Nimble Needles: Insulin Filling Station

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TABLE OF CONTENTS

ABSTRACT

The client, Michelle Somes-Booher, is the Director of the Wisconsin Small Business Development Center, and her father has type II diabetes. Due to this close relationship, Ms. Somes-Booher has become aware of the challenges involved with self-administering insulin injections for individuals with diabetes and lower dexterity, specifically when filling the syringe with insulin. When lining the needle up with the insulin vial, patients with lower dexterity often poke themselves, bend the needle or contaminate the needle, increasing the risk of injury or infection. This risk can be avoided through the creation of a syringe-filling aid, which decreases risk of contamination or needle poke while increasing the ease of use for patients. Tasked with creating this device, the team generated three cost-effective models of a syringe-filling device in hopes of decreasing needle-anxiety, financial burden, and safety risk to patients. The first design is a sliding model: one half holds the syringe holder and the other half holds the insulin vial. The two halves then slide to meet and align the needle with the vial opening. The second, a corkscrew design, utilizes two tapered cones, one threaded and one unthreaded, to secure a vial and syringe. The last, a layered design, functions in two halves similar to the sliding design, but also incorporates velcro to accommodate for length rather than a sliding mechanism. After evaluating these designs through eight carefully selected criteria in a design matrix, the team has decided to move forward with the sliding model and looks to produce a prototype upon which usability, drop, and tensile force testing can be completed.

1. INTRODUCTION

1.1. Motivation

While diabetes is mainly managed through behavioral changes, individuals with diabetes can receive supplemental insulin to maintain blood glucose levels, especially individuals with type I diabetes due to their inability to produce insulin. One form of insulin supplementation are insulin injections, which is the most affordable option and the option provided through Medicare.

Filling the syringes with insulin is technically difficult and requires fine motor control through the three steps: priming the syringe, inserting the needle into the vial, and filling the syringe with insulin. Complications of diabetes, such as neuropathy and retinopathy, further inhibit successful completion this life-saving procedure (see section 2.1 below). In addition, the populations that most often use this method - low income and elderly populations - are impacted by additional factors that can further hinder the syringe-filling process. Thus, this leads to greater risk of accidental needle pokes, needle contamination, bent needles, and insulin wastage, especially while attempting to insert the needle into the vial opening [1]. These risks are not only painful and contribute to needle anxiety, but also can be life-threatening, especially when considering the financial burden of insulin and the increased likelihood of infection for an individual with diabetes.

1.2. Existing Devices and Current Methods

Currently, there are three alternatives for insulin injections. Insulin pens contain a cartridge, dial to measure dosage, and a disposable needle. The pens can be disposable or reusable, with a replaceable insulin cartridge. This method is growing in popularity due to its ease of use and convenience [1]. Individuals with diabetes can also receive an insulin pump [2], which is a device that mimics pancreatic function by delivering small doses of insulin continuously to the fatty tissue. It is worn on the outside of the body and delivers insulin via an infusion set and catheter. These two options are both extremely expensive and require extensive training, thus less accessible for lower socioeconomic populations.

Inhaled insulin is also an option, but much less popular than the other three alternatives due to risk of complications if the user has lung problems [3, 4]. An inhaler allows the insulin to be administered via the blood vessels in the lungs. However, it is difficult to ensure an accurate dosage of insulin and is thus used as a back-up plan.

In addition, there are also devices on the market that also aim to ease syringe-filling for individuals with diabetes [5]. For example, the Prodigy Count-A-Dose allows visually-impaired and individuals with poor motor control to easily fill and accurately measure out their insulin dosage. However, it is extremely expensive at $69.95 per unit; this would still be unaffordable for the target populations - the lower socioeconomic individuals - who are most likely using insulin injections. There are also devices for visually impaired individuals that magnify the dosage markings on the syringe, but they do not address or ease the fine motor techniques required.

1.3. Problem Statement

Ms. Somes-Booher's father, an elderly man with insulin-dependent type II diabetes, relies on daily insulin injections. These injections are difficult to elderly patients, such as the client's father, who often have reduced dexterity due to aging. Currently, a treatment option is to use a syringe to inject insulin from a vial; this option is often used by lower income and Medicare insulin-dependent type II and type I diabetic patients because it is less costly. However, the elderly patients often experience difficulties lining up the syringe with the insulin vial and inserting the syringe into the vial. These difficulties frequently result in accidental pricks or bending of the needle, which renders the needle useless. For lower income and Medicare patients, this is particularly impactful, as it results in wasting syringe and insulin, and therefore financial loss. Thus, the team aims to design a device that eases filling syringes with insulin for elderly patients while remaining cost effective, affordable, and accessible.

