# ME 450
# Winter 2025 Semester
# Final Design Report

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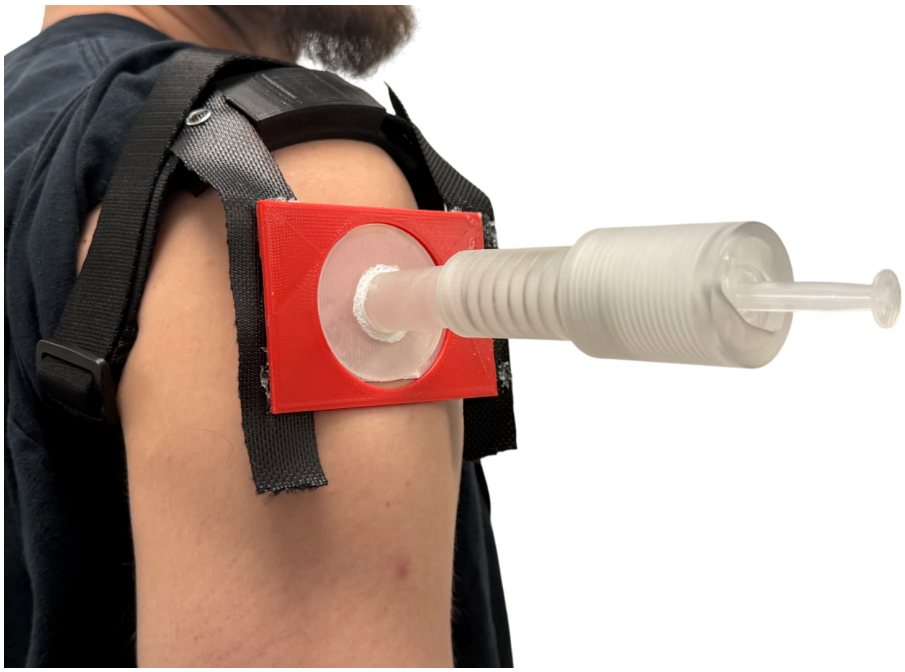
# Intramuscular Vaccine Administration Assistance Device



## EXECUTIVE SUMMARY

Access to vaccines and medication administered via intramuscular (IM) injections is severely limited in low- and middle-income countries due to a shortage of trained healthcare professionals. Numerous vaccines and medications are given intramuscularly and incorrect site selection, injection angle, depth, and speed can cause serious complications for patients. Due to these risks, there is not a reliable way for healthcare workers with less than nurse-level training to safely and effectively administer these injections. Task shifting has been shown to be an effective way of addressing healthcare worker shortages by increasing access to vaccines, improving program efficiency, and contributing to better patient outcomes.

This project aims to create an IM injection administration assistance device that utilizes task shifting to allow healthcare workers with less than nurse-level training to safely and effectively administer IM injections. A successful solution will be compatible with all IM vaccines and medications, creating easier access to IM injections within low- and middle- income countries, preventing disease outbreaks and creating a healthier world.

As part of this report, we conducted a stakeholder analysis in which we included stakeholders that we will likely interact with over the course of the semester as well as stakeholders that are outside the scope of this project. Although the stakeholders outside the scope of this project may not play a huge role in our work this semester, they are still important when considering the implications of this project.

In order to develop user requirements and engineering specifications for this project, we interviewed our mentor for this project, Dr. Thiyag, and researched applicable standards, medical best practices, and academic papers. Our highest priority is patient safety while considerations such as cost are a lower priority, as reflected by our ranking scale. Since DR3, limited changes have been made such as deleting a redundant depth specification.

This report summarizes the concept generation and selection methods that we have used up to this point including brainwriting, gut checks, and sub-function organization. Our solution includes two separate devices: one that addresses site selection and one that addresses needle safety, injection depth, speed, and angle.

Since DR3, extensive verification testing has been conducted, including a proxy usability test to quantify the device's ease of use and learnability. The results of the verification testing have strengthened our confidence in our solution.

The discussion, reflection, and recommendations sections discuss the strengths and weaknesses of our solution, the factors that influenced it, the risks it poses, and recommended next steps.

The conclusion summarizes the important points from previous sections and describes what has been learned while working on the project up to this point. This section also summarizes our design and what quality we believe it to be.

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# 1. ABSTRACT

In low- and middle-income countries, access to vaccines administered via intramuscular injections is severely limited due to the shortage of trained healthcare professionals. Incorrect site selection, injection angle, depth, and speed can cause patients to experience pain, nerve paralysis, musculoskeletal injuries, and incomplete vaccination. There is currently no reliable way for healthcare workers with less than nurse-level training to administer these injections as current assistive devices focus on subcutaneous rather than intramuscular injections. Our project aims to make vaccines more accessible by creating a task shifting device that allows healthcare workers with less than nurse-level training to administer intramuscular injections.

# 2. INTRODUCTION

The University of Michigan Global Health Design Initiative (GHDI) wants to develop a simple intramuscular (IM) vaccine administration assistance device to make IM injections more accessible to low- and middle- income regions. This section provides the necessary background information and benchmarking of existing products to give a better understanding of the motivations for this project. The information sources used include interviews with the project's mentor, Dr. Thiyag, nursing guidelines, academic journals, and standards. Relevant standards for this project include guidelines regarding vaccine administration, vaccine packaging, and ISO standards for sterile needles and sharps injury prevention.

### 2.1 Contextual Background

Cervical cancer is a growth of cells that starts in the cervix, the lower part of the uterus that connects to the vagina [1]. Despite being a preventable and curable disease if detected early and adequately treated, cervical cancer is still the fourth most common cause of cancer among women worldwide [2]. Cervical cancer is primarily caused by a subset of human papillomavirus (HPV) types [2], the most common viral sexually transmitted infection (STI) [3]. In order to combat cervical cancer, the World Health Organization (WHO) has set a global goal that by 2030, 90% of girls will be fully vaccinated against HPV by age 15 [2]. As of 2023, the global HPV vaccination rate for a full dose is 20% [4], falling significantly short of the WHO's goal. Compared to high-income countries, low- and middle-income countries have nearly twice the incidence of cervical cancer and three times the mortality rate [2]. Additionally, although the HPV vaccine has been available since 2006 [5], some countries have adopted it into their national immunization programs much more recently. For example, in 2011, Rwanda became the first African country [5] to do so and more recently, Ghana implemented the vaccine in September of 2025 [6]. As of 2025, the HPV vaccine has yet to be implemented in the national immunization programs of 54% of low-income and 37% of lower middle-income countries [4].

The HPV vaccine is an intramuscular (IM) injection that needs to be administered by someone with nurse-level training [7]. However, the critical shortage of skilled healthcare workers in sub-Saharan Africa, Asia, and the Americas [8] has made it especially difficult for people in low- and middle- income countries to obtain IM injections as they often don't have access to healthcare workers with the required level of training [7]. Therefore, in order to reach the WHO's HPV vaccination goal, it is clear that IM injections will need to be made more accessible

to people without access to nurse-level healthcare workers, especially in low- and middle-income countries.

### 2.2 Intramuscular (IM) Injections

Numerous vaccines are given intramuscularly including HPV, hepatitis A/B, influenza, and polio [9]. Human immunodeficiency virus (HIV) medication is also given intramuscularly [7]. IM injections are primarily given in the deltoid (upper arm) and sometimes the thigh [10]. As can be seen below in **Figure 1**, the deltoid injection site is surrounded by bones, nerves, and arteries that, if hit by the needle, can lead to serious complications for the patient [11].

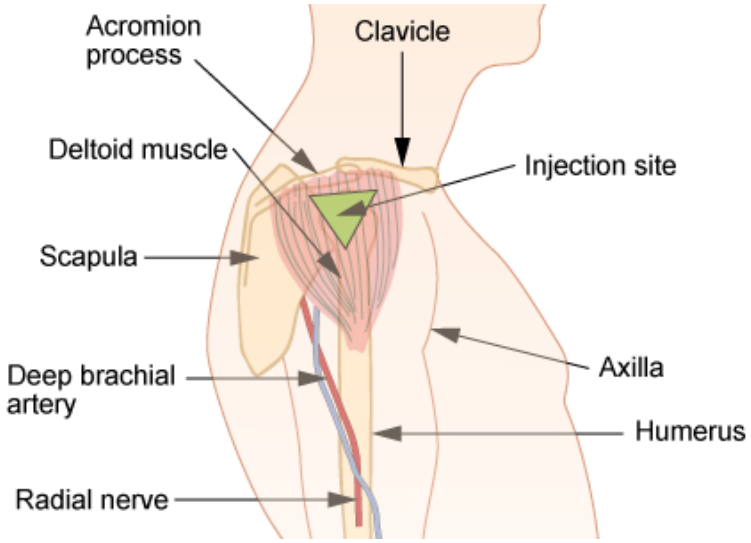



**Figure 1:** Deltoid injection site used for IM injections [12].

Regardless of vaccine type, when administering IM injections, site selection, injection angle, injection depth, and speed of injection need to be chosen correctly to avoid injury and ensure complete vaccination [9], [13]. As opposed to subcutaneous injections, such as diabetes medication, that can be self-administered by patients with little training [14], IM injections need to be administered deeper, into muscle tissue. This can be seen below in **Figure 2**.

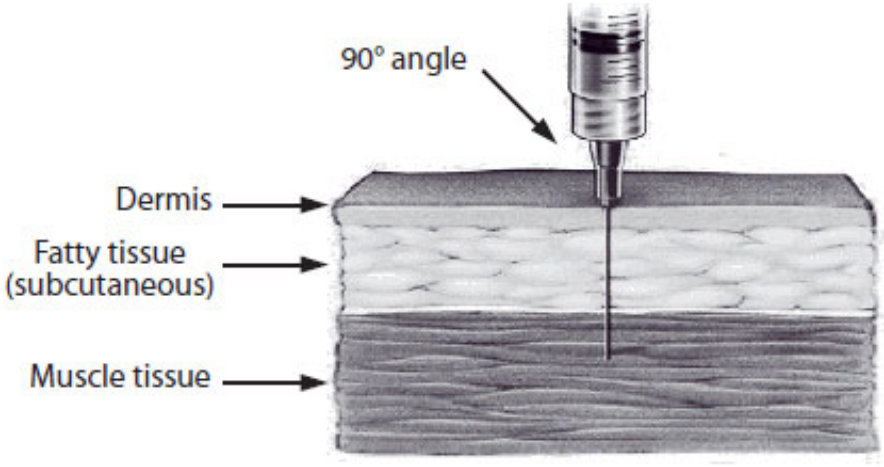



**Figure 2:** Intramuscular injection depth [15].

If the injection depth is chosen incorrectly, the syringe could go too deep and hit the bone, or not deep enough, failing to reach the muscle tissue [16]. Similarly, if the injection is not administered at a ninety degree angle, the needle may not fully reach the muscle. When administered incorrectly, patients can experience pain, decreased range of motion, nerve paralysis, musculoskeletal injuries, and incomplete vaccination [11], [17]. The risk of complications associated with IM injections is why they currently need to be administered by someone with nurse-level training or higher [7].

### 2.3 Task Shifting

Task shifting has been successful in addressing global healthcare worker shortages and inadequate access to care, such as during the Covid-19 pandemic [8]. Task shifting is defined by the WHO as the "process whereby specific tasks are moved, where appropriate, to health workers with shorter training and fewer qualifications" [18]. In short, tasks are given to less-skilled healthcare workers in order to make more efficient use of available human resources [8]. In regions with a pervasive lack of access to healthcare workers with nurse-level training and above, task shifting can be used to increase access, improve program efficiency, and lead to better patient outcomes [19]. An example of an existing task shifting device is the SubQ Assist which is designed to aid in subcutaneous contraceptive implant administration in low- and middle-income regions where women have limited access to effective contraceptive options due to a shortage of trained healthcare workers [20], [21]. The SubQ Assist, seen below in **Figure 3**, acts as a template, guiding healthcare workers during the implant insertion, eliminating the risk of unsafe administration, shifting the task from highly trained healthcare workers to community health workers [20].

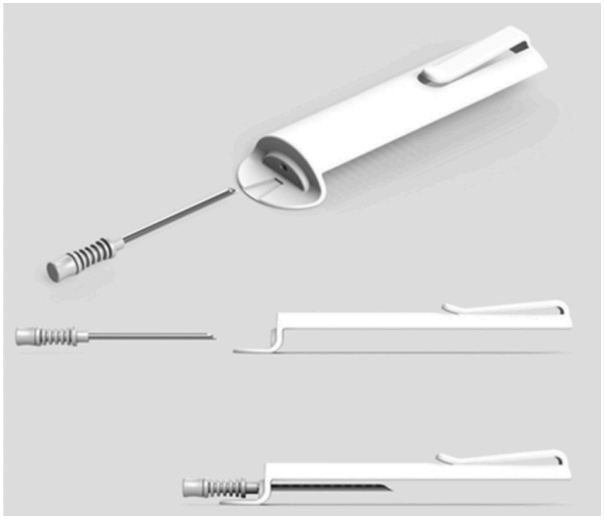


**Figure 3:** SubQ Assist [22].

Another example of an existing task shifting device is the UniJect, a pre-filled, single-use syringe used for subcutaneous and IM injections [23], seen below in **Figure 4**. The UniJect simplifies the injection process, allowing for administration by less trained healthcare workers [24].




**Figure 4:** BD Uniject Auto-Disable Prefillable Injection System [25].

Common elements of task shifting devices include ease of use, safety, and local maintenance [26]. As this project focuses on low-resource environments, a successful device will need to be easily used by individuals with little training, repaired using basic tools and knowledge, and not require reliable access to consumables or replacement parts [16]. Appropriate training and regulatory changes are also important parts of successful task shifting [18] and although they likely fall outside of the scope of this semester-long project, they will continue to be considered when analyzing the project's next steps.

### 2.4 Problem Statement

This project aims to develop an IM injection administration assistance device that allows healthcare workers with less than nurse-level training to safely and effectively administer IM injections. The solution will utilize task shifting to shift the IM injection task from healthcare providers with more training to those with less. A successful device will be compatible with all IM vaccines and medications, creating easier access to IM injections within low- and middle-income countries, preventing disease outbreaks and creating a healthier world.

### 2.5 Benchmarking

There exist many products on the market that seek to assist individuals without nurse-level training with performing injections. The majority of these products focus on subcutaneous (Sub-Q) injections. Sub-Q injections occur in the fatty tissue layer just below the skin and above the muscle. Many medications, such as insulin, require regular subcutaneous injections. Some devices are shown in **Figure 5**. The EpiPen is an emergency epinephrine injector for serious allergic reactions. It can perform subcutaneous and intramuscular injections though the injection speed and dose is dependent on the mechanical properties of epinephrine. The spring actuated dosage model is an autoinjector that automatically administers the dose but requires nurse-level training to perform the injection. The Inject-Ease and BD Physioject are both commonly used for subcutaneous insulin injections.




**Figure 5:** From right to left: EpiPen, Spring Actuated Dosage Model, Inject-Ease, BD Physioject

These types of devices are generally designed to assist individuals in administering their own medication without the need for trained medical personnel. Devices designed for subcutaneous injections are unable to reach the required depth for intramuscular injections. Some of these products are compared in **Table 1**.

| Product | Estimated prod. cost | Injection Type | Angle of injection controlled? | Training | Adaptable Payload |
|---|---|---|---|---|---|
| EpiPen [27] | ~$30 | IM or Sub-Q | Yes | Minimal | No |
| Spring Actuated Dosage Model [28] | Prototype only | IM | No | Nurse Level | No |
| Inject-Ease [29] | <$10 | Sub-Q | No | Minimal | Yes |
| BD Physioject [30] | <$10 | Sub-Q | Yes | Minimal | Yes |

**Table 1:** A comparison between current designs of inject-assist devices. Highlighted text indicates desirable properties.

From **Table 1**, it is shown that no product design currently available satisfies the conditions necessary for our design context. The product that comes the closest is the EpiPen. For its purpose, the EpiPen is not reusable and can only be used for a substance with the same mechanical properties as epinephrine for which it was designed. The Inject-Ease and BD Physioject are both used for subcutaneous injections and cannot reach the required depth for intramuscular injections.

The manufacturing cost of the EpiPen increases due to its specialized and single-use design, as it is preloaded with epinephrine. The Inject-Ease and BD Physioject both use already existing medication packaging and delivery implements, which are loaded into the assist device, which lowers the manufacturing cost. Both are both produced primarily by injection moulding, making them less expensive per unit to manufacture at a large scale.

# 3. DESIGN PROCESS

Our design process has focused on an activity-based problem-oriented model. An activity-based model focuses on the constant iteration of previous work [31]. A representation of this model is shown below in **Figure 6.** Our project has consisted of determining requirements and specifications, which we continued to modify, build on, or remove from throughout the entire course of our project design. Throughout our concept generation and prototyping phase, we constantly sought to tie our process back to the original problem statement . Problem-oriented design models consist of forming a solution around the requirements and specifications, in contrast with solution-oriented design models, which iterate on an established design to meet the requirements and specifications. Our goal, as we move forward into concept generation, is not to focus on any one potential solution but to create a broad range of potential solution concepts in order to then focus on the solution that best addresses the design problem.

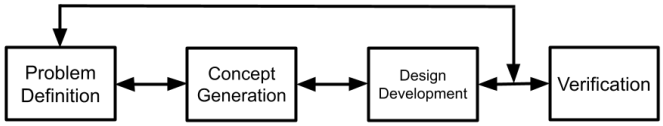



**Figure 6:** Visual representation of the activity-based problem-oriented design process model. The arrows represent the constant iteration and problem definition focus which defines the model.

Along with our primary activity-based model, we are also seeking to implement a more traditional human-centered design model. We reached out to Isabel Reynoso and Tongyue Yang, as they are also working to help ensure availability of vaccines in low and middle resource areas, but are taking a deeper dive into these environments and addressing the distribution of vaccinations. We also connected with Dr. Ibrahim Mohedas, who has worked on task shifting devices for low and middle resource areas. Through these connections we gained insights into the healthcare environment in these areas, to try to gain a better understanding of the workers who would be using our design and create something with greater ease of use. Attempts were also made to connect with a doctor from Ghana to see his insight into the hospitals in the region, but there was no success.

The ME450 design model discusses problem definition, concept generation, and solution development and verification. The model seeks to have consistent iteration between these steps. Though we have thus far been working on the problem definition, it is our goal to continue to better define our problem throughout the concept generation phase and into the development and verification phase.

# 4. DESIGN CONTEXT

### 4.1 Stakeholder and Societal Analysis: DR2

Here we have identified a core set of stakeholders through our discussion with Dr. Thiyag [7] and research into the health system relating to low/middle income countries [32], shown in **Figure 7**. This includes the immediate stakeholders such as patients, but also parties not immediately impacted by the problem or solution. This can then be used to prompt new outlooks on the issue and improve the eventual solution with thought to the impacted audiences.

