participation in this research is voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop your child from participating in the research at any time without penalty or loss of other benefits. The project investigators retain the right to cancel or postpone the experimental procedures at any time they see fit.

By signing below, you acknowledge that you have been informed about and consent to be a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

_____ Date: _____
Study Participant Signature

_____
Study Participant Name (Please print)

_____ Date: _____
Signature of Person who explained this study

Appendix I: Young Adult and Elderly Testing Consent Form

Consent Form:

Informed Consent Agreement for Participation in a Research Study

Investigators: Emma Bass, Connor Beane, Jen Mills, Nico Uy

Contact Information: gr-pillbottlemqp@wpi.edu

Title of Research Study: Redesign of a Pill Bottle Cap

Sponsor: WPI

You are being asked to participate in a research study. Before you agree, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks or discomfort that you may experience as a result of your participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

Purpose of the study: This study will be used to evaluate how long it takes patients to open our new pill bottle cap design. The results will be used to determine how quickly the target audience is able to open the cap.

Procedures to be followed: In this study, you will be given a pill bottle with our new cap design, as well as a slide key. You will be given 5 minutes to try to open the pill bottle. If successful, you will be asked to open the pill bottle within 1 minute.

Risks to study participants: You may have adverse feelings if you are unable to complete this task in the time provided.

Benefits to research participants and others: Your participation in this study will allow us to continue improving the design of the pill bottle, and work towards a future where patients with lower dexterity are able to open pill bottles independently.

Record keeping and confidentiality: Your hands will be videotaped during this session. Any and all video recordings and records of your participation in this study will be held confidential so far as permitted by law. However, the study investigators, the sponsor or its designee and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name. Any

publication or presentation of the data will not identify you.

Compensation or treatment in the event of injury: You do not give up any of your legal rights by signing this statement.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact:
Pill Bottle MQP Team - gr-pillbottlemqp@wpi.edu
IRB Manager (Ruth McKeogh, Tel. 508 831- 6699, Email: irb@wpi.edu)
Human Protection Administrator (Gabriel Johnson, Tel. 508-831-4989, Email: gjohnson@wpi.edu).

Your participation in this research is voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop participating in the research at any time without penalty or loss of other benefits. The project investigators retain the right to cancel or postpone the experimental procedures at any time they see fit.

By signing below, you acknowledge that you have been informed about and consent to be a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

_____ Date: _____
Study Participant Signature

_____
Study Participant Name (Please print)

_____ Date: _____
Signature of Person who explained this study

Appendix J: Young Adult and Elderly Testing Protocol

Participant Testing Protocol:

Where/how will we be recruiting? We will be recruiting on campus by word of mouth and emails to professors.

Where will the research take place? The research will take place on campus.

Who will be recruited in this study? Anyone who uses pill bottles, anyone who may have a disability or may have difficulty opening pill bottles.

At the beginning of the study, the participant will be asked to sign a consent form. The participants will have the ability to withdraw consent at any time if they feel uncomfortable or do not want to continue.

During the study, the participant will be given a pill bottle that has our newly designed cap attached to it, as well as a slide key that the team designed to unlock the pill bottle. The participant will have 5 minutes to try to open and close the pill bottle. During testing, the participant's hands will be videotaped and the recording will be used to further study the behaviors around pill bottles. Only the team, advisor, and the BME department will have access to the recordings.

If the participant is successful in opening the pill bottle within 5 minutes, the participant will be given the same pill bottle and slide key and will be asked to open it again within 1 minute to assess the reproducibility of the opening action. During testing, the participant's hands will be videotaped and the recording will be used to further study the behaviors around pill bottles. Only the team, advisor, and the BME department will have access to the recordings.

Feedback on the pill bottle design will also be taken from each participant. The participants will be asked these questions: How comfortable was the pill bottle to use? What (if any) difficulties did you face with the design? What features did you like about the design? Would you consider using this pill bottle design in your day-to-day life?

Appendix K: Instron Test Protocol

Mechanical testing is frequently used to assess child-resistant packages such as pill bottles. For our design and this type of testing, standard ASTM D3481 was used as a reference. These standards outlined test methods used for different bottles such as snap-fitted outer caps and thread closures on containers. Although the team's design did not fulfill the standard's design requirements, the results were useful for understanding the bottle and cap's failure states. Using the Instron 5544 machine, two methods were created: one to assess the torque retention and another to assess the force required to pry open the cap. Bluehill Universal software was used to program and set up the Instron machine.

Currently, this standard was withdrawn by ASTM and there has been no replacement for this standard but it still proved useful to use for this Instron test. The average child hand grip strength is 45.11 - 52.95 newtons (Bohannon et al., 2017) and these force values were used for the Bluehill Universal program. A tension test template was used to help make the program. In the general category, the system of units was SI and specimen parameters were turned into "Methods Default". In the specimen category, under the properties section, the geometry was changed to circular and the sample pill bottle and cap dimensions, such as length and diameter, were added to the program. In the measurements category, measurement types added were time, displacement, force, tensile displacement, tensile strain, and tensile stress. In the calculations category, under the setup section, the selected calculations added were modulus, maximum force, maximum slope, and tensile strength. In the test control, under the test section, the rate was 10 mm/min. Under the end of test section, 3 criteria were added. The first criterion was the measurement rate based on force; if the rate of force drops by 40%, the test will end. The second criterion was based on the force value above; if the force were to exceed 90 newtons, the test would end. The final criterion

was based on the standard; the test should last approximately 15-30 seconds so the test will end at the 30-second mark. Under the data section, the data capture scheme was set to have an interval of 100 ms rather than 20 ms. In the console category, under live displays, tensile strain, and stress were added. Under the soft keys section, balance force was added as a function. In the workspace category, under operator inputs, the parameters chosen were specimen label, geometry, specimen label, length, diameter, and rate 1. Under results 1, the same variables from operator inputs were added as selected results. In addition to this, maximum force, tensile stress, maximum slope, and modulus were added. Under graph 1, x-data was changed to tensile strain and y-data was changed to tensile stress. For graph 2, it was changed to have a double y-axis with the x-data being time and the y-axis being force and displacement. The raw data the team chose to collect was time, displacement, force, tensile strain, and tensile stress.

For layout, the team chose to have both graphs on the left and results on the right. In the exports category, under export 1, the frequency was changed to “at finish”, “create a file for each sample” was checked off, and “methods parameters” was checked off. For export 2, the frequency was changed to “at finish” and “methods parameters” was checked off. Methods parameters for both exports were set to show specimen geometry, length, diameter, label, and rate 1. Finally, in the workflow category, “run as a prompted test”, “prompt before a test”, and “show workspace after the test” were checked off. Under “before test,” the selected parameters were specimen label, geometry, diameter, length, and rate 1. The failure state was if the cap was damaged (i.e. cracked) or if the locking mechanism was compromised (i.e. breached). Another test used similar parameters but rather than simulating children, the bottle was pushed to failure using higher force values. The end test parameters were changed from 50 - 150 Newtons.

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