2. BACKGROUND

2.1. Diabetes Disease State

Diabetes is a disease that results in excess blood glucose levels. There are three main types: type I, type II, and gestational. Type I diabetes is caused by an autoimmune reaction that attacks insulin-producing cells, which results in insulin dependence. Thus, individuals with type I diabetes must take supplementary insulin to regulate blood glucose. Type II diabetes is caused by a combination of lifestyle and genetic factors and develops gradually into insulin resistance over a long period of time. Individuals with type II diabetes can often manage the disease through behavioral changes, but may also use supplemental insulin. Gestational diabetes develops during pregnancy but often disappears post-partum.

There is no cure to diabetes, so individuals have to manage the disease and blood glucose levels through behavior and lifestyle changes, such as through maintaining a healthy diet and exercising regularly. As previously mentioned, individuals with diabetes can also receive supplemental insulin in a variety of forms (see section 1.2).

There are also many symptoms and complications related to the disease, such as nausea, vomiting, and frequent urination. However, the most relevant complications for the project are neuropathy, or numbness and tingling in the limbs, and retinopathy, or blurry vision. In addition, having diabetes can increase the risk of infections and conditions that often result in poor motor control, such as stroke [6].

The epidemiology of diabetes is also important to acknowledge because it so disproportionately impacts low socioeconomic and lower educational levels, as well as certain racial groups [7]. These populations also tend to be impacted by additional barriers to diabetes management, such as limited resources due to geographic location or financial constraints. Thus, the public health implications of this device are significant, as reducing barriers and increasing accessibility to self-administration of insulin injections is vital to addressing disparities in diabetes treatment and management.

2.2. Client Information

Ms. Somes-Booher wants to improve her father's ease of taking vital and regular insulin injections. She is the Director of the Wisconsin Small Business Development Center at the University of Wisconsin - Madison and has done thorough research on the viability of putting this product to market. In addition, her father, an elderly individual with type II diabetes, originally created a prototype and received feedback from other elderly individuals that use insulin injections. Not only will his prototype and peers' feedback be extremely useful, but his entrepreneurial experience will also add be vital guidance throughout the design process.

2.3. Design Specifications

This product will primarily be aimed at making diabetes treatment easier, safer, and more affordable for people with low dexterity. Therefore, the main specifications for the design include being cost effective, reducing errors, and increasing ease of use for the user to make treatment more ergonomic.The client requires that production of the device be cost effective enough to produce a profit, yet affordable as it still be accessible to lower-income patients. The cost of manufacturing per product must be under three dollars per device. The device must also increase ease of use in filling a syringe with insulin, so the user must be able to grip it more easily and visually measure how much insulin is entering the syringe. Because the client hopes to take this product to market, the exterior must be personalizable.

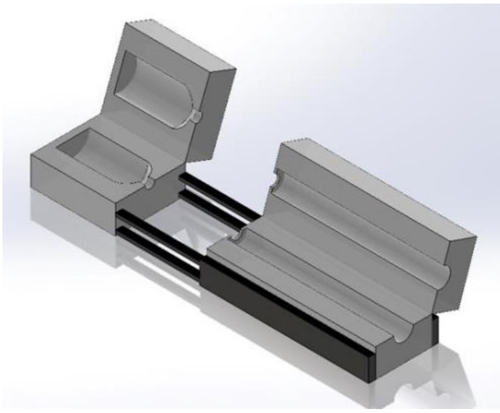
The device must decrease the occurrence of broken or bent needles during attempts to fill syringes from insulin vials. The device must also allow for visual measurement of the amount of insulin entering the syringe. Therefore, there must be a window or a read-out for the units of insulin in the syringe. In addition, the device must be able to withstand tensile and compressive forces that come with syringe-filling. The user needs to be able to strongly grip the vial and syringe to prevent slippage or insulin waste. With every insulin injection, this device must maintain adequate performance while being used two to four times each day, every day for at least five years. The device must be able to withstand repetitive environmental conditions of up to 75°C [7, 8] through the dishwasher. The product will have to sustain in 15%-50% humidity levels [9], and an average outdoor temperature range of 4°C-32°C [10], due to the product is being marketed to the United States climate. It must survive under all of these conditions for at least five years. The device must also be able to withstand drops from up to three meters. For similar reasons, the device should maintain easy to grip, even when in contact with water, since most consumers will be injecting themselves in bathrooms or kitchens [11], and should not weigh more than 0.5 lbs with the syringe and vial included [12]. This means that the device alone can weigh no more than .472lbs [13]. This is to ease the effort placed on the low dexterity user. The device must have a flat base when in use, so it is not sliding around, or rolling, making loading the syringe and vial difficult for the consumer.