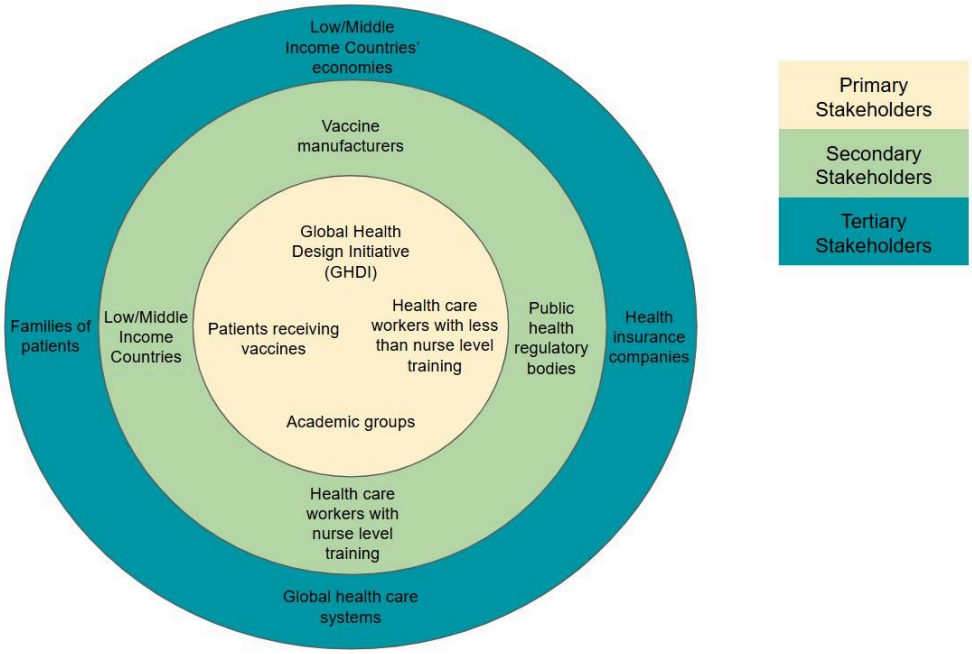



**Figure 7:** Key stakeholders related to our project. The primary stakeholders are those that experience direct impact and/or who would be involved within changes in the issue. Secondary stakeholders are significantly affected, but not directly, and would become aware of changes within the issue. Tertiary stakeholders can feel downstream effects of changes within the issue, and may have indirect impact on the problem context.

Our main engagements as of now are with Dr. Sienko and Dr. Thiyag within GHDI to share insights on task shifting devices and IM injections, and through this engagement have had contact with other stakeholders. There is another group at the University of Michigan conducting research into the same topic, but not with the direct intent of creating a medical device and instead looking into other potential solutions to the issue of making vaccines more attainable in low/middle income countries. We met with Isabel Reynoso, a member of this group, to compare their early stage findings from research and interviews to the information we had obtained. We also met with Dr. Mohedas from Duke University to discuss his experience with the creation of task shifting devices to gain valuable insight into what creates a successful design. We ideally would engage with nurse level trained workers in low/middle income countries, but as this is a connection we do not have, we will be taking steps to engage with nurse level trained workers at the University of Michigan to gain their insight as early prototypes are developed. Their insight will be valuable as we gain a new perspective from people directly involved in vaccine administration on the successes and flaws within our design.

The patients, low/middle income countries, these countries' economies, and the families of patients will feel the greatest positive impact from our project. Success in this project would allow more patients in these low/middle income countries to become safely vaccinated against disease, than in turn being beneficial for their families as the people they are in close contact with are now less likely to experience complications regarding the patient getting sick. This subsequently positively affects low/middle income countries' communities as a whole following the same reasoning, and these countries' economies as they will have a larger and more stable

work force. In correlation to this, vaccine manufacturers would also see positive benefits as the demand for their product rises. The party most likely to be negatively affected is health insurance companies, as there is a risk involved with less trained individuals administering vaccines, and they are more likely to get involved in cases of improper administration, and therefore may oppose our project. Other opposition could be seen coming from health care workers with nurse level training or public health regulatory bodies such as the World Health Organization, as they may think there is too much risk in someone with less training administering a vaccine.

**4.2 Societal Analysis: DR3**

The main use case for our solution will be non-nurse level trained healthcare workers administering vaccines. Originally, we had thought the problem at hand to be applicable only to the HPV vaccine, but with discussions from our sponsor we have grown our understanding to develop a solution applicable to all vaccines. Another use case could be a nurse level trained worker using this device, although unlikely, because if it were to be developed to such a degree perhaps it would even make the work easier for them. Somebody could also choose to use only one of our devices (a location aid and an injection aid device are being developed separately, discussed in later sections) as opposed to both devices in sync. This is not inherently wrong, as either device can be used independently, and if the user is sufficiently trained in some of the work, they may not benefit from use of both devices, which opens up more opportunity for use as someone can decide what combination of the devices they use.

These devices could have some negative side effects on public health and safety though, as someone may overestimate their abilities, choose to only use part of the device, and cause injury related to injection. This is not an inherent problem of the device, but we must be aware of someone choosing to use it incorrectly. Another unintended way a user could choose to use our devices is for a variety of illegal injections. Allowing this would be unsafe for the public, as there are already many health concerns related to a variety of illegal injections, and we would not want to increase this. And so it is in the public benefit this device would be only sold to certified medical institutions in an attempt to lower this risk. It can be said though, that if the devices fall into the wrong hands for illegal injections, at least they will now be safer doing it and the cause of them doing it would most likely not be because they had our devices.

**4.3 Power Dynamics**

After looking at the groups affected by our project, we can see the societal aspect driving this project to be done. As the negative side effects are largely based upon new risk, if this risk can be minimized with proper instruction and precautions the positive impact of more people being protected from diseases outweighs the risk of an increased chance in injection related injuries. This can then be viewed as a project geared towards social benefit, rather than a project for the private sector of the sponsor, and we believe our sponsor sees it the same way. The priorities of the project are based on the health, safety, and welfare that stands to be gained from success, all to be a guiding force in our design and ideally making the positive social impact as discussed above, while remaining mindful of the power dynamics involved. As we have a shared view of the priorities of the project regarding societal/private goals, our team will work together to complete the project as seen fit, aiming to meet our sponsors expectations but not straying from the needs of the end user in doing so. In an ideal scenario, power dynamics do not come into play and all three parties mentioned here share the same goals, but if all three parties do not see eye to

eye the needs of the users will have hidden power over the desires of the sponsor in our work. And our work is ultimately under the visible power of the expectations of the University of Michigan Mechanical Engineering Department, as we must follow their formal rules and processes within our project. All of this said, we hope our project creates an invited space where stakeholders of all kinds can provide their input into our project and no power need override another group's power for the influence of our project.

**4.4 Environmental and Ethical Considerations: DR2**

At this point in our design process, it is difficult to draw concrete conclusions on the environmental impact of our design. From what we can see in our benchmarking and the general ideas behind our top concepts, we can see it is likely our design will be largely made of plastic components. In the assumption our design would ultimately be mass produced, this means it is likely that the product would be injection molded. Injection molding draws similar energy to other common machining processes like sand and die casting, often around 11-15 MJ/kg of material [33]. With mass production, this can have great effects, as the energy used for just one kg of material produces similar greenhouse gas emissions to driving a gasoline car for 3 miles [34]. Once you take into account the other materials and possible manufacturing processes, you will realize that the likely production of this design will have a notable negative impact on the environment. To minimize this, we must strive to create a design that uses minimal materials and the most energy efficient production processes we can.

If our design does follow the idea of being largely made of plastic materials, we would not be injection molding our prototypes though. As we are closer to entering the true prototype and iteration phase, we can make a more clear conclusion on the environmental impact of this. Our prototypes will most likely consist of mainly 3D printed materials, and we know the usage of electricity for FDM printers ranges from 10.8-21.5 kJ/cm$^3$ of print [35]. Even if our design would be a solid chunk of material on the larger side of the possible range, this still only equates to 375-750 kJ of energy (see 9.1 Frontrunner Prototyping for current working dimensions), which is comparable to running a 10W light bulb for 10-20 hours. The electricity consumption during FDM printing accounts for about 50-70% of the carbon footprint [36], meaning this electricity use accounts for over half of the negative impact to the environment. Although this is not an insignificant amount and it would be better to not cause this footprint, we can do many rounds of prototyping in good conscience as the potential societal good would outweigh this environmental impact.

Although our aim is to design a reusable device, for safety concerns, the needles and syringes cannot be reused. Our device is an aid added to a standard medical syringe, where the entire syringe must go through the correct disposal process after use. This would mean that our device is only increasing the amount of material and energy used, as it would not reduce the amount of syringe disposal and increase other material used. Once we are further into the design process and have a better understanding of the exact dimensions and materials our design will make use of, we may perform an eco audit to gather an assessment of the energy use and $CO_2$ production related to the entire lifecycle of our design as opposed to just the manufacturing. Using this data, we can assess the need to use materials or processes with a lesser environmental impact, but we must be conscious of the possible consequences of such changes in our design. If the design

becomes too expensive to produce due to cleaner materials and processes, it may not be accessible to enough people, negating the positive impact the design could have.

We would like our design to yield a sustainable solution, and with the positive impacts towards societal health goals likely outweighing the negative environmental impact our design has a high chance of being sustainable [23]. Our ethics drive the improvement of public health on this project, which may come at a tradeoff with the ethics to minimize environmental impact. This will be a dilemma we are likely to face, but we will plan to prioritize the improvement of public health. We believe this falls in line with what the University of Michigan and future employers may expect of us, as we are conscious of the negative effects of our project, and driving for a sustainable answer to unmet societal goals.

Our project aims to be as inclusive as possible, allowing the largest group to benefit from our design. We plan to accommodate a large range of body types in our design, and not produce something that properly injects for only a select group of people. We would want our design to become accessible to as many low/middle income countries as possible, with an inclusivity to all who may benefit from its use. As we get further into the prototyping and iteration phase of our design process, the best practice will be to fit our design to a 5th percentile female and a 95th percentile male [38], although we do not yet know what the human dimensions are that we need to pay attention to and how this will correlate into device dimensions. This will come into play as we attempt to meet our design requirements for proper injection, where we will strive to not only define this as success across one body type. A limitation for this may be seen as we reach our testing phase, as we plan to use rudimentary equipment for the verification of our design.

**4.5 Environmental and Ethical Considerations: DR3**

Expanding on what has already been discussed on the environmental and ethical considerations, much more can now be said as we have a more concrete plan for materials and manufacturing. Taking from Section 10.1, we have the information we need for the materials and mass of the injection device from prototyping to draw stronger environmental conclusions on that device. The prototypes will consist of 22 g of clear resin, 16g of PLA or ABS, and one spring. The PLA or ABS can be printed on a FDM printer, using the same source from the previous environmental considerations and the known densities of these materials [39], it can be estimated that this portion of the prototype will account for the use of up to 350 kJ. Again following the same logic, this is then at most half of the carbon footprint from this part of the print, falling in line with our previous estimates. The clear resin parts must be printed on an SLA printer, which is shown to use about 116.8 kJ/kg printed [40]. Meaning the rest of the printed parts for the injection device will use up to 2570 kJ. This is notably higher than the FDM parts of the print, making a significantly larger environmental impact.

The location device prototypes will consist of PLA, TPU, and nylon webbing. No printed prototypes have been done on this yet, and so conclusions are harder to draw. But with similar materials and size, we can assume the printing of this prototype will double the overall environmental impact, significantly increasing our projections past the initial estimates in previous design reviews. This does not yet even account for the materials we will be outsourcing, only adding to the impact. It will be hard to draw much further conclusions past this point

without use of advanced tools like eco audits and life cycle analysis, but we can already say there would be some benefit to us limiting the amount of prototypes made.

Looking at the scale of mass manufacturing, all 3D printed materials in prototyping will become injection molded. Using the same mass assumptions as above and the previous source for injection molding, we see that the injection molding for one set of each device alone accounts for up to 1150 kJ. With similar outsourced materials being used, we can say the energy consumption when turning to mass production will be less than half of the energy consumption during prototyping, and therefore less than half of the $CO_2$ production. If we feel the need for even further insight into the impacts of our prototypes and mass manufactured designs, the lifecycle analysis will take a look into the afterlife of the products and account for how PLA and ABS are quite recyclable, yet things like clear resin and TPU are not.

Our ethics still drive the focus of this project to be on the public health and safety benefits that can be seen from success in the devices, but will undoubtedly come at the cost of environmental impact. Although some changes can likely be made to ensure less energy is consumed during prototyping, like the reuse of available parts and printing of FDM instead of SLA when we can get away with it, we must iterate through our design multiple times to ensure its success. We will be conscious of the negative impact this has, but we still see our ethics driving us to complete this project to its fullest due to its potential of public benefit. Further discussions of ethics regarding the inclusivity of the designs is discussed in the next section.

**4.6 Inclusivity Considerations: DR3**

To make our device as inclusive as possible, there are four main parts of our project that must be designed with inclusive consideration; the adjustable depth of the injection, the circular base to assist with the angle of injection, the shoulder pad on the location assistance device, and the adjustable side and shoulder straps of the location assistance device.

Firstly, the depth must be adjustable to males and females of all ages and weights, and the CDC has resources explaining how these factors change the required injection depth [9], [41]. From this, we know we must make our device adjustable to depths of 16, 25, and 38 mm. We account for these needs by making the threaded cap able to extend or retract the used part of the needle within this range (assuming a long enough needle is selected for use). As well as for the needle guard to be transparent and with markings at 16, 25, and 38 mm so the user can easily see the effective length of the needle that will be injected. This allows and supports injection depths for all sexes, ages, and weights per the CDC guidelines.

The circular base of the injection device provides assistance for the angle of injection to be as close as possible to 90 degrees, as the relatively large flat area it provides will conform with the relatively flat area of injection on the deltoid. The main issue within this process to make it inclusive is the varying shapes of the human shoulder across different sexes, ages, and weights, and due to these differences is why we opted out of developing a shape to conform better to the degree of roundness present within the injection site. For if the shape of the injection device base were chosen to be optimized for one shape of the shoulder, it will now be un-optimized for other shapes. This thought process of not neglecting the needs of various people is why we chose the base of the injection device to simply be flat, as we believe this does not prioritize or neglect any

body types. Although admittedly, we have very limited technical data to back up the use of this base shape, as our testing to confirm the potential success of this solution has so far been limited to only one body type. In our time frame and with available resources, we likely will not be able to confirm this base shape does in fact provide sufficient angle assistance from the 5th percentile female to the 95th percentile male [38]. Further testing within our capabilities must be conducted to improve this, and the lack of technical support we have behind this design choice is a current flaw in our project.

The shoulder pad of the location assistance device must be designed to fit all ranges of shoulder shapes as it rests on top of the acromion. Comparable to issues of fitting the injection base to a range of body types, this pad could not be designed to perfectly fit everyone. As a decision to make the design inclusive, the pad will be processed out of TPU for prototyping and silicone gel for mass manufacturing, both being flexible materials and having the ability to comfortably rest on a wide range of body types, supported by its common use in medical devices [42]. We will also encounter similar issues as the injection base in being able to test if this pad comfortably fits on all body types due to our limited resources.

The shoulder strap of the location aid device is a simpler piece to fit all body types, as all that is needed is a large enough strap and the ability to tighten it to make it successful on all body types. We do not currently have sources showing to what length the strap would need to be to account for this, and is a current flaw in our design. We will likely have trouble being able to find data on this size requirement and again will not have the resources to test if it does fit everyone, but are more likely to be able to still be accommodative with a large enough strap. The adjustable side straps for the location aid device must also be inclusive for all sexes, ages, and weights, but the only one affecting the distance from the acromion is the age of the patient as per the CDC [9], [41]. This lets us know the side straps must be adjusted for two different lengths, which our design has accounted for and incorporated.

**4.7 Intellectual Property**

At this point in our project, intellectual property has played a minimal role. During our design generation phase, we did not feel as though we were breaking into the intellectual property of existing designs or patents that we had found, meaning our designs did not need to be altered to avoid this even though we were conscious of the possibility. We still need to do a more in depth search into patents regarding products like the EpiPen and Inject-Ease to ensure we do not infringe any intellectual property, and the fact we have not yet fully explored this is a potential flaw within our design, even though we do not believe this is a likely issue with the lack of true similarity. If our project is to successfully develop the device in question, it may be eligible to be protected through a patent. In this case, our team will have the option amongst ourselves to pursue a patent. But if not, the University of Michigan has the right to pursue a patent on the design for their own regard, giving them the intellectual property with our group listed as inventors on the patent.

# 5. REQUIREMENTS AND SPECIFICATIONS

## 5.1 User Requirements and Engineering Specifications

Our user requirements and engineering specifications are largely derived from our interviews with our sponsor, Dr. Thiyag, along with research into standards and guidelines from global health organizations, shown in **Table 2**. The requirements are sorted by priority level and have each been given a confidence rating reflecting how complete we believe the requirement to be.

| Priority | Requirement | Specification(s) | References |
|---|---|---|---|
| High | Prevent needle-stick injury. | -After completing an injection, the needle shall be fully covered within ≤ 1 s.<br>-The device shall have 0 mm of exposed needle when the device is not actively performing an injection (before and after use). | [7]<br>[43]<br>[44] |
| High | Allow for correct IM injection speed. | -The device shall allow the vaccine to be administered at the rate of 10 seconds/mL. | [7]<br>[43] |
| High | Ensure correct IM injection angle. | -The device shall constrain needle insertion angle to 90° ± 3° relative to the skin surface during injection. | [9]<br>[45]<br>[45] |
| High | Ensure correct IM injection depth. | -The device shall maintain the target insertion depth within ± 2 mm during use under simulated skin and muscle conditions.<br>-The device shall include an adjustable depth feature to accommodate youth and adult patients. | [7]<br>[9]<br>[15] |
| High | Ensure correct injection site for IM injection in shoulder. | -In simulated-use testing, ≥ 90% of users shall place the device such that the needle is within ±10 mm of the center of an approved deltoid injection. | [7]<br>[9]<br>[15] |
| Medium | Be durable. | -The device shall withstand ≥ 300 use cycles without functional failure. | [7]<br>[13]<br>[46] |

| Priority | Requirement | Specification(s) | References |
|---|---|---|---|
| Medium | Be universally compatible with IM syringes. | -The device shall accommodate standard 0.5 mL, 1 mL, and 3 mL syringes from multiple manufacturers.<br>-The device shall support intramuscular injections using standard needle lengths of 16-38 mm. | [7]<br>[15]<br>[47] |
| Medium | Be easy to use with minimal training. | -A user with ≤ 15 minutes of training shall successfully complete a simulated injection task.<br>-The device shall require ≤ 5 discrete steps to complete use.<br>-System Usability Scale (SUS) score of ≥ 70 when tested by targeted users. | [7]<br>[22]<br>[8]<br>[48]<br>[49]<br>[50] |
| Medium | Be easy to repair in low-resource environments. | -The device does not require access to a reliable power supply.<br>-Device can be repaired in ≤ 15 minutes by an average user.<br>-Device can be repaired using ≤ 3 basic tools. | [13]<br>[51]<br>[52] |
| Medium | Be easy to appropriately sanitize. | -Materials are non-porous and durable, allowing for repeated sanitization with low- to intermediate-level disinfectants.<br>-Device design allows for sanitization of all surfaces that contact the patient in ≤ 2 minutes. | [16]<br>[53]<br>[54]<br>[55] |
| Low | Minimize cost. | -The device shall have a production cost of less than $15. | [13] |
| Low | Ensure correct injection site for anterolateral thigh vaccination. | -In simulated-use testing, ≥ 90% of users shall place the device such that the needle is within ±30 mm of the approved anterolateral thigh injection site. | [7]<br>[9]<br>[56] |

**Table 2.** User requirements and corresponding specifications for the intramuscular injection assistance device, including priority level, confidence level, and supporting references.

Engineering targets were determined mostly from CDC [9], [15], [56] and WHO [45] guidelines for HPV and general intramuscular (IM) vaccine administration, which specify acceptable injection angle, depth, and location. Additional safety specifications are drawn from ISO

standards 7864 [43] and 23908 [44]. Currently there are no commercially available devices that assist with intramuscular (IM) vaccine administration. While IM devices do exist such as epinephrine auto-injectors, they are designed for emergency use, have preloaded doses, not location-specific or accuracy-guided, making them poor direct comparators [27].

The relative importance of requirements was determined based on patient and provider safety, alignment with clinical guidelines, with safety-critical requirements prioritized highest. All key requirements are stated at this stage of the project. Requirements related to injector and patient safety are considered must haves and are well defined, while goals for long-term durability, cost minimization and thigh vaccine support are considered wishes and subject to change as the design evolves and more information is gathered through prototyping and testing. The durability requirement may be refined to include cost per injection, based on total device cost and the expected number of safe reuse cycles. Each specification has been quantified using measurable parameters that can be verified through testing. The specified values are considered reasonable, because they align with CDC and WHO vaccine administration guidelines.

### 5.2 Requirement-by-Requirement Rationale and Evaluation

Requirement: Prevent needle-stick injury.
This requirement is based on ISO 7864 [43] and ISO 23908 [44] standards, which address safety for sterile hypodermic needles and sharps injury protection. Reducing exposed needle time and ensuring full coverage before and after use minimizes the risk of accidental injury to users.

Evaluation: Synthetic tissue testing will be used to simulate injections and verify that the needle remains fully covered before and after use, and measuring the time it takes to hide the needle.

Requirement: Ensure correct IM injection speed.
A controlled injection rate helps reduce pain, tissue damage, and the risk of dosing errors by ensuring the vaccine is delivered smoothly into the muscle. The injection speed specification aligns with CDC [15] and WHO [45] guidance for safe IM vaccine administration.

Evaluation: Test on synthetic tissue to confirm controlled injection speed and that the needle only deploys with proper skin contact.

Requirement: Ensure correct IM injection angle.
Correct injection angle is important to ensure the vaccine is delivered into the muscle rather than subcutaneous tissue. CDC [9] and WHO [45] IM vaccination guidelines specify an approximately 90° insertion angle for deltoid injections, so the device must help users consistently achieve this angle. Maintaining the correct angle also helps prevent injury to surrounding tissue or nerves.

Evaluation: User testing with prototypes will assess whether the device consistently guides users to achieve an injection angle within the acceptable range defined by CDC and WHO guidelines.

Requirement: Ensure correct IM injection depth.
Specifications are based on CDC [9] and WHO [45] guidelines for intramuscular vaccine administration, including recommended insertion depths. Sponsor feedback indicated that nurses typically select needle length based on the patient, but since this device is intended for task-shifting, the user may rely on a standard needle length. To address this, the device needs an adjustable setting that controls effective insertion depth for adults and youth patients.

Evaluation: Synthetic tissue testing will be used to confirm that the device reaches the intended IM depth across different simulated tissue thicknesses and maintains consistent insertion depth and complete dose delivery.

Requirement: Ensure correct injection site for IM injection in shoulder.
The landmarking and safe injection zone are based on CDC [9] and WHO [45] guidelines for intramuscular vaccine administration, including HPV vaccination recommendations. These sources define the appropriate deltoid location and boundaries, which the device aims to outline and guide users to consistently reach. Accurate site placement is important to ensure proper vaccine delivery into muscle tissue and to reduce the risk of nerve or tissue injury, especially for minimally trained users.

Evaluation: User testing with prototypes will measure how far the placed injection point is from the defined safe injection zone.

Requirement: Be durable.
Durability is very important for reusable devices, especially for those used in low-resource environments where repairing or replacing the device may be more difficult. The specification for this requirement is based on interviews with the project sponsor [7], [13] as well as literature reviews regarding the life cycle of surgical instruments and the number of use cycles they are typically expected to withstand [46]. This requirement was given a medium priority ranking because although durability is important for the effectiveness of the device, it does not directly impact patient safety and is therefore not the highest priority.

Evaluation: Repeated testing with prototypes will determine how many use cycles the device can withstand.

Requirement: Be universally compatible with IM syringes.
There is no single standard syringe manufacturer used globally, so the device must work with commonly used IM syringe sizes. Most IM vaccines are 0.5 mL doses, typically delivered using 1 mL syringes [9], though 3 mL syringes are also commonly used depending on what the clinic has. Since there is no single standard syringe manufacturer or barrel dimensions, the device must

accommodate multiple syringe sizes to ensure compatibility across different healthcare settings. The device must also accommodate standard needle sizes used in IM vaccinations, as described in the CDC and WHO guidelines [15], [47]. This requirement was given a medium priority ranking because although it will be extremely important for the effectiveness of the final product, it does not directly relate to user safety and is therefore not the highest priority.

Evaluation: Test the prototype with syringes from multiple manufacturers in 0.5 mL, 1 mL, and 3 mL sizes and standard needles 16-38mm long to confirm fit, stability, and function.

Requirement: Be easy to use with minimal training.
As a task shifting device, it is imperative that it be easy to use with limited complexity [8] to ensure that our target users can safely administer the injections. Therefore, the associated specifications aim to limit the amount of time needed for training as well as the number of steps for successful use. As there is no standard that sets a hard limit for training time or necessary steps, these specifications were developed based on discussions with the project's sponsor [7], articles regarding successful task shifting devices used in similar environments [22], and studies analyzing task shifting for immunization activities [48]. To further quantify the usability of the device, a target System Usability Score (SUS) is also included in the specifications. The SUS model is used across many fields, including medical, to quantify the perceived usability of a device. An average score is 68 [49], slightly below the score, 70, targeted by this specification. This requirement is rated a medium priority because although ease of use is very important for task shifting, the injection could ultimately still be carried out safely even if the device is difficult to use.

Evaluation: Usability testing conducted by nursing students and staff at Michigan Medicine using device prototypes.

Requirement: Be easy to repair in low-resource environments.
In order to achieve the previously mentioned durability requirement, the device needs to be repairable in a low-resource environment. In low- and middle- income countries, healthcare equipment often falls into disuse when it can't be repaired due to factors such as lack of skilled technicians and spare parts [51]. According to the project's sponsor, in community health centers where the device will be used, repair will likely need to be conducted by individuals without high levels of training with basic tools [13]. Therefore, the specifications state that the device can be repaired in fifteen minutes or less by an average user with a maximum of three basic tools required. Additionally, as the need for reliable power is one of the most common reasons devices are not repaired [57], the specifications state that the device should not require access to a reliable power source. The sponsor of this project has said that the design developed during the term is likely to be a proof-of-concept rather than a final product [7]. Therefore, although

reparability is very important for the effectiveness of this device, it is not the main focus of our work this semester, hence its medium priority ranking.

Evaluation: Design prototypes (3D printed) can be created to determine likely points of failure and develop repair techniques.

Requirement: Be easy to appropriately sanitize.

Sanitization and sterilization are very important for medical devices, especially those that are reused for different patients. Based on conversations with the project sponsor, this device doesn't necessarily need to be sterile but rather sanitizable with cleaning supplies available in the target setting [16]. The specifications for this requirement are based on CDC guidelines [55] and research papers [53], [54] involving disinfection and sterilization of medical devices. Based on these resources, the device would likely be categorized as "noncritical", requiring disinfection with low- or intermediate-level disinfectants.

Evaluation: Prototyping the device would help identify areas that may be difficult to clean as well as components that could come in contact with hazardous biological materials.

Requirement: Minimize cost.
Our sponsor indicated that this project is primarily a proof of concept rather than a production-ready device [13], so cost is a lower priority at this stage. However, keeping the design relatively low cost supports future scalability and accessibility if the device moves toward real world use. Cost targets were estimated by looking at the price of reusable subcutaneous self-injection aid devices as a general comparison.

Evaluation: Come up with an estimated total cost of all the prototype materials using a bill of materials.

Requirement: Ensure correct injection site for anterolateral thigh vaccination.
Although the primary focus of the device is accurate deltoid IM injection, it should also support use on the thigh in order to vaccinate children who are too small or young for deltoid injections. The deltoid injection site requires more precise landmarking, while CDC and WHO guidelines [45] for the thigh specify a broader, less location specific, making this a low priority requirement

Evaluation: User testing will assess whether participants can correctly place the device on the thigh using the training guide. Placement accuracy will be measured, without a separate location thigh guide for the device.

### 5.3 Additional Considerations

Due to the success of our project depending on the ability of the user to operate the device safely and effectively, we believe the development of a training guide to be a necessary step within the project. There are many techniques and practices involved with training, but it has been shown that a 4 question questionnaire at the end of pre-service vaccination training is deemed beneficial [58]. Although this is helpful to know in regards to vaccination training, we need in-service training rather than pre-service. This review on in-service training shows the benefits of having a form of interaction with the device being taught within the training module, and shows that online/self-lead training is believed to be as beneficial as instructional lecture style learning [59]. Once we have a better understanding of our design and what level of training is needed, we can implement the ideas above. We will likely be pursuing a combination of a self-guided training manual including visuals, at least one point of encouraged interaction with the device, and a knowledge check questionnaire if applicable.

## 6. CONCEPT GENERATION & SELECTION

Our design generation and selection process has included many steps of divergence and convergence, where ideas will be generated and evaluated, subsequently down selecting the idea pool. Yet at many points the design space would be opened back up to revisit ideation, to ensure fresh ideas were considered as understanding of the problem grew and the ideas we were working with were not limited. **Figure 8** shows a mapping of how this process was conducted.

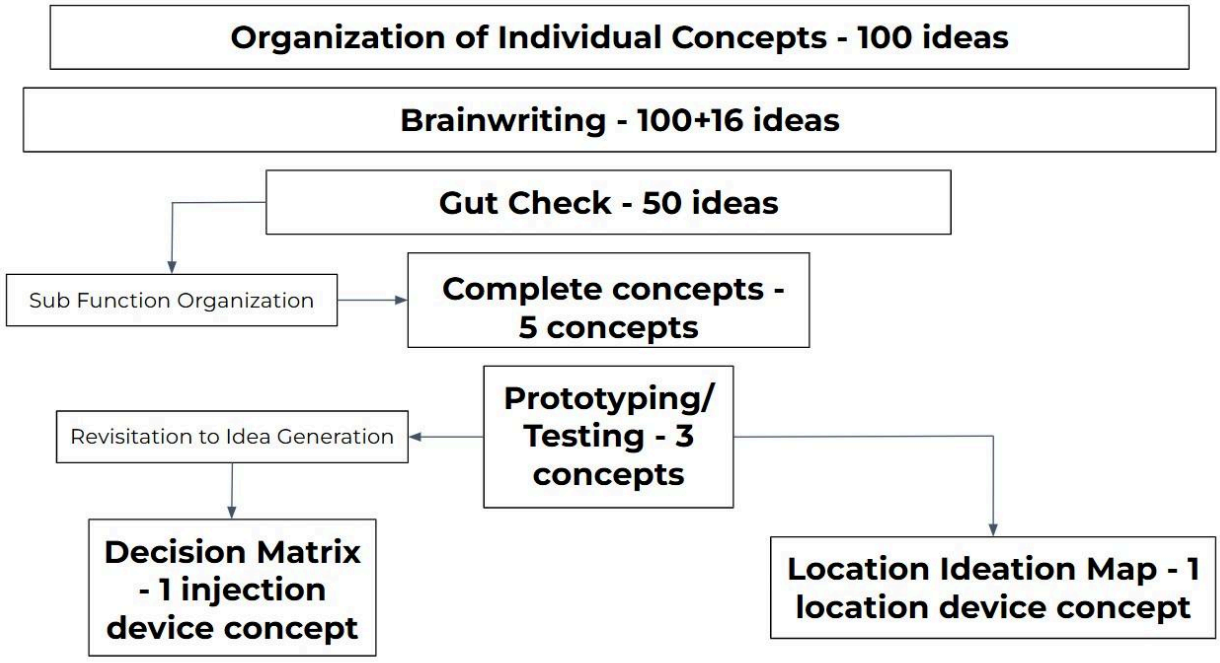



**Figure 8:** The flow of our ideation process, with convergence occurring linearly and branches showing a deviation from linear progression.

This section will walk through each step of the process through the complete concept step, explaining what was done and why it was done. Further sections of the report will dive into the later steps of the process, leading to the eventual result of alpha designs of two separate devices meant to be used together.

### 6.1 Individual Concept Organization

Through the Concept Generation Learning Block, each team member had individually generated 20 concepts through methods of their choice such as brainstorming and morphological charts (all concepts are laid out in Appendix A). Our first action for concept generation as a team was to share and organize these concepts. After everyone had shared their ideas, we divided them into four groups based on the approach taken to allow non-nurse level trained individuals to administer vaccines; devices that entirely reworked the injection device (syringe), devices that strapped onto a patient's arm, devices that would rest on a patient's arm, and modifications to a syringe needle. The most notable concepts of each member were written out on small pieces of paper and grouped together, creating a visual representation of where our ideation had been focused, and where it was lacking. These groups are shown in **Figure 9**. This visual representation allowed key insights into our ideation process as a whole, among these four categories our ideas had a relatively equal spread yet some vastly different ideas within them.




**Figure 9:** Notable individual concepts organized into four groups. Top left: entire injection device rework. Top right: device resting on patient's arm. Bottom left: device strapped onto patient's arm. Bottom right: syringe needle modifications.

### 6.2 Brainwriting

After our group had organized our individual concepts, we started a collaborative effort with other ME450 teams. We swapped team members around, so that one of our team members stayed to represent and explain our project, while the others went to join other projects. After our project was explained to the other teams' members that had joined, we engaged in a brainwriting activity, where each person would generate one design concept and then pass their concept around to allow the next person in the group to iterate on it. Within this iteration, the SCAMPER method and Design Heuristic cards were utilized. These specific methods were used as they focus on the change and iteration of a previous idea, providing helpful tools to further develop and create new ideas off of an existing one. The results from this brainwriting activity can be seen in **Figure 10**.

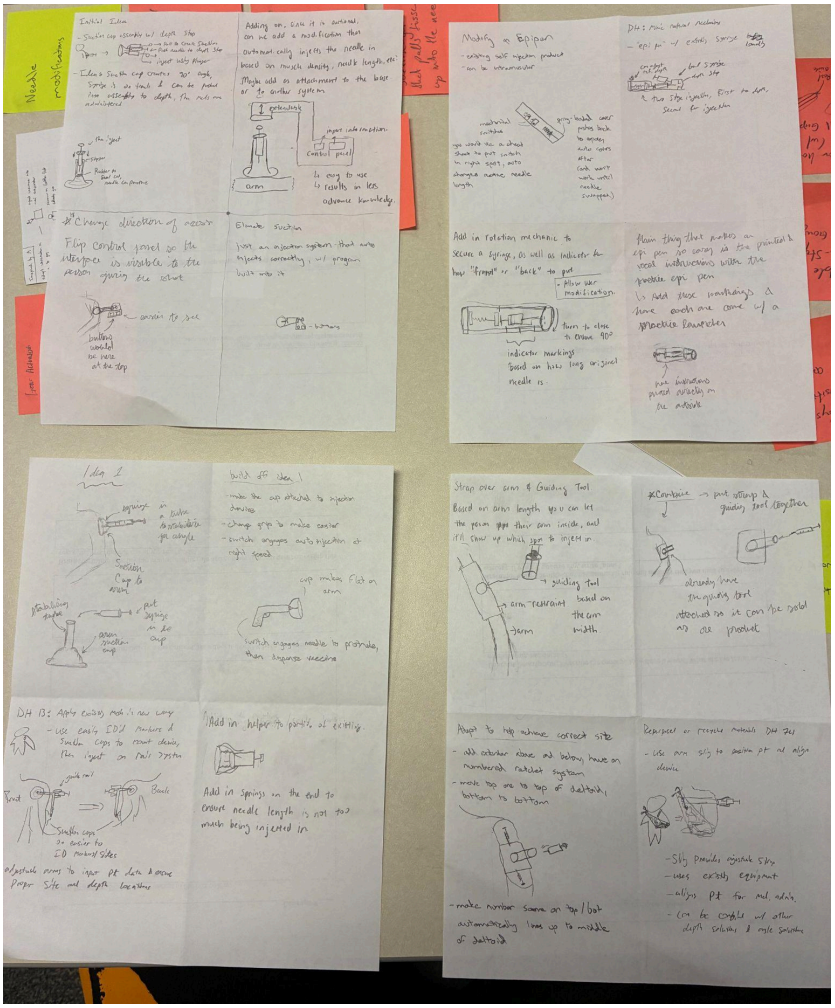


**Figure 10:** The four papers used within the brainwriting activity, where the initial concept was described in the top right corner, and other members of the group subsequently iterated off of it.

What was specifically helpful about this brainwriting activity was the inclusion of new minds and perspectives into the design space. It allowed the generation of completely new concepts separate from what our team alone had generated, and at least one idea has been later utilized within a more developed concept.

### 6.3 Gut Check

Once combining our individual ideas with the new ones generated from the brainwriting activity, we had compiled over 100 ideas. Our first step in narrowing down this long list was a gut check. This consisted of each team member individually assessing their own ideas based upon physical viability, general practicality, and our own technical ability to design and manufacture this idea within the time frame we had. The ideas eliminated at this stage fit into one of three categories; the unrealistic ones, the impossible ones, and the lesser option ones. The unrealistic ones were straightforward to eliminate, including ideas like a robotic nurse, which was easily eliminated as we do not have the skills, budget, or time to construct such a concept, and would not be practical within a low/middle resource setting. It was also easy to cross off some impossible ideas like inhaling the vaccine, because as far as we know there's no way to turn things like the HPV

vaccine into an inhalant. The lesser option ideas were not as straightforward to cut out, but would be determined that there was an improvement of the same concept within another idea, such as a flat base for the injection device to control angle as opposed to a construction triangle with clips to attach a syringe to it. The metrics used were therefore the individual's opinions on the factors discussed, and although metrics would be used in each person's mind to assess the solutions, it was subjective as to whether the design was realistic for us to make and to appropriately address the problem, ultimately acting as a way for each team member to pick the top concepts from their own that they would still want to work with.This significantly cut down the amount of viable ideas we were working with, leaving about 50 ideas and allowing us to use new methods to approach the needed concept selection.