The biggest safety requirements involve sterility of the device. The device must be made of sanitary, non-toxic materials, and contain minimal crevices so no bacteria easily grows. Easy sustainability of sanitization must be ensured throughout usage. This requires that the device must be easily washable, ideally dishwasher safe. One of the biggest requirements is that the design must be able to accommodate all differing standardized syringe and vial sizes to allow for a bigger consumer market (see Appendix 7.2).

3. PRELIMINARY DESIGNS

3.1. Sliding Model

The idea of this design is to have the vial and syringe in separate compartments that are connected by a sliding mechanism so that the distance between them is adjustable. This design ensures that the needle is inserted into the vial in a straight line and without being bent. The sliding mechanism will be designed so that specific lengths can be locked in place by the user using either notches or friction. Being able to adjust the lengths between the two components is advantageous because it can accommodate various needle lengths especially since needle sizes vary drastically (see Figure 3). This design also adjust accordingly to the volume of insulin left in the vial. Since insulin is extremely expensive, being able to use all of it is beneficial to our target consumers.



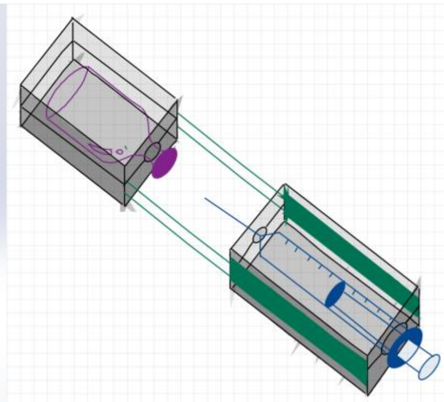


Figure 1: Depicted above is the sliding model in Solidworks. **Figure 2:** Drawn above is the sliding model.

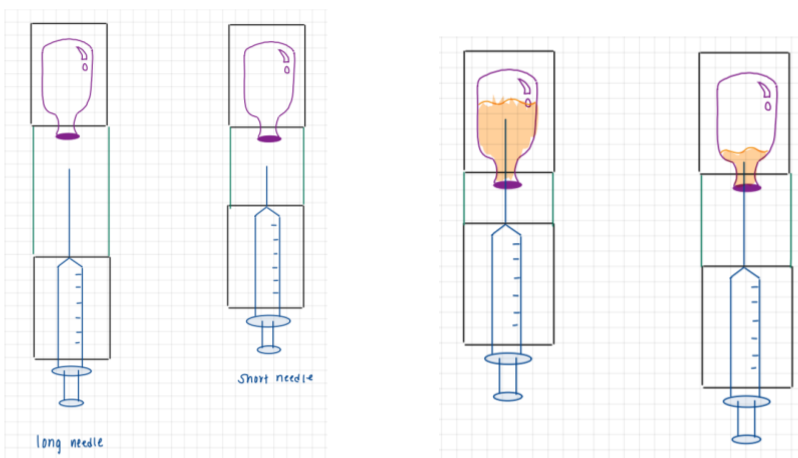
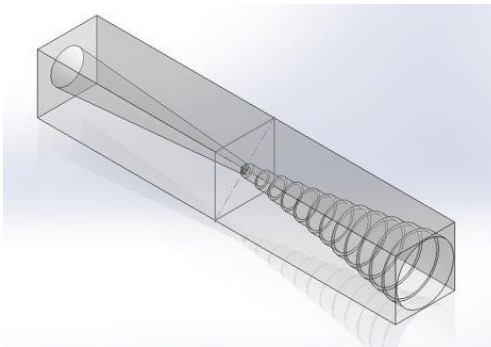


Figure 3: This design is able to accommodate for the greatest range of length, which is optimal due because levels of insulin within the vial are not consistent.

3.2. Corkscrew Model

The design uses a cone-shaped insert to fit various sized syringes and uses a threaded cone insert to fit various sized vial heads. The vial end would be a threaded cone so that any radius of vial head could be twisted snuggly into the device. The design is simple and easy to fabricate as it only requires drilling and threading. The lip of the vial fits is twisted into threads and stops accordingly to its size. (see Figure 6). The syringe is pushed into the tapered cone and snuggled in based on its radius. (see Figure 7). Both the threaded and tapered cones accommodates for varying vial and syringe.