### 6.4 Sub-function Organization

With less ideas to work with, we decided to group the remaining ones by the sub function within the whole device that they would address (seen in **Figure 11**), directly relating these to our requirements. This allowed a more clear view of recurring ideas, and a direct comparison between them. Within these subfunctions we now conducted a pro/con analysis among the frontrunners, leading to an eventual narrowing down of the design aspects we found most promising to address each subfunction.

| Sub Function | Seen in | Target Need | Top Contendors |
|---|---|---|---|
| Needle covering | #Z14, #Z18,#Z12 #N1, #E1, #F2, #F12 | Safety | #F2 |
| Base for injection angle assistance | #Z14, #Z18, #Z11,#Z12 #N2 #J1, #J2, #F6, #F22 | Angle | #J1, #J2 |
| Controlled dose delivery (speed) | #Z14, #Z18, #Z11 | Delivery | counting/timer |
| Site selection assistance | #E4 #J4, #F6, #F7, #F17, #F22, #F23, #F24, #N2 | Site | site selection still under development |
| Adjustable injection depth | #E3 #J3, #Z14, #Z18, #Z11,#Z12, #F14, #F22 | Depth | depth control still under development |

**Figure 11:** The remaining ideas organized by the sub function they address, connected to the target need (more explicitly to requirements later in this section), and the top contenders representing the most promising aspects within each subfunction.

For the needle covering and injection angle base categories, we selected top contenders by analyzing each design and considering its pros and cons. **Figure 12**, seen below, shows two of the needle covering concepts that were considered.

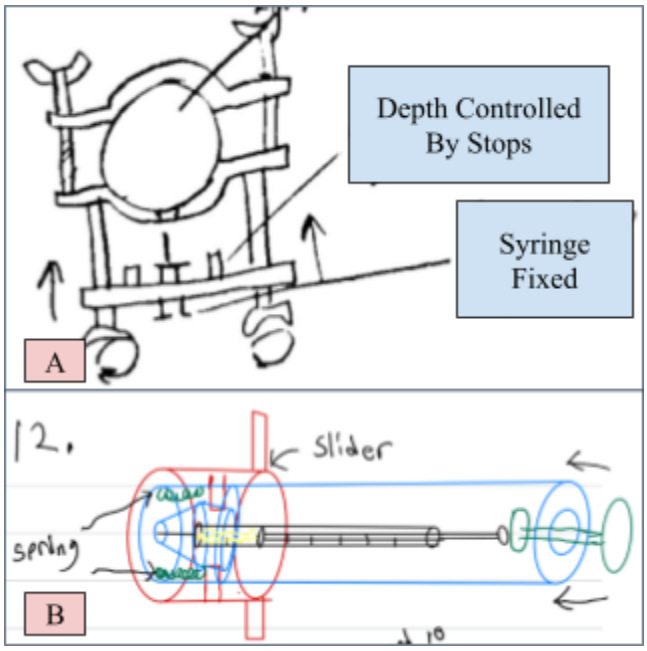



**Figure 12:** Two concepts considered for needle covering.

In **Figure 12A**, the needle is covered when the device is in use but exposed during the setup, requiring careful handling when loading the syringe. For the device shown in **Figure 12B**, springs are used to ensure the needle stays fully covered before and after use, only being exposed during the injection. Of these two, the second design was selected for further consideration. The pros and cons of the designs were also considered from the perspective of angle control. An example of this is shown below in **Figure 13**.

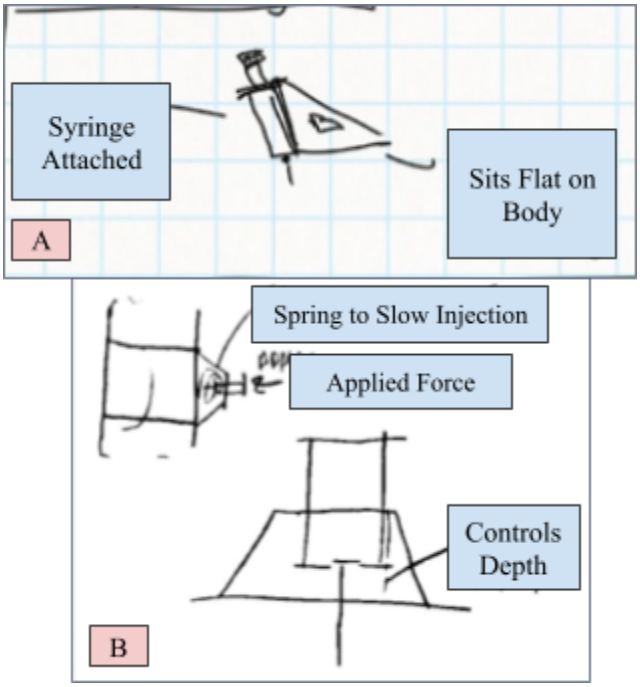



**Figure 13:** Two concepts considered for angle control.

In **Figure 13A**, the device appears to still be able to move when pressed which would change the angle of injection. Also, the rigid stand may not sit flush on the arm with certain shoulder shapes. The device shown in **Figure 13B** has a large base that improves the stability of the syringe and keeps the injection angle consistent. Of these two designs, the second was selected for further consideration and development.

Based on discussions with our sponsor, controlling the rate of injection could be achieved by having the injection administrator count or use a timer [16]. Therefore, we decided that our existing designs for this category were overly complicated and moving forward, we will just use counting to control the injection speed. For the adjustable injection depth, we initially thought that the injection depth could be safely controlled by the injection administrator selecting the appropriate needle. However, recent discussions with our sponsor have revealed that needles are not usually selected based on individuals but rather what is expected to work for a wide range of patients. As we initially set the injection depth category aside, it still requires significant development. For site selection assistance, we realized that we had limited ideas that actually made the site identification easier than the current standard practice. Because of this, we decided to create a map of our current site selection ideas, shown below in **Figure 14**, which allowed us to identify areas that needed further development.

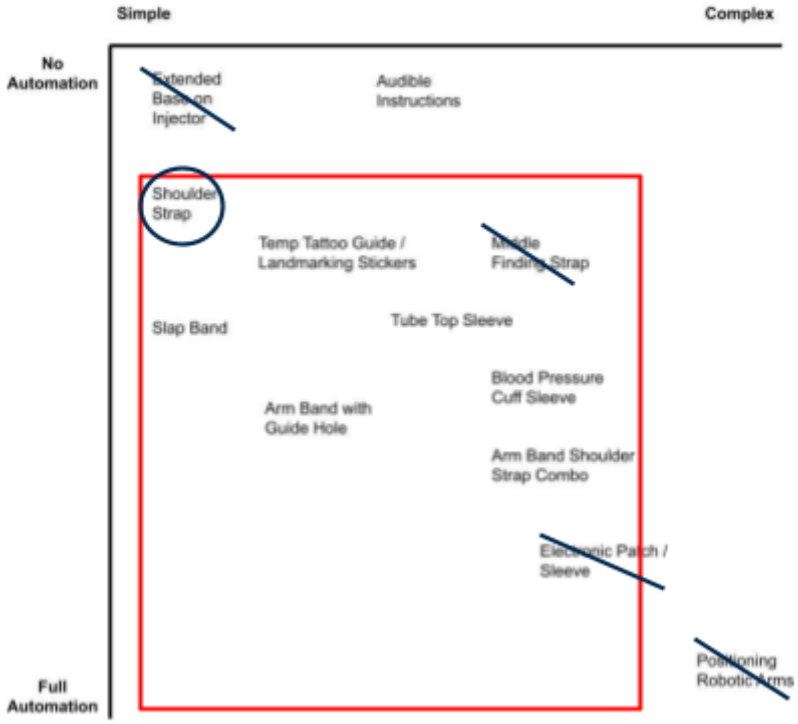



**Figure 14:** Idea map of site selection assistance designs. The designs are placed based on their complexity (horizontal axis) and automation level (vertical axis).

On the idea map, seen above, the region surrounded by the red box indicates where we plan to conduct additional concept ideation. In this area, there is moderate to high automation which will

be helpful for task shifting as it places less responsibility on the healthcare worker administering the injection. Additionally, this area has low to moderate complexity which will help the device be durable and repairable in the low-resource environment. The designs that have been crossed out are either not feasible for this semester (i.e. self-positioning robot arms), or do not guarantee correct site selection. The circled design, “shoulder strap”, is one that we intend to continue developing and is explained further in a future section. Based on discussions with the project’s sponsor as well as our intuition, the location assistance device will be separate from the injection device controlling needle covering, injection depth, and injection angle.

### 6.5 Complete Concept Selection

After organizing the designs by sub-function and identifying the top contenders for each category, we found that none of the designs adequately satisfied all of the requirements. Therefore, we conducted another round of individual concept generation with each of us developing one main design that addressed all of the requirements, resulting in five new concepts. Then, as a group, we selected the top three concepts based on uniqueness and how effectively they addressed each of the requirements. Because many of our concepts had similar elements (wide base, spring covering, etc.), when selecting our top three, we focused on designs that were seen less often to make sure that we had a wide range of ideas to develop. To determine how effective each design was in addressing the requirements, we discussed each design as a team, considering what aspects of the designs satisfied or missed our top requirements. Designs that seemed likely to meet more requirements were chosen over others that would meet less. As part of an in-class activity, we conducted preliminary analysis of potential engineering analysis methods for each concept, identifying testing issues for each. Based on this analysis, we determined our top two concepts to move forward with for the injection device, and worked on one idea for the location device, which are described in detail in the next section. Note that the location device was first prototyped before the ideation map had been truly analyzed and put to use, and so the first discussion of it appears in the testing section, with further discussion of the location device selection in the section after.

## 7. FRONTRUNNERS: DR2

At this time, we have two frontrunner design concepts that we will continue to develop and analyze to fulfill the primary design requirements. We have created crude prototypes of both of these designs to begin to test design worries. Neither of these two designs addresses the problem of landmarking, so we have a third design and prototype that seeks to address this problem independently from the first two designs.

### 7.1 Injection Device Design 1 Overview

Design 1, seen in **Figure 15**, resulted from the complete concept selection process described in Section 6.5, addressing most of the requirements the team was focused on at the time of generation. It proposes a 150 mm cylindrical body in which to house the syringe, holding it in place using a screw-on lid with a hole for the plunger to protrude through. A retractable needle guard projects from the needle side of the device, allowing the sharp to be fully covered while the injection is not actively taking place. An internal spring and corresponding spring stops passively press the guard out from the body, allowing it to slide in during injection and return to its safe position after the administration has been completed. An extended base provides a wider area for the device to rest against the patient’s arm, ensuring that the insertion occurs near 90°.

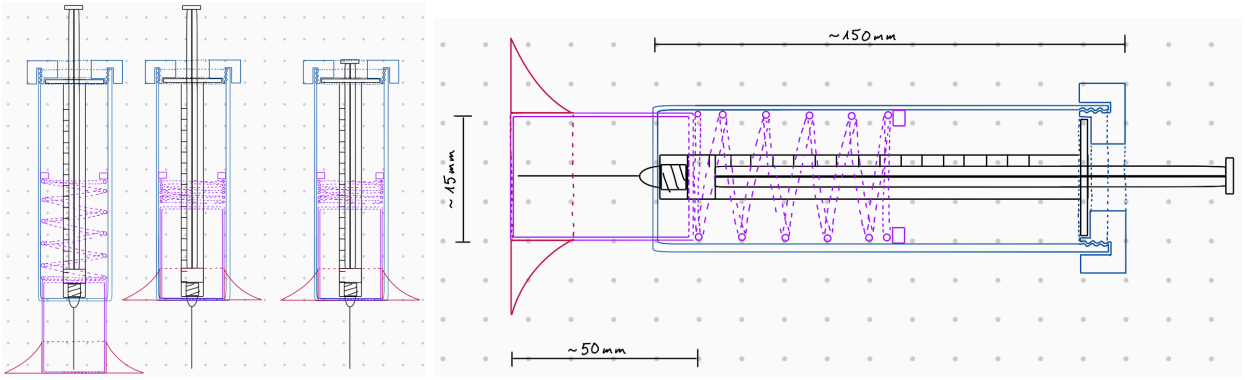



**Figure 15:** Diagrams of Design 1 depicting approximate dimensions and actuation.

Since the time of this design's inception, the team has obtained new information regarding the injection depth requirement. While it was initially thought that this part of the process was solved as a result of needle length selection, our sponsor has informed us that this is not the case; as a result, further iteration will be necessary to expand the concept to include this need. The design also fails to address the site selection criteria, however this is being attended to by a separate concept, seen in Section 8.3, Location Device Prototyping.

### 7.2 Injection Device Design 2 Overview

Like Design 1, Design 2 features a circular base to fulfill the requirement of a near 90° angle of needle insertion. The syringe and needle are fixed in a cylinder with the plunger exposed, which slides into a primary casing during injection, as shown in **Figure 16**. A spring compresses as the syringe casing is pressed down during the injection. As the spring is fully compressed, the syringe casing locks in place as the needle is fully injected to the correct depth. Once the syringe is locked in place, the plunger will be pushed down, administering the dose. After the dose is fully administered, the syringe casing will be unlocked, and the spring will retract the needle. This fulfills the requirement of concealing the needle before and after the injection to ensure safety.

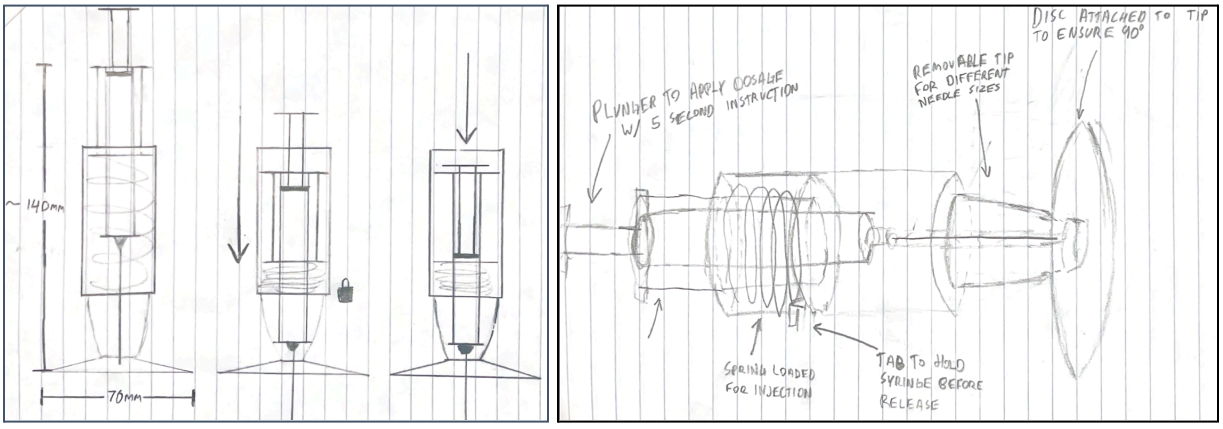



**Figure 65:** Diagrams of Design 2 depicting the spring loading mechanism and dimensions.

This design concept also includes a detachable tip which will be able to be replaced with tips of varying length. This seeks to fulfill the requirement of variable depth control which, as

previously mentioned, is unsolved, though this specific part of the concept requires more ideation.

# 8. PROBLEM ANALYSIS & ITERATION

## 8.1 Frontrunner Prototyping

The low-fidelity prototype for Design 1 is shown in **Figure 17**. The prototype includes the needle guard which retracts and compresses the spring during the injection. The prototype explores the functionality of this guard and does not include the wide circular base for the 90° requirement or screw on cap. It consists largely of PVC tubing and the spring mechanism is made of several smaller springs stacked in series against a wire backstop.

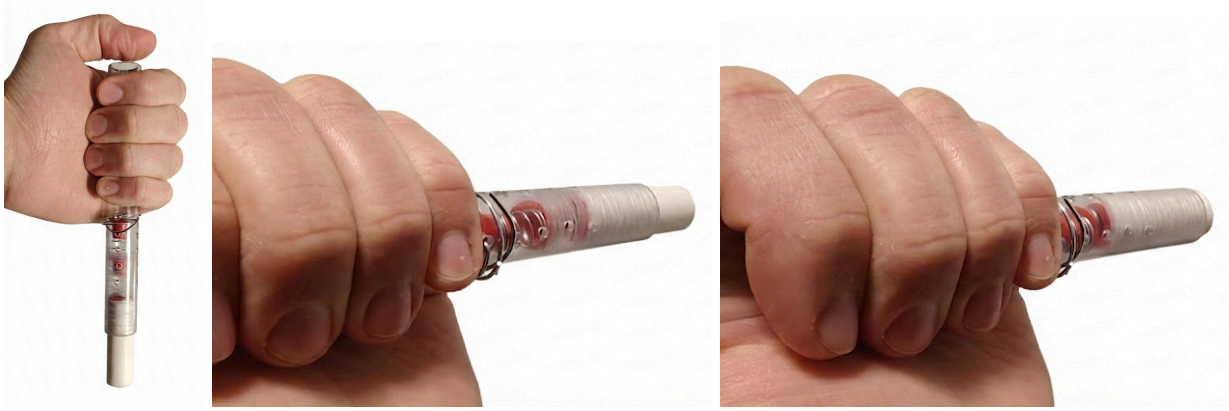


**Figure 17:** Low-fidelity prototype for Design 1 demonstrating the functionality of the spring retracted needle guard.

The low fidelity prototype for Design 2 is shown in **Figure 18**. It features a wide circular base for ensuring a 90° angle of entry. It also features a spring for needle retraction to fulfill the specification that the needle be concealed before and after injection. It also includes a wider section opposite the needle end to represent the syringe and plunger more effectively. This prototype does not include the locking mechanism described with the concept or the removable tip. The fundamentals of solid mechanics could be applied for analysis of this prototype. This would be applied for finding an appropriate spring constant.



**Figure 18:** Low-fidelity prototype for Design 2 with wide base and spring loaded retraction.

### 8.2 Early Testing

Design 1 testing was aimed at assessing the dimensional viability of the proposed solution. The prototype confirmed that the cylindrical body would be sufficiently grippable and, with modifications to the diameter, would be capable of containing an IM syringe. The cylindrical shape is easy to grip and the length provides a reasonable amount of space to grasp the device for stable injection. The basic functionality of the spring return needle guard was successfully demonstrated, proving that this solution can effectively guard the needle before and after use.

While the prototype did prove the concept's viability in terms of ergonomics and the practicality of the needle guard, several worries remain that require additional prototyping and analysis. The concept lacks needle depth control and will be iterating from previous design concepts to address this. While this prototype is rudimentary, it did highlight the concern of spring binding; a higher fidelity prototype with a dedicated spring will verify if this concern is warranted. The needle guard also slips out freely from the device as of now, highlighting the need for a stop which keeps it captive within the device body. The prototyping material for this device was largely clear, allowing for the theoretical payload to be visible. This material consideration will be carried forward through future designs. Finally, the current prototype does not include the cap to hold the syringe in place, not a stop for the needle side of the syringe to rest against, indicating that further features will be needed to account for this.

The goals of the Design 2 prototype were to test the viability of the spring system, the ergonomics of the plunger and spring compression, and the viability of the wide circular base. This testing revealed that the spring used for the prototype is too stiff to be used effectively. We will require further testing to determine a suitable spring stiffness that will not be as difficult to compress. We also tested the ergonomics of being able to compress the spring, and independently press down the plunger to administer the dose. This testing revealed that the ergonomics for this action are valid as created in the prototype.

The primary worry that arises from the Design 2 prototype is finding a viable spring. Along with that worry, the circular base did provide some stability but this prototype did not fully implement

this design element as the circular base was too flexible. The prototype did not include the locking mechanism described in the design concept, so we will require further prototyping and testing to determine a suitable design for that. The prototype also did not include the removable tip described in the design concept so that will remain open for prototyping and testing.

Both designs utilize springs; to ensure that these are adequate for the devices' functions, theoretical spring force calculations, an application of solid mechanics, will be done in combination with empirical load testing to ensure that the force required to retract the needle guard (Design 1) or depress the syringe (Design 2) is sufficient.

To assess the circular base concerns related to both designs, a minimal viable test has been done. The test was to hold multiple sized cylinders (seen in **Figure 19**) up to the injection site of a shoulder, where a protractor would then be used to measure its difference from a 90 degree angle to the injection site, where a difference of 0 being the ideal performance. This test was conducted by 3 participants, where each one would use every cylinder and then a "needle" as a control test. Results shown in **Table 3**. This testing approach was chosen because it would provide insight into the physical realization of our ideas using materials readily available to us, requiring no major assumptions since a real shoulder and a true to design geometry were used.

The test was conducted on only one person's shoulder, meaning it was far from a full test where all body types were accounted for. There were three participants, all taking one measurement with each cylinder or the "needle". All participants and the person whose shoulder was used are members of our group. To improve this test to obtain more accurate and meaningful results we must at a minimum conduct tests on the shoulders of everyone in our group, or ideally recruit people from outside our team for the test.




**Figure 19:** The three sizes of cylinder used in the test, along with the "needle" and protractor.

| Diam Cyl | 70 mm | Diam Cyl | 53 mm | Diam Cyl | 22 mm | "needle" | ~2 mm |
|---|---|---|---|---|---|---|---|
| diff from 90 | 1 | diff from 90 | 5 | diff from 90 | 5 | diff from 90 | 2 |
| | 4 | | 0 | | 5 | | 10 |
| | 2 | | 2 | | 3 | | 3 |
| avg | 2 | avg | 2 | avg | 4 | avg | 5 |

**Table 3:** Results from the cylinder test, organized by each cylinder size, compared to the control test, with the average difference from 90 degrees shown in the bottom row for each size.

As we can see from the results, every cylinder improved the performance in injection angle relative to the "needle" angle, with the 70 and 53 mm diameter cylinders performing the same and better than the 22 mm cylinder. This leads us to believe that the benefit from increased diameter stalls out around 50 mm, and so we will start our design with a 50 mm base but must do further testing if we hope to find the truly optimal size. This was not a complete or comprehensive test, just a proof of concept, validating the design choice of a round base to assist in injection angle. Through this test we know our design has potential and is worth pursuing, but further testing with more cylinder sizes, more participants, and more individuals' shoulders must be done to achieve results strong enough to determine the final dimensions of our design. This means we have made progress towards achieving the requirement for ensuring the correct IM injection angle, and have improved but have not fully de-risked this aspect of the design.

### 8.3 Location Device Prototyping

**Figure 20** shows our original site selection prototype. Our team had limited early concept development for locating the injection site, so this prototype was built directly in the lab to quickly explore a physical solution. The device is separate from the device responsible for housing the syringe and injection system. This prototype is designed to help users without nurse-level training consistently locate the correct deltoid IM injection site. A shoulder band wraps around the upper arm with a soft pad that sits on the acromion to serve as a landmark, as shown in **Figure 21**. Straps extend downward roughly 2–3 finger widths to position a guide template over the safe injection zone. Biomechanics and basic solid mechanics help us understand shoulder anatomy and how the band stays aligned on the acromion.

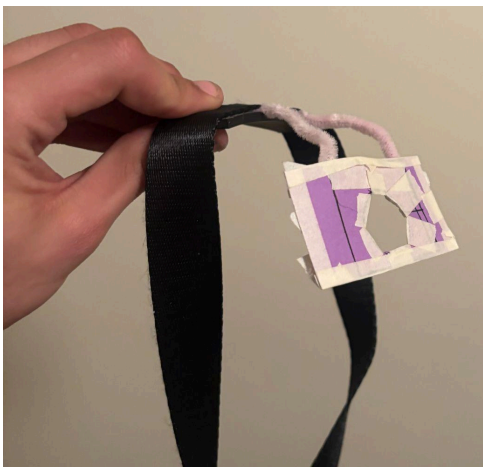


**Figure 20**: Shoulder Placement Guide prototype with acromion pad and hanging guide to help locate the deltoid injection zone.

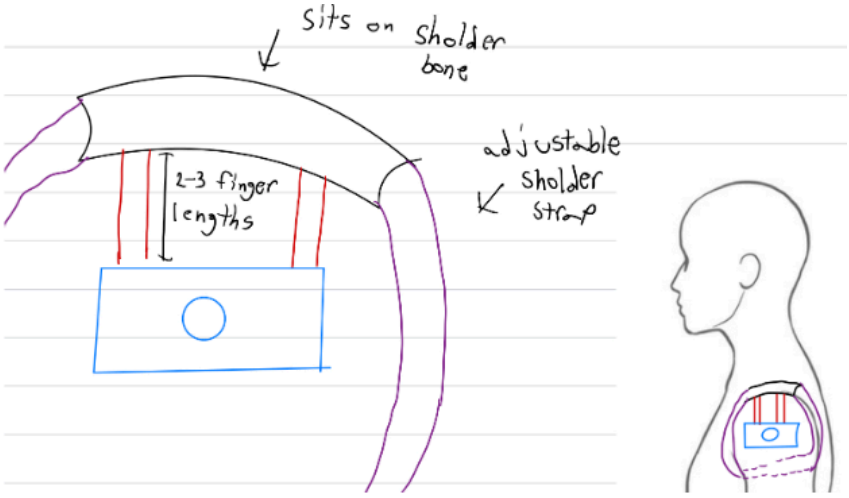



**Figure 21:** Post-prototype sketch refining placement and adjustability of the shoulder-band concept.

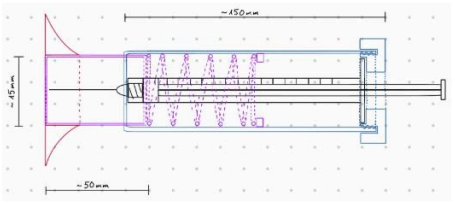
Initial testing will evaluate fit, stability, and placement accuracy across a variety of different users. First we will check whether the acromion pad can be placed correctly and stays in position during normal arm movement. Secondly we will assess fit across different shoulder sizes and body types. Lastly we will run short training sessions to see if users can consistently place the device accurately and measure how close they are to the center of the safe injection zone.
Key concerns are slip, misalignment, and user error. The pad may not consistently sit on the acromion for all body types, and the band could shift when pressure is applied, causing the zone the guide provides to shift. Another concern is that a 2-3 finger finger width varies by person, so the guide strap length may need to be adjustable. Finally, we are concerned that minimally trained users may misidentify the acromion or orient the band incorrectly, which could place the injection guide outside of the safe region.

# 9. SELECTION OF ALPHA DESIGNS

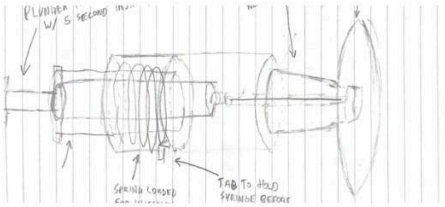
### 9.1 Injection Device Decision Matrix

After seeing potential in both of our injection device frontrunners, we decided to revisit the design space before moving forward. We wanted to ensure that the space had been fully explored, and gaps of potential solutions had been made. The team looked through our collection of original ideas and the categories we had organized them into, opening the floor for more ideas to be generated where we did not find ourselves developing novel ideas past what we had already generated. Although we had started to feel as though the design space had been narrow as we had been working with relatively similar concepts for a while at this point, we realized we had started with a wide range of concepts that had simply been subsequently cut out through the gut check and stripped of their key points during subfunction organization. Naturally, we have not considered every possible solution to this problem, but felt as though the design space had been sufficiently explored within our capabilities and it was reasonable to move forward with our two frontrunners. To fully compare these two concepts, it was decided metrics must be incorporated into the determination of which design we were to move forward with, as seen in **Figure 22**.

| Criteria | Weight | Design 1 | Design 2 |
|---|---|---|---|
| Complexity | 1 | 0 | -1 |
| Repairability | 2 | -1 | -1 |
| Number of Parts | 2 | 1 | -1 |
| User Involvement | 2 | 1 | 0 |
| Universal Syringe Compatibility | 2 | 0 | 0 |
| Manufacturability | 1 | 1 | -1 |
| Ensures Correct Angle | 3 | 1 | 1 |
| Prevent Needle Stick Injury | 3 | 1 | 1 |
| **Score** | | 9 | 0 |



Design 1



Design 2

**Figure 22:** A decision matrix comparing injection device Design 1 to Design 2.

Each design was ranked from -1 to 1 on the aspects of the device we determined most essential to meeting stakeholder requirements and the likelihood of its success. The weight of each aspect was from 1 to 3, with 3 being of the highest priority to satisfy requirements. Each rank was multiplied by the appropriate weight, and these numbers were tallied to get the score for each device, where a higher score was desired. Key aspects that we saw and were able to quantify for this were the concerns over the higher complexity and number of parts, in turn negatively affecting the manufacturability. Due to Design 2's incorporation of a locking mechanism, it was deemed it would be overly complex compared to Design 1 avoiding this mechanism and using less parts with better manufacturability. On top of this Design 2 required an extra step from the user, as they would push the device down, lock it, and plunge the syringe whereas Design 1 only requires pushing the device down and then the syringe, Design 1 had favor here as well. With all other aspects graded being deemed equal between the two devices, Design 1 had shown more promise in a direct comparison and was chosen as the design we would pursue and further iterate on.

It is also worth noting that at this point it was decided to specialize our design for one syringe type. Ideally our device would universally fit all syringes, but this was too large of an ask with our limited time frame and need to move forward at this point. We have decided to design our device to fit with a BD 3mL Leur-Lok syringe so that we could find out if this design truly works, and with time permitting adapt the model to fit more syringe types or create other iterations of the same model for different syringes.

### 9.2 Inclusion of Depth Control

As mentioned previously, a key aspect both of our frontrunner injection devices needed improvement on was control of the injection depth. We held a brainstorming session as a team related to Design 1 that we had chosen from the decision matrix to see different ways we thought to control the injection depth. **Figure 23** shows some of these ideas drawn out.

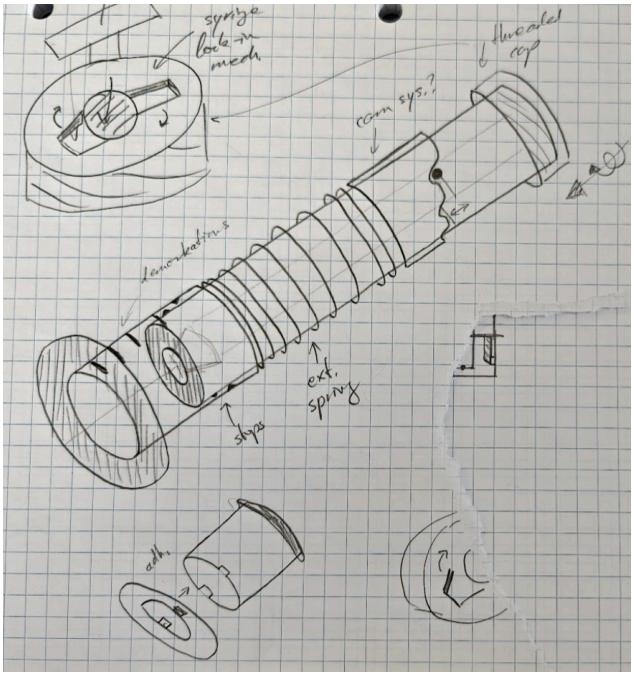



**Figure 23:** Drawings used during our brainstorming of injection depth control.

Drawing these ideas out was very helpful to show each other what we meant, and one of the most helpful things ended up being using the chunk of paper to create the shape being discussed. This is why a chunk was torn out of the paper, to create a very low fidelity model of what was being described in the most upper left drawing. This was great to explain what was being described, and this idea was actually incorporated into our alpha design. See Section 10.1 to see how we have incorporated these ideas into our design.

### 9.3 Use of Location Device Map

After creating the ideation map seen in Section 6.4, we were ready to move forward with choosing an initial design to pursue for the location device. The main influence here ended up being from discussion with our sponsor, where they had liked the direction being taken with the shoulder strap prototype. Through this discussion and our own thought process, it was realized the complications with creating a device involving too much automation, how it would be too technologically advanced for the regions we hope to see use in and therefore incorporated more difficulties in longevity and repair. We had originally been hoping to see the realization of a device that would take almost all the steps to find the correct injection site for the user, but realized this was unrealistic. Through guidance from our sponsor it was determined that it was within reason to expect the non-nurse level trained health care worker to find bones as landmarks on the body, but not specific points within the deltoid. Although the region of the map we had originally marked as the most promising was still quite unfilled with ideas, we saw this area shrinking through these realizations and evolution of the design problem. We chose to go forward with the shoulder strap device, as this takes the steps for finding location from two down to one, and only requires the user locate a bone rather than a muscle, making it a promising solution to the issue of finding the correct injection site.

# 10. ALPHA DESIGN BUILDS

## 10.1 Injection Device

The injection device is designed to house a standard IM syringe and to provide needle safety, adjustable depth control, and angle stability. The current version (**Figure 24**) is specifically designed for a BD 3cc Luer-Lok syringe; the syringe is inserted through the back of the cap, where it is twisted and locked in place (see Section 10.3). This cap is then threaded onto the body until the needle reaches the desired length into the needle guard. After this, the syringe cap may be removed, the injection completed, and the cap replaced before disposing of the syringe safely.

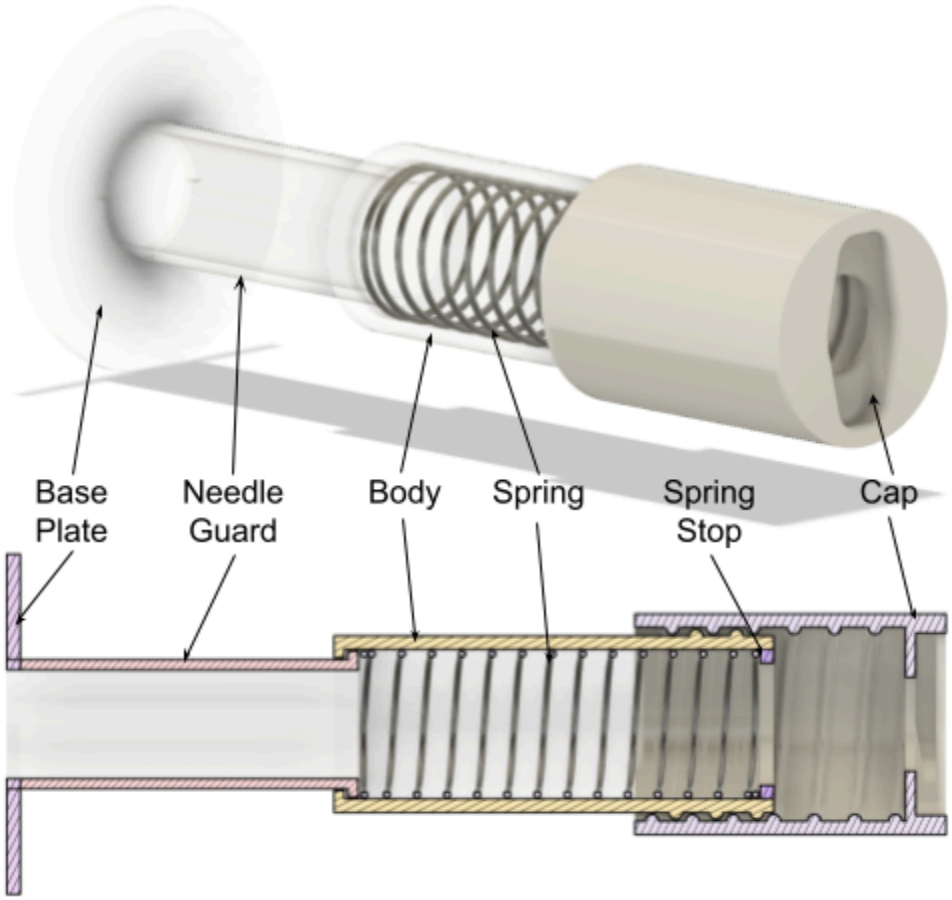



**Figure 24:** Current CAD model of injection device (Top: Isometric view; Bottom: Cross-sectional view).

When fully extended, the device has an adjustable length of approximately 125 to 155 mm and a widest diameter at the base plate of 50 mm as per stability testing (see Section 8.2). Individual dimensions are shown in **Figure 25** below.