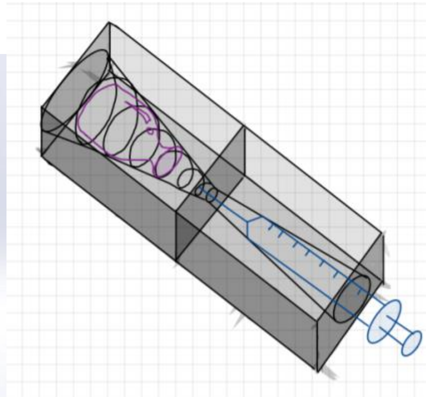


Figure 4: Depicted above is the corkscrew model in Solidworks.

Figure 5: Drawn above is the corkscrew model.

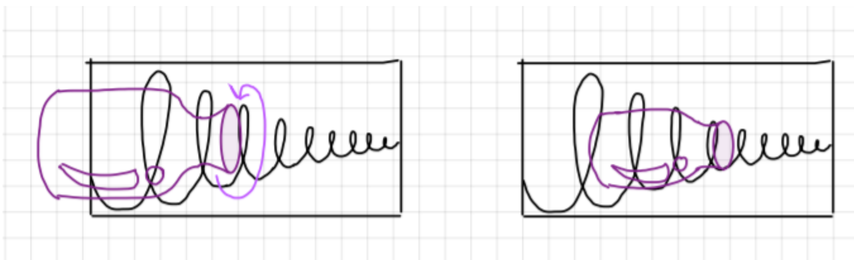


Figure 6. As the vial, shown in purple, is twisted into the device, the lip of the vial itself will be screwed in tightly.

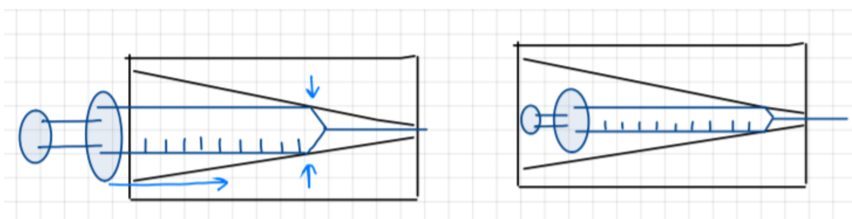
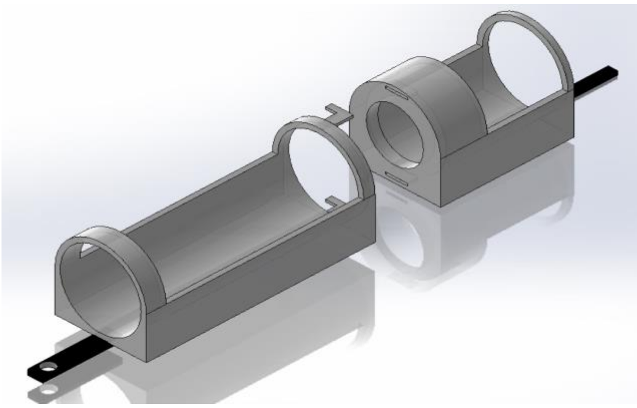


Figure 7: As the syringe, shown in blue, is pushed into the device, the threaded cone will eventually inhibit forward motion, but ensure that the syringe is snug within the device.

3.3. Layered Model

The Layered model design consists of three separate layers, a velcro component, and a clip in function. It also possesses a pocket for advertisement. The innermost layer would be made of a grippy firm material. This would interact with the syringe and vials directly, applying even pressure to the vial and syringes surfaces, thus ensuring a snug fit. The middle layer is a squishy form of silicone to accommodate different radii of vial or syringe. The outermost layer would be a hard external silicone shell. This layer enhances the devices durability, and gives the user a hard skeleton like component to interact with and hold firmly without give. There would also be an open window so the user would easily see how much insulin is being drawn.

The velcro would attach to the outer layer of the device and further secure the syringe and vile inside the device. On the syringe side, there would be a slit for the plunger to protrude out of to allow proper visualization and function. The vile would be supported from behind with the velcro as well, and the pressure from the squishy middle, and grippy innermost layer would help minimize vile and syringe movement during drawback.



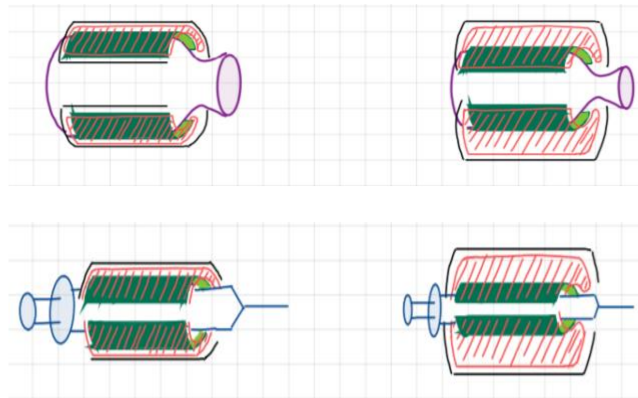


Figure 8: Depicted above is the layered model in Solidworks.