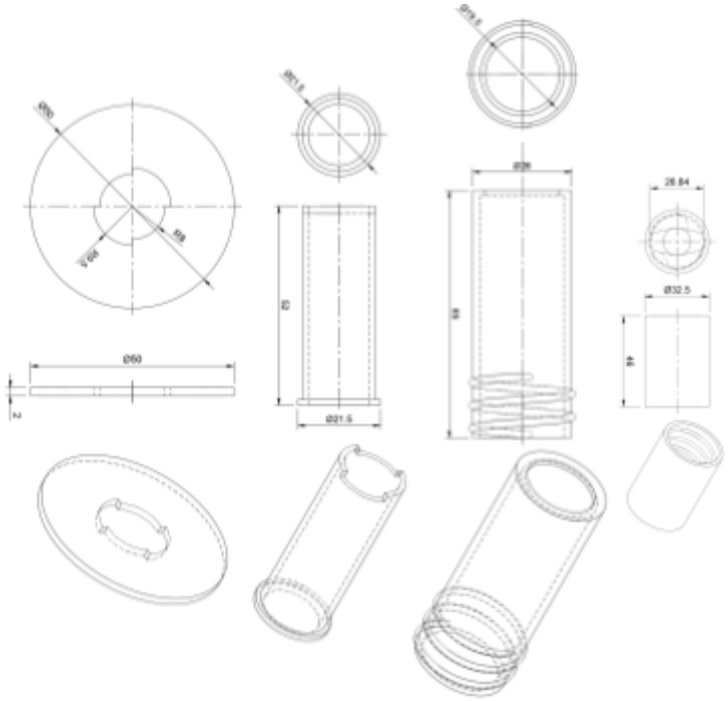


**Figure 25:** Dimensions of injection device components (Base Plate, Needle Guard, Body, Cap).

The prototype injection device consists mostly of additively manufactured parts, with the only purchased part being a spring. The 3D printed components are to be made from PLA or ABS for non-clear components, while clear components (ie, the needle guard, body, and base plate) are to be made from Formlabs Clear Resin v4.1 as can be seen in **Table 4**. The spring will be purchased as per the results of our analysis. For the ultimate mass produced components, materials will transition to injection molded polypropylene or PEEK for the opaque components and polycarbonate or acrylic for those which are to be translucent. These materials are approved for biocompatibility in medical devices [60].

| Component | Prototype Material | Prototype Manufacturing | Mass Production Material | Mass Production Manufacturing |
|---|---|---|---|---|
| Cap | PLA/ABS | AM (3D Printing) | Polypropylene/PEEK | Inj. Molding |
| Body | Clear v4.1 Resin | AM (3D Printing) | Polycarbonate/Acrylic | Inj. Molding |
| Spring Stop | PLA/ABS | AM (3D Printing) | Polypropylene/PEEK | Inj. Molding |
| Spring | SS / Music Wire | Purchased | SS / Music Wire | Coiling |
| Needle Guard | Clear v4.1 Resin | AM (3D Printing) | Polycarbonate/Acrylic | Inj. Molding |
| Base Plate | Clear v4.1 Resin | AM (3D Printing) | Polycarbonate/Acrylic | Inj. Molding |

**Table 4:** Injection Device Materials and Manufacturing Methods (Prototype / Mass Production).

An early FDM prototype (seen in **Figure 26**) was made entirely from PLA to prove that the concept is sound and to determine what changes must be made to tolerances in the design. Since this version was created from just 40 grams of PLA, the cost is minimal (below 1 USD in materials) which allows the version to be printed using the more expensive resin to more accurately address the design needs and mechanics involved. Future alterations include the design of the threads, gliding surface of the needle guard inside the body, and the incline plane of the cap's syringe locking mechanism. Additional design concerns for this version include spring binding, ensuring that the device remains safe for both the administrator and patient, and expanding compatibility to a wider range of syringes.



**Figure 26:** Initial FDM prototype of injection device fitted with a BD 3cc Luer-Lok syringe.

### 10.2 Location Device

The shoulder placement device is designed to guide a minimally trained user to the correct intramuscular injection site on the deltoid. The user first identifies the patient's acromion bone and places the acromion pad so the landmark is fully covered. The adjustable shoulder strap is then tightened to secure the device. Once positioned, the side straps automatically place the injection guide stencil at the appropriate distance below the acromion, indicating the correct deltoid injection site for the injection device.

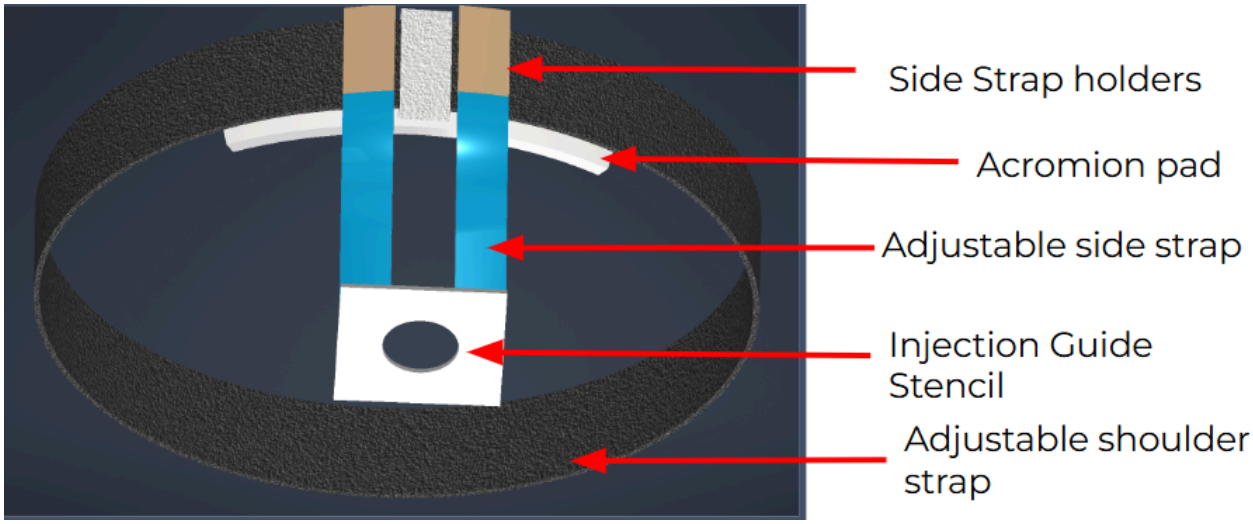



**Figure 27:** CAD model of the shoulder placement device with labeled components for alignment, adjustment, and injection site guide.

The location device consists of several components that work together to ensure consistent placement and secure attachment to the patient's shoulder, as shown in **Figure 27**.

The acromion pad serves as the primary alignment feature and is positioned over the acromion to establish a consistent anatomical reference point. The geometry and dimensions of the acromion pad are shown in **Figure 28** to illustrate its curvature and fit.

The adjustable shoulder strap wraps around the top of the shoulder and around the armpit to secure the device in place and maintain contact between the pad and the shoulder. The side strap holders provide a fixed connection point between the acromion pad and the side straps, ensuring proper alignment. The adjustable side straps extend from the shoulder strap to the injection guide and control its vertical position relative to the acromion. The injection guide stencil defines the target injection location on the deltoid. Once the device is secured, the stencil is automatically positioned at the correct distance below the acromion based on the side strap configuration.

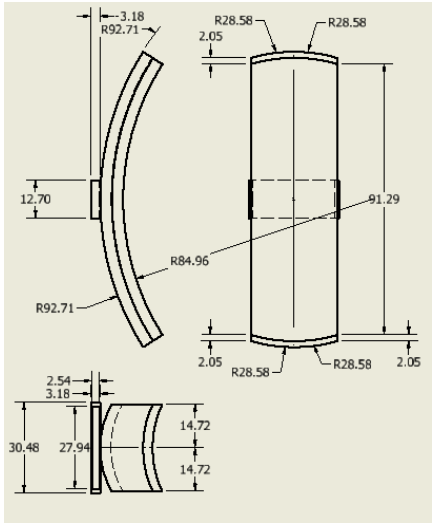



**Figure 28:** Dimensioned drawing of the acromion pad showing curvature and overall geometry.

The injection guide stencil includes a circular opening sized slightly larger than the injection device to allow for proper alignment and ease of use. This clearance ensures the device can be positioned accurately without interference while maintaining guidance to the correct injection site.

The side straps are spaced sufficiently apart to accommodate the injection device between them. This spacing allows unobstructed access to the injection site while maintaining stability and keeping the guide centered on the correct location on the deltoid.

The distance from the acromion to the correct injection site is relatively consistent across users, with clinical guidance indicating approximately 3 finger widths [10]. As a result, variation in side strap length is not a primary concern for accurate placement. The main design concern is ensuring that the acromion pad remains properly positioned during use and that placement is consistent across users. This depends on the user correctly identifying the acromion and tightening the shoulder strap. The strap is intended to keep the device stable, but this will need to be confirmed through user testing.

| **Component** | **Prototype Material** | **Prototype Manufacturing** | **Mass Production Material** | **Mass Production Manufacturing** |
|---|---|---|---|---|
| Acromion Pad | TPU | 3D printed | Silicone Gel | Injection molding |
| Shoulder Strap | Nylon webbing | Purchased component | Nylon Webbing | Textile manufacturing |
| Adjustable Side Straps | Nylon webbing | Purchased component | Nylon Webbing | Textile manufacturing |
| Injection Guide Stencil | TPU | 3D printed | TPU | Injection molding |
| Side Strap Holders | PLA | 3D printed | Acetal (POM) | Injection molding |
| Custom Strap Attachment Clips | PLA | 3D printed | Acetal (POM) | Injection molding |
| Velcro Fasteners (Hook & Loop) | Nylon Hook & Loop | Purchased component | Nylon Hook & Loop | Textile manufacturing |

**Table 5:** Location Device Materials and Manufacturing Comparison.

Materials were selected to support both rapid prototyping and scalable manufacturing. Prototype components were primarily 3D printed using TPU and PLA. TPU was used for the acromion pad and injection guide due to its flexibility and comfort, while PLA was used for structural parts such as clips and strap holders for its rigidity and ease of printing. Straps, Velcro fasteners, and adjustment components were purchased using nylon webbing and plastic hardware to simplify assembly.

For mass production, materials transition to more durable, industry-standard options commonly used in medical devices. The acromion pad uses silicone for comfort, while clips and holders use acetal (POM) for strength. Straps and Velcro remain nylon, and the stencil uses TPU, all manufactured using injection molding or standard textile processes. Nylon webbing was selected due to its common use in load-bearing applications such as backpack straps, providing strength and durability. Silicone was selected due to its widespread use in medical devices for skin contact applications, including prosthetic liners and wearable supports [42]. A summary of material selections and manufacturing methods for each component is provided in **Table 5**.

### 10.3 Mass Manufacturing

In addition to material selection, a simple fabrication plan was developed to guide assembly of the device. The prototype (ME450 build) is assembled using 3D printed components (TPU, clear Resin and PLA), nylon straps from the X-50 room, with parts connected through clips and rivets. The injection device components are 3D printed and lightly sanded where needed to achieve proper fit and tolerances.  Assembly consists of attaching the acromion pad clip to the shoulder strap, securing the side straps to the shoulder strap using male and female rivets at fixed locations, and bonding the injection guide stencil at a set distance from the edge of the acromion pad to ensure proper positioning. This process requires minimal tools and can be completed using basic hand tools.

The final design follows the same overall assembly process but replaces 3D printed components with injection molded parts and textile-manufactured straps to improve durability and consistency, with rivets installed using a mechanical press for reliable and repeatable attachment. Tables 4 and 5 summarize the materials and manufacturing methods for both the prototype and mass production designs, highlighting the transition from rapid prototyping methods to scalable manufacturing while preserving the same functionality.

Benefits from the transition to mass production will include improved cycle times and tighter tolerances, which will improve the fit of both the threading on the cap and device body as well as the sliding of the needle guard into the device body. Additionally, the needle guard and device body will be fully transparent when molded in acrylic as opposed to the opaque quality seen in the current prototype. This will allow the administrator to more precisely see the depth to which the needle is being set and the needle’s placement against the patient's tissue during the injection.

### 10.4 Combined Devices

The injection device and location devices function in tandem to satisfy the requirements that have been set. First, the location device is attached to the patient using its straps, locating the injection site. Then, the syringe is loaded into the injection device cap and the cap is then threaded onto the body until the needle shows the correct injection depth on the needle guard

(**Figure 29**). The injection device may then be held to the guide of the location device and the injection will be completed by first depressing the needle guard and needle into the patient's tissue and then depressing the syringe (**Figure 30**).

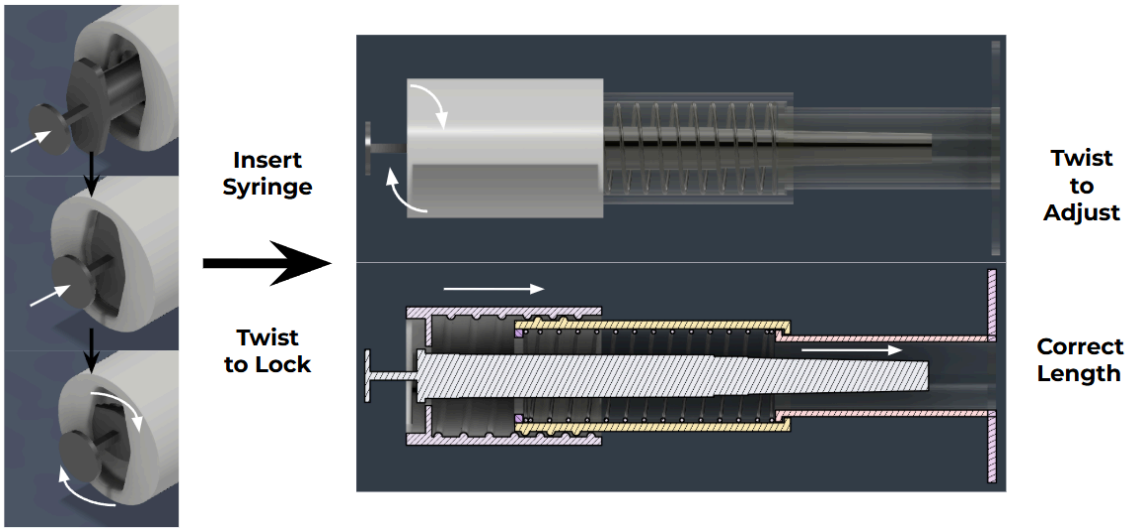



**Figure 29.** Loading of the syringe into the injection device.

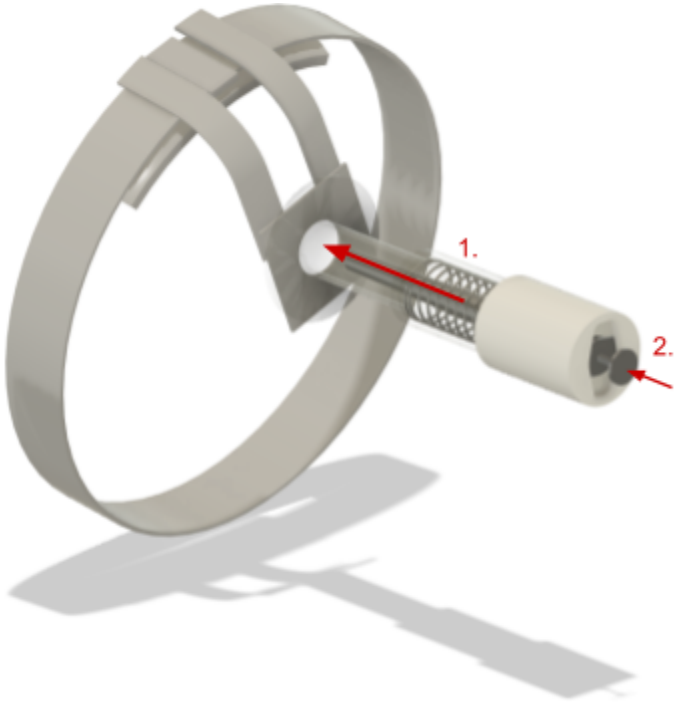



**Figure 30:** Use of injection and location devices in tandem.

## 11. ALPHA DESIGN ANALYSIS

This section describes the engineering analysis that was conducted for the alpha design. Prior to these analyses, the primary design concerns were spring selection, overall patient and administrator safety, and side strap length compatibility. To address spring strength, a force

analysis and shopping cart analysis were conducted to determine an appropriate spring constant and make sure that there were springs available for purchase that fit our design criteria. To address overall patient and administrator safety, failure modes affects analysis (FMEA) was conducted to identify potentially harmful aspects of the design so that we could focus on them and reduce the risk. Finally, for the side strap length compatibility, we analyzed anthropometric data in order to determine appropriate strap lengths. This allows us to make sure that our device is compatible with as many people as possible.

### 11.1 Spring Selection

At this point in the design, we wanted to address our concerns on the effectiveness of the spring regarding finding one of the right size that would not require too much force to compress. To first find what would be an unreasonable amount of force, we searched for information on the force required to inject the needle into the muscle. A Polish university conducted a study on this, showing that the average max force during injection is 0.87 N [61]. Note that this study was conducted on animal products rather than human tissue, and they used needles of 25-27 gauge whereas IM injection is recommended to be at 22-25 gauge [41]. These factors would affect the results of the experiment, but as we are not concerned with exact numbers and rather general forces this is sufficient for our later comparisons.

The CAD model for the injection device was being developed at the same time as this analysis on springs, and realizations of the needed measurements of the spring changed through this progression. Springs were originally sought to be a close fit to the syringe, using measurements we took of a BD 3mL, seen in **Figure 31**. It was later realized this would not leave enough space for the needle guard, and so the needed dimensions of the spring were driven by the CAD model dimensions, depicted in Section 10.1.




**Figure 31:** BD 3mL syringe depicted with the varying outer diameter.

In our design, the needle guard will always be pushed back by the full amount allowed. We need to design for injections up to 38mm deep, and so will assume the needle guard is being pushed back 40mm every injection. Using Hooke's Law, we know the maximum force exerted during this process will be at the maximum point of compression, 40mm. Initial searching for springs showed surface level offerings of springs requiring around 40 N of force at this max compression, which in comparison to the standalone force required to inject the needle we deemed far too high. More specialized searches for springs did show further promise, as ones with lower and lower compression rates were found. **Table 6** shows the specifications for two potential springs as of this point.

| Option 1 | Option 2 |
|---|---|
| Length = 54.86 mm<br>Max Deflection = 46.23 mm<br><br>ID = 18.89 ± 0.2 mm<br>OD = 20.60 ± 0.2 mm<br><br>k = 0.088 N/mm<br>Max Compression Force = 3.52 N | Length = 57.15 mm<br>Max Deflection = 46.79 mm<br><br>ID = 19-20 mm, not explicit specification<br>OD = 21.46 ± 0.2 mm<br><br>k = 0.071 N/mm<br>Max Compression Force = 2.84 N |

**Table 6:** Two frontrunner spring options showing the specifications most critical to our design.

Both springs allow as much compression as we will need, plus room to spare depending on how far we decide for the guard to extend past the body of the device. As of right now our key needs for the diameter of the spring is for the outer diameter to be between 20-22 mm, with a minimum inner diameter of 18 mm, so both springs meet this need. The max compression force each would require during the extent we plan to compress the spring is notably higher than the 0.87 N to inject the needle into the skin, but is a huge improvement over the 40 N we were first seeing. Although there is still a question as to if this is too high, we believe either value would be low enough to be worth trying. For reference, the higher force from the two options of 3.52 N is about the same force it takes to hold a 12 oz canned drink, which we believe would be a reasonable amount of force to expect the user to maintain during the injection.
In regards to the friction between the spring guard and the body of the device, this is not a concern of ours. The dimensions of either can be altered slightly to loosen the fit between them, and ways to minimize the friction like lubrication can be used if necessary, and so we do not expect the friction to drastically change the force required to retract the guard or to stop the guard from pushing back out after use. One possible issue regarding this though is the tolerances in 3D prints being large enough this could become dependent from prototype to prototype, and so physical testing will have to be done on each iteration to ensure the friction force has not become too high to greatly alter the operation. We will move forward with one of these springs or another if a superior alternative is found, and this spring analysis has confirmed this aspect has potential and does not require a redesign.

Update: Spring 2 was chosen as we thought the wider OD might be the safer fit for our device, and we desired to keep the required force as low as possible.

Ensuring the spring operates as intended is essential to meeting our requirement on preventing needle stick injury, as the proper retraction and extension of the needle guard is how we plan to address this. This grows our confidence in meeting this requirement, but without enough testing to support that these springs exert the right amount of force this part of the design has not been completely de-risked. These springs we are currently exploring are intended to be a part of our final prototype, rather than just the initial iterations of it.