Figure 9: Drawn above is the layered model.

4. PRELIMINARY DESIGN EVALUATION

4.1. Design Criteria

Safety: The goal of this insulin filling aid is to reduce the number of unnecessary needle pricks and bends, ensure a sterile environment, and improve dose accuracy, thus this category was given a weight of 20/100. It is the highest ranked criteria because these specifications all improve safety of user. There should also be a reduced number of crevices where bacteria could gather, and the material must be non-toxic.

Ease of Use: The insulin filling aid should be easy to use, meaning the device should limit the amount of steps and movements necessary to operate effectively. The viewing window of the syringe should be large, it should be easy to grip, and the cleaning technique should be quick and simple. This category was given a weight of 15/100 because the device is meant to make filling a syringe with insulin easier, meaning the process of using the device should take less time, steps, and energy than filling a syringe without the device.

Manufacturing: The device is meant to be a lower-income alternative to other syringe-filling aids, meaning the device's manufacturing must be three dollars per device or less to be cost-effective enough for the lower socioeconomic market. This criteria should also include cost of manufacturing equipment. This category was given a weight of 15/100, equal to ease of use, because the manufacturing method, and therefore price, could determine the product's success.

Adaptability: The aid must be able to accommodate various sizes and lengths of insulin vial, needle, and syringe because they are not standardized. Any size should fit snugly within the device while also allowing for easy removal. This was given a weight of 15/100, equal to manufacturing and ease of use, because it has the ability to greatly increase the market population.

Durability: The device must be able to withstand drops, bumps, and extreme temperatures. This was given a weight of 10/100 because the use of this device does not warrant large distance drops or the use of large force upon the device.

Feasibility: The aid should be able to be fabricated with ease due to the time constraints of the project and limited experience of the fabricators. This category was given a weight of 10/100 because none of the proposed designs were above the team's ability to fabricate. Ensuring university access to manufacturing equipment and tools is a component of feasibility.

Marketability: The outer surface of the device must have the ability to be personalized, and market cost must be affordable for the lower-socioeconomic class. This was given a weight of 5/100 because as long as the device is within the manufacturing guidelines, it will be within an affordable market price range. Also, each of the designs has the ability to be customized.

4.2. Design Matrix

Table 1: Design Matrix

Design Criteria	Weight	Layered Model		Corkscrew Model		Sliding Model	
Safety	20	3/5	**12**	2/5	**8**	5/5	**20**
Ease of Use	15	2/5	**6**	5/5	**15**	3/5	**9**
Manufacturing	15	3/5	**9**	4/5	**12**	5/5	**15**
Adaptability	15	5/5	**15**	4/5	**12**	3/5	**9**

Durability	10	4/5	**8**	5/5	**10**	4/5	**8**
Feasibility	10	3/5	**6**	4/5	**8**	5/5	**10**
Marketability	5	4/5	**4**	5/5	**5**	5/5	**5**
Total	100		**60**		**70**		**76**

4.3. Design Matrix Evaluation

4.3.1. The Sliding Model

The Sliding model scored the greatest evaluation score at 76/100. With the top score in safety, the sliding nature of the device greatly reduced the risk of contamination, needle pokes, or needle bends. This decreased risk is because the needle doesn’t come into contact with any material until it pierces the vial head. Moving into ease of use, there are many steps necessary to effectively use the Sliding model, so it was scored just a three out of five. In manufacturing, however, this model has another top score because the design incorporates halves, which would be very easy and cost effective to injection mold. Scoring only three out of five in adaptability, this device accommodates different lengths very well, but does not have the best mechanism set in place to accommodate for different vial and syringe radii. Additionally, because there are fragile sliding tracks incorporated in this model, it is more likely to break and thus scored just four out of five on durability. For feasibility and marketability, the Sliding model received top marks because the team has access to injection molding equipment and there is a great surface area to personalize in marketing. Overall, the Sliding design was also the most intuitive design to the client due to it’s easy to use and familiar sliding nature.