### 11.2 FMEA

To address our design concerns regarding user safety for both the injection device and the shoulder placement guide, we conducted engineering analysis in the form of failure modes affects analysis (FMEA). The framework used for this analysis is based on information from the "Engineering Analysis and Testing Block" [62] and a journal article describing FMEA's role as a patient safety tool [63]. FMEA was chosen over other safety analysis tools, such as risk matrices or hierarchy of controls, because it combines elements of the other tools for a more in-depth analysis. Risk matrices focus on ranking the likelihood and severity of a hazard [64] while hierarchy of controls visualizes ways to de-risk potential failures. FMEA combines elements of both of these by categorizing the severity and likelihood of a failure while also describing ways to reduce the risk. FMEA was used at this stage in the project because we had a more detailed idea of our devices but had not yet started fabrication so we would still be able to make design changes if we discovered any serious safety concerns. To conduct FMEA, we named the major components in our devices, their main function, potential failure mode, potential effect of that failure, potential cause of the failure, and steps that we plan to take to reduce the chance of that failure occurring in the future. Each failure was given a severity (S), probability of occurrence (P), and failure detection (D) score from 1-10 which were used to calculate the risk priority number (RPN). A higher RPN means that failure is more likely to occur in that component and may require a design change. We plan to focus on the components with higher RPNs so that we can minimize the failure risk of our overall design. The parts chosen for the injection device are the wide injection base, slot for syringe plunger, threaded cap, and spring. The results of the FMEA are shown below in **Table 7**.

| Part | Function | Potential Failure Mode | Potential Effect of Failure | S | Potential Cause | P | D | RPN | Recommended Action |
|---|---|---|---|---|---|---|---|---|---|
| Wide injection device base | Ensure 90 degree injection angle | Design is not compatible with all arm sizes | Injection is delivered at an incorrect angle, medication does not reach muscle, incomplete vaccination | 8 | Injection device base is too wide or not wide enough for certain arm sizes | 3 | 2 | 48 | Further testing of different base sizes on different arms. Research on anthropometric data regarding typical arm measurements |
| Slot for syringe plunger | Fully contain the syringe, allowing for depth control | Design is not compatible with all IM syringes | Syringe cannot be properly inserted into the device so depth is not controlled. Incorrect depth, incomplete vaccination, patient discomfort | 9 | Different plunger shapes and dimensions | 8 | 1 | 72 | Prototype testing with different syringe sizes. Additional design ideation |

| Part | Function | Potential Failure Mode | Potential Effect of Failure | S | Potential Cause | P | D | RPN | Recommended Action |
|---|---|---|---|---|---|---|---|---|---|
| Threaded Cap | Control injection depth | Cap doesn't move as expected, doesn't stay in place, or is difficult to accurately adjust. | Too much or too little needle is exposed and injection depth is incorrect. Can cause incomplete vaccination and patient discomfort | 9 | Issues with the cap threads such as misalignment, stripping, or poor manufacturing | 5 | 5 | 225 | Durability testing with prototypes of the cap design |
| Spring | Ensure the needle is covered when not in use and easily uncovered when in use. | Needle is difficult to uncover (too much force required) or needle is not fully/quickly covered when not in use | Injury to both patient and injection administrator. Needle stick injury, transmission of bloodborne pathogens, force related injuries, incomplete vaccination | 10 | Spring constant is too big (too much force required to expose needle), or too small (needle is not fully covered) | 7 | 4 | 280 | Further engineering analysis regarding spring constants. Potentially additional design ideation |

**Table 7:** FMEA for the injection device. The highest RPN is highlighted.

The highest RPN for the injection device was from the spring. Moving forward, we plan to continue our spring analysis to mitigate this risk. The parts chosen for the shoulder placement guide are the injection guide, shoulder pad, side strap, and shoulder strap. The results of the FMEA are shown below in **Table 8**.

| Part | Function | Potential Failure Mode | Potential Effect of Failure | S | Potential Cause | P | D | RPN | Recommended Action |
|---|---|---|---|---|---|---|---|---|---|
| Injection Guide | Indicate appropriate area for injection | Guide does not indicate the correct injection area | Injection is given in the wrong location. Patient injury, nerve paralysis, incomplete vaccination | 10 | Injection guide is too big or small for some arm sizes | 3 | 7 | 210 | Fabrication of prototype and testing on various users. Research into variation of arm sizes among targeted users |

| Part | Function | Potential Failure Mode | Potential Effect of Failure | S | Potential Cause | P | D | RPN | Recommended Action |
|---|---|---|---|---|---|---|---|---|---|
| Shoulder Pad | Allow device to be comfortable and stable on patient's arm | Device is installed or uncomfortable on patient's arm | Device moves during injection, causing it to be given in the wrong location. Can lead to patient pain, nerve paralysis, and incomplete vaccination | 10 | Shoulder pad is not compatible with different arm sizes/shapes | 5 | 5 | 250 | Fabrication of prototype and testing on various users. Research into variation of arm sizes among targeted users |
| Side Strap | Set vertical distance between injection site and Acromion process | Straps place injection guide too high or low on patient's arm | Injection is given in the wrong location. Patient injury, nerve paralysis, incomplete vaccination | 10 | Side strap length is not compatible with different arm sizes | 1 | 5 | 50 | Fabrication of prototype and testing on various users. Research into variation of arm sizes among targeted users |
| Shoulder Strap | Attach device to patient, allowing for different arm sizes | Shoulder strap is too loose or tight on patient | Injection guide could shift during the injection if the strap is too loose. If too tight, strap could cause discomfort to the patient | 10 | Shoulder strap is not compatible with different arm sizes | 2 | 5 | 100 | Fabrication of prototype and testing on various users. Research into variation of arm sizes among targeted users |

**Table 8:** FMEA for the shoulder placement guide. The highest RPN is highlighted.

The highest RPN for the shoulder placement guide was from the shoulder pad. Moving forward, we plan to continue with research and fabrication of our prototype so that we can conduct user testing, reducing the risk of failure.

Overall, the results of this FMEA has shown us what components we need to focus on as we move forward with prototyping and user testing. Although this analysis has yielded some helpful results, its effectiveness is limited by our knowledge of what failures could happen and what consequences they could cause. Based on the results of this analysis, our design seems functional and the recommended risk-reducing actions we have described are well within the scope of this semester. At this time, we do not plan to conduct other types of risk/safety analysis however, we plan to revise this analysis as we prototype and test.

### 11.3 Side Strap Length Selection

The side strap lengths were selected to ensure consistent placement of the injection guide relative to the acromion while minimizing user error. Clinical guidance from the Centers for Disease

Control and Prevention recommends locating the deltoid intramuscular injection site approximately 2–3 finger breadths below the acromion, corresponding to the central region of the deltoid muscle [10].

Anthropometric data indicates an average hand breadth (four fingers) of 79.4 mm, based on measured population data [65]. Approximating three-finger breadth as 3/4 of this value gives: 59.55mm.

This aligns with the expected adult landmark range and confirms that the required offset varies within a relatively narrow band.

To simplify use for minimally trained users and reduce variability associated with continuous adjustment, two discrete preset positions were selected:

- 1.8 in (youth/small)
- 2.4 in (adult)

These values span the clinically relevant range while maintaining a slight lower bias, as injections placed too close to the acromion increase the risk of improper placement, including bone contact or shoulder injury. The use of two preset positions balances anatomical coverage with ease of use, improving repeatability and reducing the likelihood of user error.

# 12. VERIFICATION AND VALIDATION

### 12.1 Current Scope: DR3

Once we finish our prototyping and initial testing, we will move into verification which involves comprehensive testing of the device to make sure that our requirements and specifications are met. After we have verified the device, the next step would be validating the device to ensure that the device is a solution to the sponsor's problem. For our project this would involve coordinating with Michigan Medicine to conduct larger clinical studies. As of DR3, it is not currently within our plans to conduct validation testing before the end of the semester. Post-validation the next steps would involve seeking FDA approval, which is also not within our current scope for this semester.

### 12.2 Current Scope: End of Semester

After completing our final prototypes for both the injection and location device, verification was performed. This included needle insertion angle, depth, and distance from the injection site as well as a usability test involving subjects who have not received formal medical training. These conditions were chosen to mirror those being targeted by the device, where the vaccination process is task shifted to less than nurse level health care workers. Validation such as clinical trials and FDA approval remain beyond the scope of this semester and have been handed off to our sponsors.

### 12.3 Verification Plans: DR3

Prior to beginning our testing we created verification plans. Our full traceability log of our verification and validation plans can be seen in Appendix D.

For our requirement of preventing needle stick injury, we have two specifications. One requires that the needle be fully covered in ≤1 s post injection. We plan on using simulated injections into simulated skin made from silicone and measuring the time it takes for the needle to be covered. This testing method comes recommended by our sponsor, Dr. Thiyag, as an alternative to using a more developed skin simulator [7]. The limitations and uncertainties for this method stem from how silicone would act differently than real skin in a testing environment and how this may affect the covering and uncovering of the needle. Our second requirement is that the needle can not be exposed at all when not injecting. This verification will come from our design intentions and the quality of manufacturing. The limitations of this method stem from how the covering of the needle would interact differently with skin verses with the silicone. The validation of this requirement will involve a larger study to determine if the design truly prevents needle stick injury.

For our requirement of allowing the correct injection speed of the vaccine, we have one specification. The specification requires that the device allow for the vaccine to be administered at 10 sec/mL. The verification method will be testing the prototype with a syringe and timing the injection speed to determine if 10 sec/mL speed is feasible on the device. This verification method is in line with CDC and WHO recommendations for safe vaccine administration [15]. The limitations of this verification is that it would not test a realistic tissue resistance to the injection. This would only be possible with more advanced testing. The validation of this requirement would require a larger study to determine if the design allows for the safe and proper injection speed in a more realistic setting.

For our requirement of ensuring the correct angle of injection, we have two specifications which will utilize the same verification method. The first specification states that a 90°±3° angle of injection be maintained during injection, and the second states that the device shall maintain the angle constraint for at least the first 15 mm of insertion, in ≥ 90% of trials. This will be best tested using the same simulated injections as the needle stick injury requirement as recommended by Dr. Thiyag. The limitation of these tests will stem from the silicone having different properties than the muscle tissue. The validation of this requirement will require a larger clinical study to determine whether the device ensures the correct angle of injection.

For our requirement of ensuring the correct injection depth, we have two specifications. The first specification states that the device shall maintain the target insertion depth within ± 2 mm during use under simulated skin and muscle conditions. The second specification states that the device shall include an adjustable depth feature to accommodate youth and adult patients. This will also be conducted with silicone of varying thickness in order to determine whether the device is able to be effectively adjusted and maintained to the correct injection depth. The limitations of this test will stem from the different properties of the silicone from the tissue. The validation of this requirement will require a user study to determine whether the device ensures the correct depth of injection.

For our requirement of ensuring the correct injection site on the deltoid, we have one specification. The specification states that in simulated-use testing, ≥ 90% of users can place the device such that the needle is within ±10 mm of the center of an approved deltoid injection. The verification test for this specification will involve observing the use of the device prototype,

likely by other x50 students or other untrained individuals to find if they can determine the correct location. The limitations of this test come from that most of the subjects of the observation will be university students which may not give an accurate assessment of how the device will be utilized. The validation of this requirement would require a clinical study to determine whether the device would assist in determining the proper location of the injection on the deltoid.

Our requirement of being easy to use with minimal training has three specifications. The first specification requires a user with ≤ 15 minutes of training shall successfully complete a simulated injection task. Training materials are not currently within the scope of our project. The verification testing for this specification would involve training x50 or other University of Michigan students to use the device. The limitations of this test would again be that the users would be university educated individuals and possibly not representative of the intended users. The second specification is the device shall require ≤ 5 discrete steps to complete use. The verification for this will come from our design intent to make the device simple, and we will test this through the same training testing involving University of Michigan students. The limitation with the test is similar to the previous as we will be training university students who may conceptualize the number of steps required differently from the intended users. The final specification is that the device has a System Usability Scale (SUS) score of ≥ 80 when tested by targeted users. This follows ISO standards for usability and consists of a questionnaire for intended users. We will be once again utilizing x50 and other University of Michigan students. The limitation again stems from students being different from the intended user.

At this time we still need more development for verification on 6 of our 12 requirements. The durability requirement includes the specification that the device shall withstand ≥ 300 use cycles without functional failure. We are still researching ways to effectively test this requirement in a reasonable amount of time especially with the goal of having multiple trials. The universal compatibility requirement for syringes and needles will likely be verified by our design intentions though, as previously stated, we are currently designing for a singular syringe and not actively pursuing this requirement which was deemed appropriate by our sponsor, Dr. Thiyag. The repairability requirement and sanitization requirement will both require more ideation for the verification though the validation will require a larger usage trial. The cost requirement includes the specification that the device shall have a production cost of less than $15. This verification is done through our design intent and cannot be validated until the design moves into the production phase. The site selection requirement for the thigh location is another requirement that we are not actively pursuing as it was deemed as a low priority and would have required more concept development and likely an entirely different design of site selection device.

### 12.4 Verification Testing: End of Semester

Verification testing was performed with six participants; training consisted of a physical demonstration of the devices in tandem and reading of the manual developed for these. The total time for the training was under five minutes and was implemented in a group setting. Following the training, each participant performed the following tests individually: needle insertion angle, needle insertion depth, distance from center of injection site, and usability testing.

For the measurable testing on a silicone tissue analog (**Figure 32A**), i.e., angle, depth, distance, participants completed 3 trials each, during which data was collected (Appendix F). The results of these tests are discussed in the next section. Usability testing was conducted holistically, with the participant performing the entire procedure described in the Training Guide (Appendix E) on a patient volunteer (**Figure 32B**), albeit without the needle to ensure both participant and patient safety. Each participant was subsequently interviewed and answered the standard usability testing questions and scoring [50] before being asked to provide additional comments regarding their experience using the devices.

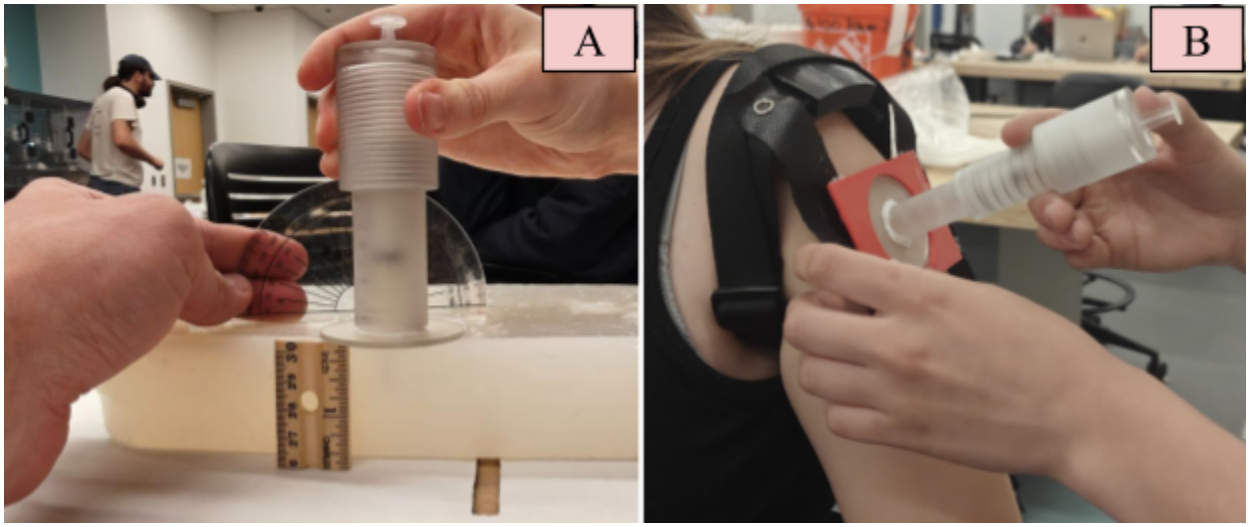



**Figure 32:** A: Testing being conducted using silicone tissue analog, B: testing being performed with a patient volunteer.

### 12.5 Verification Results

All results of the usability and simulated testing from the participants can be seen in Appendix F, while summarized results can be seen in **Figure 33** where the error bars represent the standard deviation divided by the square root of the number of trials (standard error) across each participant's trials. The status of each specification relative to its verification can then be seen in **Table 9**, an excerpt from Appendix D.

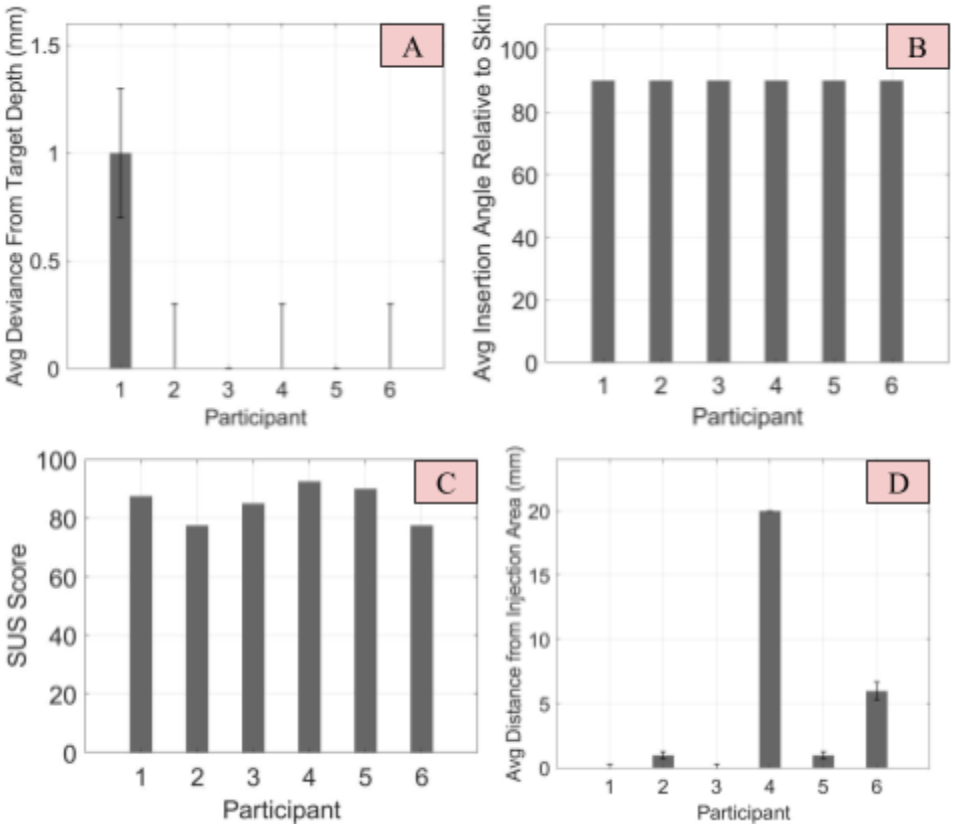



**Figure 33:** A: Data relative to each participant of average deviance away from the targeted injection depth (top left), B: average insertion angle relative to injection surface (top right), C: the system usability score (bottom left), D: the average distance away from the center of the correct injection site (bottom right).