4.3.2. The Corkscrew Model

The Corkscrew model scored second highest in the design matrix. It received a low safety score due to increased risk of needle contamination within the tapered-cone syringe side; this tapered cone also introduced increased risk of needle bending, as they are extremely fragile and cannot withstand great force. The Corkscrew model did receive the highest score in ease of use due to the two-step nature of use: users simply put the syringe in one side and twist the vial into the other. With four out of five in both adaptability and manufacturing, this design is able to accommodate different lengths and radii well, but there was concern of how stable those tight fits would be, so it did not have a perfect adaptability score. Manufacturing did not receive perfect notes due to the closed design, making it difficult to injection mold and mass produce. The heft of the design, with no small pieces, awarded the Corkscrew model a perfect score in durability. It received a four out of five in feasibility due to the challenge of creating a thread that is both tapered and big enough to accomodate all vials, and it also received a perfect score in marketability due to the extremely large surface areas on which to market. Although this design is scored just six points beneath the sliding model, the risk of contamination is of great importance in the design of this product and thus takes the Corkscrew model in the current state out of consideration.

4.3.3. The Layered Model

The Layered model, the lowest scoring model, received highest marks only in adaptability. The model has great adaptability, as it accommodates for any length or radius of needles, vials, and syringes. However, the intricate design caused the Layered model to score very low in ease of use and manufacturing, with three and four out of five, respectively. The design has many steps in use as well as many steps in manufacturing, which drives cost up and ease of use down. Regarding safety, the velcro straps and crevices of this design introduce breeding grounds for bacteria, which increase the risk of infection to the user. The Layered model also received relatively low scores for durability, feasibility, and marketability, again because of the intricacies of this design. Small components mean the design is more fragile, harder to fabricate within the desired time frame, and creates less surface area upon which to market. The mechanical mismatch between layers also introduces points of strain. Overall, this design does an impeccable job of adapting to different sized needles, syringes, and vials, but forfeits many other qualities in the effort to adapt. For this reason, it was awarded the least amount of points.

4.4. Proposed Final Design

After evaluating the three proposed design ideas (see section 4.3), the sliding model will be used as a preliminary prototype. This model was chosen because of multiple aspects that will benefit the client and the diabetes community in general. Most importantly, it reduces the risk of contamination during insulin syringe filling. It is vital to keep insulin injection process sterile to avoid any risks of infection from the needle. Also, the device is easy to manufacture. The proposed method of manufacturing is injection molding. Using this process, the sliding device will be efficient to manufacture because of its two half design. The two halfs could be injected at the same time and then could be easily attached to create the whole device with a few extra steps for full manufacturing. Similarly, the sliding mechanism of the device is simple to fabricate. The sliding portion requires a small amount of material, which can also be injected molded similar to the other aspects of the device. This lowers cost and time of fabrication, making the manufacturing process more affordable and time-effective. The sliding aspect also provides easy slide tracking ability. Specifically, the user can easily slide the syringe half towards the vial with little trouble. This also removes visual obstacles of the syringe, needle, and vial, which is important for lower visual dexterity users. Finally, the device, if needed, can be customizable for the user. As mentioned previously, the client requires a device that is marketable. The large surface area of the device can accommodate for various levels of marketing (personal sleeves, stickers, etc.). Because the sliding model provides necessary safety, mobility, customizability for the user, while also being easy to fabricate, the sliding model will be the design used to create a preliminary prototype.

5. FUTURE WORK

In the upcoming weeks, the team has many goals to accomplish to finish the semester with a successful prototype. Primarily, the SolidWorks design needs to be finalized. A grip enhancer and easy-access visual window must be incorporated into the device to minimize hand slip during use and to accommodate users with lower visual-ability. After implementing these requested specifications, the next step is to 3D print a preliminary prototype. This will be used to test the usability of the device and the accommodation of standard syringe, vial, and needle sizes. Ultimately, the team will also fabricate a functional prototype via injection molding. The functional prototype will go under additional testing, consisting of general usability, force and drop testing, and measurements of ultimate tensile and compressive forces involved in the syringe filling process.

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7. APPENDIX

7.1. Appendix A: Product Design Specifications

Insulin Filling Station

Preliminary Product Design Specifications

Team Members:
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Date: September 16, 2019

Biomedical Engineering 200/300:
Biomedical Engineering Fundamentals & Design
Fall 2019

Client: Michelle Somes-Booher

Advisor: Dr. John Puccinelli

Function:

Ms. Somes-Booher's father, an elderly man with insulin-dependent type II diabetes, relies on daily insulin injections. These injections are difficult to patients, such as the client's father, who has reduced dexterity due to age. Currently, a treatment option is to use a syringe to inject insulin from a vial; this option is often used by lower income and Medicare insulin-dependent type II and type I diabetic patients because it is less costly. However, the elderly patients often experience difficulties lining up the syringe with the insulin vial and inserting the syringe into the vial. These difficulties frequently result in accidental pricks or bending of the needle, which renders the needle useless. For lower income and Medicare patients, this is particularly impactful, as it results in wasting syringe and insulin, and therefore financial loss. Thus, we are aiming to design a device that eases filling syringes with insulin for elderly patients while remaining cost effective, affordable, and accessible.

Client requirements:

- This device's production must be cost effective enough to produce a profit, but it also must be affordable. Thus, the cost of manufacturing per product must be under $3 per device (see Cost section under Production Characteristics for more details).
- The device must increase ease of use in filling a syringe with insulin, so the user must be able to grip it more easily and visually measure how much insulin is entering the syringe.
- The external material has to be customizable (ex. silk screen, engraved, etc.) for advertising and marketing purposes.

Design Requirements:

Physical and Operational Characteristics

1. *Performance Requirements:* The device will decrease the occurrence of broken or bent needles during attempts to fill syringes from insulin vials. The device must also allow for visual measurement of the amount of insulin entering the syringe, so there must be a window or a read-out for the units of insulin in the syringe. In addition, the device must be strong enough to not break under shear and compressive forces, and torques while filling the syringe. The device also must be able to strongly grip the vial and syringe to prevent slippage or insulin waste. To be used with every insulin injection, this device must maintain adequate performance while being used two to four times each day, every day [8].

2. *Safety:* The device must maintain a sterile environment to minimize chances of infection upon insulin injection, so washing protocol must be outlined for user to follow [9]. As this device is intended for at-home use, maintenance of the device will require manual ccleaning, whether that involves sterilization via dishwasher or by hand. In addition, the device design must reduce crevices or pinch points where bacteria communities could form and lead to secondary infections. Also, the device cannot be made out of any material that is toxic or dangerous to humans, specifically avoiding materials that include skin contact toxins [10].

3. *Accuracy and Reliability:* The device must allow the user to view and quantify how much insulin is entering or exiting the syringe because the insulin doses must be precise. This will require a window of 7.8 mm to ensure full visibility of measurement marks on the syringe, since this is the outer diameter of a 2 mL syringe [11].

4. *Life in Service:* The device will be used two to four times [12] per day for regular injections. The device should also be portable so the client can use it for injections

outside of the home. The device should last for at least five years of use, as the daily forces and torques imparted on the device are not significant.

5. *Shelf Life:* The device should be comfortable staying at normal room temperature, 23 °C [13], when not in use by the client. The device should be able to endure refrigerator temperature, 4 °C [14], since insulin normally is stored in colder temperatures to prevent bacteria from breaking down the insulin [15].

6. *Operating Environment:* The operating environment for this device will be nonclinical, namely the patient's home [16]. The device must be operable in temperatures from 4 °C to 32°C [17]. The relative humidity in this environment is between 15% and 50% [18]. As the user may drop the device, it should also expect and be able to withstand drops from up to three meters [19]. During storage or idle time, the device may be stored within the household in these same conditions, or within the refrigerator at around 4°C where it must remain intact and a viable solution.

7. *Ergonomics:* The product must be able to be easily gripped by the user, especially when wet, since the device will likely be used in the bathroom or kitchen. Specifically, the exterior of the device must induce sufficient friction to withstand resulting shear forces and torques caused when filling the syringe with insulin. This will be a feature that will be tested after fabricating the prototype.

8. *Size:* The device must be able to accomodate the standard sized syringe, needle, and insulin vial. That noted, the standard insulin vial is 10 mL [20], the standard syringe is up to 2 mL [21], and the standard short needle length is 8 mm [22]. The maximum length of the device should only be slightly longer than the lengths of the vial, needle, and syringe combined when the syringe is not extended. The width of the device should be easy and comfortable to hold in an average size human hand per client’s request; average hand width ranges between 38 and 50 mm. The device size should be portable so, if needed, the user can take their device and administer injections in various locations. The device shape must inhibit rolling, thus cannot be a cylinder or spherical. See Appendix B for more information on syringe, needle, and vial size variations.

9. *Weight:* Keeping the weight of the syringe, needle, insulin vial in mind, the weight of the device should be no greater than 0.5 lbs. Any greater weight could hinder the process of filling due to strength restrictions for elderly patients [23]. That noted, the syringe, needle, and insulin vial weigh an estimate of 0.0028 lbs [24], leaving 0.472 lbs for the device weight.

10. *Materials:* The client requests that the material be economical and easy to fabricate, resistant to slipping, as well as easily sterilized in a household setting. As sterilization processes may include using a dishwasher, the material must be dishwasher-safe and

thus, withstand temperatures of at least 75 degrees Celsius for four hours [25, 26]. Furthermore, the material must be safe for human skin contact.

11. *Aesthetics, appearance, and finish:*. The shape and form of the device will form around the needle and vial of the user. The texture of the exterior should allow the user to firmly grip the device while filling the syringe, even when the device is wet. The device will also be designed so that the exterior is customizable for advertising and marketing purposes. Thus, it should allow for personalization through methods such as using dyes, silk screening, or other customization methods.

Production Characteristics:

1. *Quantity:* The quantity per user of the device is intended to be two as the client intends to sell the device in packs of two. This is so the customer can keep one device at home and keep the other portable. However, for this semester, the client only requests one prototype.

2. *Target Product Cost:* To provide access lower income and underrepresented communities in the diabetes population, cost should not be a barrier for consumers. The client advised that the product could be sold for $19.99 in a two pack, thus manufacturing costs per product should not surpass $3.00. This limit is to ensure that the product is affordable for all diabetes patients, regardless of socioeconomic standing, yet still makes a profit. Comparing this cost with the competition listed in the next section, it is obvious that this device will be the most cost effective alternative to more high-tech solutions.

Miscellaneous:

1. Standard and Specification: This device would be categorized as a Class II medical device according FDA regulations [27, 28, 29]. This is due to the risks involved with using the device, such as accidental needle pokes, or contamination of the syringe needle. Because of these factors, there is a moderate to high risk to the user. Thus, FDA standards for Class II medical devices must be fulfilled prior to releasing this product on the market.

2. Customer: The targeted customer population are elderly diabetics (over the age of 65). Not only is this population rapidly growing (by 2030, an estimated one in five U.S. residents will be over the age of 65), but all will qualify for Medicare, which only provides materials for insulin injections [30, 31]. Thus, these individuals will be using needles for injections. In addition, motor deficits occur more frequently with age, and concurrent conditions, such as diabetes, can lead to higher risk of disease states, such as stroke [32, 33]. While there are alternative products currently on the market, these products are expensive. As diabetes already disproportionately affects underrepresented groups, such as Hispanics and Blacks, it is vital to reduce these health disparities by providing a product that improves accessibility to receiving life-saving insulin injections and prevents wasting needles and insulin [34]. Thus, this will also help reduce health disparities in diabetes management. In addition, this aging population will respond well to easily understandable language, familiar components, and the ability to personalize the device [35].

3. *Patient-Related Concerns:* The product must be able to be sterilized, since it will be used to assist insulin injections. As diabetes patients are already more susceptible to secondary infections, maintaining sterility of the syringe needle is vital [36]. Thus, the prototype must be able to withstand repeated use in a household dishwasher, and therefore temperatures of at least 75 degrees Celsius for four hours.

4. *Competition:*

    Prefilled insulin pens [37]: This product is a combination of vial and syringe that has a specific amount of pre-filled insulin. It is accurate, easy to use, and convenient to carry around. However, it is very expensive, as it is not usually covered by insurance and always wastes insulin. A box of five pens costs around $500 [37].

    Insulin Pumps [38]: This product is an automated continuous delivery system for insulin using a catheter. It closely monitors insulin levels in the body and delivers insulin accordingly. It is more accurate and eliminates the use of needles. However, it is extremely expensive, at a cost of around $6,000 out of pocket [39].

    Diabetes Pills [40]: This product entails a variety of pills that push the pancreas to release insulin or regulate glucose levels. It is a very cheap option, as one of the medications, Metformin, costs $11 for 14 tablets [41]. It helps with fear of needles, but it is not as effective as insulin because it may not reach targeted sites and has varying side effects.

7.2. Appendix B: Standards Tables

7.2.1. Syringe Standards

Table 1: The table below provides information on the different standard insulin syringe volumes [42, 43, 44].

Volume (cc)
0.3
0.5
1

7.2.2. Needle Standards

Table 2: The table below provides information on the different standard insulin needle gauges and lengths [45, 46, 47].

Gauge (Thickness)	Length (Inches)
28	5/16
29	3/8
30	1/2
31	

7.2.3. Vial Standards

Table 3: The table below provides information on the different standard insulin vial volumes, heights, and diameters [48].

Volume	Height (mm)	Outside Diameter (mm)	Inside Diameter (mm)
10 ml	46	22.6	12.5
	54.5	23	12.7
		22.5	
		20	