From the simulated use testing, the average deviance from target depth across all users was found to be 1 mm, meaning the specification regarding maintenance of correct injection depth was passed, although this test did see some issues. The markings on the device that would denote the correct injection depth were mistakenly put in the wrong spot, forgetting to account for the thickness of the needle guard and how that would affect the depth. This made all injection depths off by 2 mm more than what is shown in **Figure 33**, but once accounting for the incorrect markings we can see the device injected to the desired depth for all users. The insertion angle relative to the skin was recorded at 90 degrees for every trial, meaning we passed the specification for the device constraining the angle relative to skin surface. The average system usability scale (SUS) score across all participants was 85, passing our specification of >70 across all users. The average distance away from the targeted injection site for each user showed that one third of the users could not get within 10 mm of the center of the injection site, meaning we failed our specification of having >90% of users within 10 mm of the correct injection site. For one of the users, they routinely placed the location device in the correct spot, while another user struggled to consistently place the device but was operating on a patient that was very small, adding difficulty. All users were trained in under 15 minutes via the training guide, passing the specification on training time.

| Specification | Status | Specification | Status | Specification | Status | Specification | Status | Specification | Status |
|---|---|---|---|---|---|---|---|---|---|
| After completing an injection, the needle shall be fully covered within ≤ 1 s. | Pass | Maintain desired depth ±2 mm during use | Pass | The device shall accommodate standard 0.5 mL, 1 mL, and 3 mL syringes from multiple manufacturers. | Fail | System Usability Scale (SUS) score of ≥ 70 when tested by targeted users. | Pass | Marerials are non-porous and durable, allowing for repeated sanitization with low- to intermeddaite-level disinfectants. | Pass |
| The device shall have 0 mm of exposed needle when the device is not actively performing an injection (before and after use). | Pass | Includes adjustable depth feature | Pass | The device shall support intramuscular injections using standard needle lengths of 16-38 mm. | Pass | The device does not require access to a reliable power supply. | Pass | Device design allows for sanitization of all surfaces that contact the patient in less than 2 minutes. | Pass |
| The device shall allow the vaccine to be administered at the rate of 10 seconds/mL. | Pass | In simulated-use testing, ≥ 90% of users shall place the device such that the needle is within ±10 mm of the center of an approved deltoid injection. | Fail | A user with ≤ 15 minutes of training shall successfully complete a simulated injection task. | Pass | Device can be repaired in ≤ 15 minutes by an average user. | Inconclusive | The device shall have a production cost of less than $15. | Inconclusive |
| Device constrains angle to 90±3° relative to skin surface | Pass | The device shall withstand ≥ 300 use cycles without functional failure. | Inconclusive | The device shall require ≤ 5 discrete steps to complete use. | Fail | Device can be repaired using ≤ 3 basic tools. | Pass | In simulated-use testing, greater than 90% of users shall place the device so it would inject within 30mm of the approved anterolateral thigh injection site. | Fail |

**Table 9**: The verification status of each specification. The priority of the specification descends down the first column, then continues at the top of the second column, and so on.

The specification on 0 mm of exposed needle when not performing an injection is passed by design, as the needle guard will always be in a forward position unless pushed back by the user. The specification of administration at a rate of 10 seconds/mL was met by design, as syringes are already capable of this and the design does not interfere with this function. Compatibility of the device with syringes of various sizes from various manufacturers is failed by design, as we had made the choice to focus our design to fit one syringe with the hope of later being adapted to other sizes. The devices have failed the specification for <5 discrete steps to use, because as shown in the training guide found in Appendix E, there are more steps than 5. For the repair requirement, the specification of no access to power supply is passed by the design, as well as the specification of being able to be repaired with less than 3 basic tools for if no new parts are needed to be manufactured the device can be assembled without tools. For the sanitization requirement, the specification of non porous and durable materials is passed by the design choices to be made entirely of plastics. The specification regarding the correct injection site for the thigh was failed by design, as we chose to focus our time on creating a device for deltoid injections rather than thigh, and the device can not be used on the thigh.

For the specification regarding the needle to be covered in <1 second of use, we ran 10 test trials of fully retracting the needle guard, and saw that each time the guard would go back to the extended position within 1 second, passing this specification. The specification for the devices to be sanitized in under 2 minutes was tested 10 times, where a team member would rub a paper towel (representing a sanitizing wipe) on the surfaces that would come in contact with the patient, and in each test the process was done in under 2 minutes, passing this specification.

Durability can be evaluated through repeated use testing by cycling the device through at least 300 simulated uses, this would include adjusting the shoulder strap, assembling and disassembling of the injection device. This can be done manually or with a simple test setup to replicate typical user interactions, but we did not pursue this as we did not have time to push our only prototypes to failure. Repairability can be tested by timing how long it takes an average user to fix a common issue, such as reattaching a strap or replacing a rivet using a simple rivet tool. For the injection device, damaged parts would be replaced rather than repaired. The total time should be under 15 minutes without specialized tools.

| Participant | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| Comments | - Difficult to depress syringe | - Wants tactile feedback for syringe lock<br>- Wants visibility of syringe to know fully depressed | - Thought device was very sturdy<br>- Liked not interacting much with uncapped needle | - Learned that needle cap could be put back on safely while syringe was in device | - Wants detent for injection depth and syringe-in-cap mechanism<br>- May want to be able to lock syringe into cap without holding needle side, but felt safe | - Was confused by the instructions at many points (admitted to being quite behind on sleep and not attentive) |

**Table 10:** Summary of additional comments left by participants of proxy usability tests.

Looking into the additional comments left by the participants from the proxy usability tests (**Table 10**), we can find a few themes that show strong and weak points of our devices. Multiple participants commented on the success of minimizing the interaction with the uncapped needle, yet one participant did feel uncomfortable holding the needle side of the syringe while locking it into the device cap. This was not the only comment left expressing dissatisfaction with the locking mechanism, where we can see people would like a way for locking the syringe into the cap that would make them more confident it was securely in place. We were also told that being able to see the syringe was desired, and this is something that we know would ideally be a part of this device, but were not able to successfully include in this prototype. There was also some confusion mentioned on the training guide where the participant noted they may have not been the most attentive, yet this comment still holds value. These comments overall allow us a better view into how users felt about the device, and raise awareness of aspects that may need improvement such as the locking mechanism and the training guide.

We believe the results of this verification do show that this design has promise. There are many areas for improvement such as the location device, the syringe compatibility, and some more minor things within the injection device, but the injection device has overall met our

expectations. Our testing has not been as comprehensive as would be desired, in the future there would need to be many more participants involved who ideally do have some background in the health care field, with testing conducted on a broader range of patients. That said, we believe the methods we followed with the resources we had were sufficient enough to provide valuable insight into the use and operation of both of the devices, showing that the concepts do have potential with further iteration.

### 12.6 Validation Plan

As stated previously, the validation testing, including but not limited to clinical trials, will be handed off to our sponsor and will not be conducted by the team prior to the end of the semester.

According to NIH recommendations regarding approval of medical devices, clinical testing usually proceeds through a sequence of studies, starting with first-in-human evaluations and advancing to large, multicenter, prospective randomized controlled pivotal trials. Pivotal trials may enroll up to 1,000 participants, run for 1–2 years, and include approximately 1 year of post-treatment follow-up. The scope and complexity of these trials depend on the type of device and its intended use [66]. These clinical trials will test the outcomes of our device rather than the specifications. The primary concerns for these clinical trials will be the safety of the participants and the efficacy of the vaccine when administered under these conditions.

Along with clinical testing, validation would involve a summative usability test. Summative usability testing involves attempting to recreate the specific use environment for the device. It would likely begin with attempting to recruit representatives who match the ultimate intended users. For this assist device, it would be non-nurse level trained healthcare workers, who would be similar in education level to the workers who would be using the device in low-resource settings. Along with replicating the users, summative usability testing would involve replicating the specific setting in which the device would be used. In this case, this would be attempting to replicate the resources and environment of a smaller local healthcare clinic in a low-resource country. Summative usability also relies on minimal additional training, focusing on specific tasks which affect safety, and specific use errors. For our purposes, this would likely focus on relying on the provided training guide, preventing needle stick injury, and ensuring that the vaccine is properly administered to ensure complete vaccination and minimal injury due to the vaccine itself [66].

### 12.7 FDA Clearance

The FDA currently requires that medical devices be classified into one of three classes [60]. Class I is the lowest risk category of medical device. Class II devices are considered to be of moderate risk to patient/user. Class III medical devices are the FDA's highest-risk devices, which are often life-sustaining or implanted.

The location aid device would likely be classified as a Class I device similar to bandages and blood pressure cuffs. The location aid presents little risk to the patient/user and utilizes well understood technology. As a Class I device, FDA approval would require that the location assist device be subject to General Controls, which consist of rules relating to facility registration and device listing, proper labeling, quality manufacturing practices, and required adverse-event reporting, to help ensure devices are made and marketed safely. Class I devices are often exempt from 510(k) premarket submission. A 510(k) premarket submission is where a company shows

its medical device is substantially equivalent in safety and effectiveness to a legally marketed predicate device.

The injection assist device would likely be considered a Class II device. This is consistent with previous benchmarked items such as the Inject-Ease and the BD Physioject. This device would be considered to present a moderate risk to the patient/user. Along with General Controls, Class II devices are subject to Special Controls which are device specific and often include rules concerning postmarket surveillance, patient registries, and special labeling requirements. Class II devices would most likely require a 510(k) premarket submission. Class II devices require clinical trial evidence to be considered for approval [66].

# 13. PROBLEM DOMAIN

### 13.1 Problem Domain Analysis: DR2

Our end goal for this semester is to create a working prototype of the injection and location devices along with a training protocol to use them. It will be a challenge to achieve all of this in the remaining time we have, but our early prototyping and testing has given us a start for the devices, yet it cannot be said for certain how much iteration it would require to get to the desired point. Research has already been done into the training protocol, and an idea developed as to what it contains, but it cannot be fully developed without a better understanding of the final designs. Our design is driven by the requirements to make the correct injection site, angle, and depth more attainable for non-nurse trained health care workers while maintaining patient and user safety. As of this point we believe to have a strong start on a way to assist angle and safety from needle stick injury during injection, but have much to be accomplished for site selection and injection depth. Site selection has seen some early prototyping and an emphasis on concept exploration, but still needs much more progress to see full realization. Although ways to control injection depth have been explored, none have been incorporated into our current frontrunner designs and leaves a large gap in what needs to be accomplished. We believe that we possess the knowledge to further site selection and injection depth assistance, and the biggest issue as of this point is incorporating these aspects into our project. We must continue concept development to address and fix these issues, making use of our sub function organization chart and site selection ideation map to incorporate what we have determined as potential solutions.

With the knowledge we have attained up to this point, we foresee no need for specialized equipment to reach the desired point of our project, yet still need more knowledge and insight into technical experience. Our largest gap within this is the lack of input from trained nurses into what they see as a successful task shifting device, and we plan to address this through contact with University of Michigan medical staff. We have gained much understanding into the medical operations of some low/middle income countries and what should be expected within the realm of available equipment for maintenance and sterilization, yet we still would benefit from knowing more. Through discussion with Isabel Reynoso and Dr. Thiyag we better understand how these resources are limited, and know how to design with a limited use of these resources, there is still some ambiguity that is likely to remain unresolved as there is no exact definition of what is available since it will be too dependent on location.

### 13.2 Problem Domain Analysis: DR3

Much progress has been made on the injection device and the location device. Both have seen much progress through the CAD models, helping us get a better understanding of dimensions and materials involved with the models we will make in class and the mass manufacturing versions of the devices. The injection device specifically has much improvement in how it handles injection depth, but this aspect has yet to see any testing. We do not believe any analysis must be done on this aspect prior to prototype testing, yet without any information on it we have no concrete evidence supporting the planned method. The location devices main improvements have been selection of materials, as this was one of the bigger questions regarding the system. Both devices have had FMEA conducted, allowing us a specific view into what we should put the highest attention into to de-risk.

A large change in the end goal for the semester is that we have put the requirement to make the device fit all syringes to the side for now. We are specifically designing for the BD 3mL Leur-Lok syringe, and ultimately would like to see variations of the design for other syringes or this one altered to fit multiple different kinds, but we chose to push this back so we can ensure we see the realization of our design for at least one syringe type. Another change is that we believe we may not be able to create a full training protocol for the device in our allotted time. This would still be essential to the usage of the device, and so we will plan to include all that is necessary to use it within these reports, but may not have the time to develop a true finalized product for the guide.

### 13.3 Anticipated Challenges: DR2

Our largest challenges we face at this point is the incorporation of injection angle control and a site selection device. Both of these feel to be lagging behind the emphasis on injection angle and user/patient safety we have placed on our designs at this time. It will be a challenge to continue the design generation and development process for these components, yet making use of our previous work and methods gives us a path to follow moving forward. Getting the input we need from nurse trained health care workers will also be a challenge, yet we believe through use of other UM contacts this is an attainable goal. On top of this we still have not fully addressed what our design needs to fit the common syringe sizes by different manufacturers. We have an understanding of what will change between syringes, yet exact measurements still need to be attained. Gaining this information should be attainable through research, yet all the information we desire may not be readily available, leading us to either purchasing syringes from different manufacturers or attempting contact with them. And it is still uncertain how this will ultimately play into our design. Can we create one device that fits all syringes? Will we need to make different versions of the same device? If so can this be achieved by simple scaling of some aspects, or will this require fundamental changes across iterations? Overall a great challenge looking forward, where our key next step is the acquiring of information on measurements and sizes to answer these questions.

### 13.4 Anticipated Challenges: DR3

As of right now, our biggest challenge is arguably time. If we hope to fully develop the design, we will have to cut back on things like universal syringe compatibility and the training guide for the devices. One of the largest anticipated challenges is getting a sufficient amount of tests in, like finding the correct base plate size of the injection device, and then verify all the

specifications for this device as well as the location device. Getting enough participants, specifically people in the health care field, is still a challenge with our lack of connections, and admittedly no progress has been made here at this point. Overall, the greatest challenge is de-risking and verifying our design, but this boils down to time for analysis and testing. Besides the participants, we do not feel as though we have a lack of resources to accomplish this.

# 14. DISCUSSION

### 14.1 Problem Definition

If we had more time and resources to better define the problem, one of the main questions we would address is: what are the resources available at health care centers in low- and middle-income regions? Although there are many references regarding ideal intramuscular injection procedures, we found that they do not always translate to the realities of healthcare delivery in these regions. For example, we initially operated under the assumption that the injection depth would be correctly controlled by needle selection, as described in CDC and WHO guidelines. However, discussions with our sponsor revealed that in low-resource settings, typically only one needle/syringe size is used and the depth is left to the administrator's discretion. Ideally, to fully understand the situation, we would conduct interviews with healthcare workers who would be using the device to better determine what training they receive, what medical supplies they have access to, and the typical workflow of an injection in that setting. However, we were limited by the project's timeline and such interviews, unfortunately, did not fall within the scope.

Further research to define the problem would also strengthen the requirements developed for this project, specifically those regarding durability, ease of use, repair, and sanitization. As we are not fully satisfied with their current state, these requirements could benefit from additional knowledge of the specific use-case scenario for this device. The current durability specification is based on sponsor interviews and general medical standards; however, because available literature is relatively broad, this specification should be further refined. The ease of use specifications were primarily developed from general guidelines regarding medical devices rather than specific quantitative guidelines and could benefit from additional research. Ease-of-repair specifications are derived from general information regarding tools and personnel in low-resource settings. However, we recognize that these environments vary significantly, necessitating a targeted, site-specific approach that requires additional research and stakeholder interviews. Finally, although the sanitization specifications reflect sanitization standards from the CDC, it is still unclear what kind of cleaning resources are available in the target setting.

### 14.2 Design Critique

Overall, we are satisfied with our current design although we do recognize that there are still several areas for improvement. The most notable strength is how easy it is to learn and use, based on feedback from the proxy usability test that we conducted. The high system usability score and other positive feedback from this testing makes us confident that our design can be used safely with little training which is crucial for a task shifting medical device. Another strength is that although the device did fail some of the verification usability tests (depth, location), the discrepancies were primarily due to marking and instructional errors on our end, rather than the device itself. We believe that these issues would be easily fixed with a future

higher-fidelity prototype or mass-manufactured model with tighter tolerances. When accounting for these mistakes, the device easily passes the verification testing for all of our highest priority specifications.

The most significant weaknesses in the design is that it has limited syringe compatibility. It was built with only one syringe in mind when ideally, it would be compatible with any syringe used for any intramuscular vaccine. As such, universal syringe compatibility would be our primary focus if we had more time. Additionally, the site selection device may add unnecessary complication to an already fairly straightforward injection process. Current practice requires administrators to locate the acromion process and inject several finger lengths below. Our location device still requires the user to locate the acromion in order for the device to indicate the correct injection site. Therefore, the vaccine administrator still has to accurately landmark which may negate the helpfulness of the device. Finally, the prototype presented in this report and used for the verification testing is somewhat rough due to tolerance and post-processing issues during the 3D printing process. For example, some of the components were over-filed leading to loose connections and the depth demarcations were made without accounting for the thickness of the base, leading to incorrect injection depths during testing. However, we believe that many of these issues could be easily addressed by another round of prototyping.

### 14.3 Risks

Throughout this process, the biggest challenge we've faced has been understanding the setting this device would be used in and what it really needs to accomplish. Misunderstanding the project's scope caused several missteps, especially during the design generation phase where we either focused on elements that were later found to be inconsequential or ignored elements that were very important. For example, several of our early designs involved apparatuses that controlled the injection speed but discussions with our sponsor later revealed that simply having the administrator count would be acceptable. We also struggled with site selection designs as we originally thought we had to completely eliminate any landmarking. However, our sponsor later told us that requiring landmarking of a bone rather than a muscle would still be helpful for task shifting. Finally, as previously mentioned, early designs ignored depth control which turned out to be very important. To mitigate the risk of us missing important design elements or over-complicating the design, we made sure to communicate often with our sponsor. We also conducted proxy usability testing to determine if individuals unfamiliar with the project could safely use the device.

As a medical device, the risks associated with the end-user are very serious because a device malfunction could cause severe injury to the patient or injection administrator. As mentioned in section 12, full validation for this device would require rigorous clinical trials, usability testing, and FDA clearance that would hopefully identify any serious safety risks before mass production.

## 15. REFLECTION

This section serves as a revisitation and update of the key concepts explored within section 4, from the perspective of reaching the end of our time on this project.

### 15.1 Societal Analysis

As was anticipated at the beginning of the project, public health, safety, and welfare was the core of our work. The goal of our project was to improve all these aspects through the creation of a device that would make vaccinations more attainable. Our verification testing has shown that our combined devices are not perfect, but have potential to successfully administer vaccines, and through our proxy usability testing it has shown that these devices are usable to non-nurse level trained individuals. Again, they are not perfect, but these devices do seem to serve the purpose of allowing non-nurse level trained health care workers to administer vaccines, meaning more people have access to vaccinations, and therefore increased public health.

This project was specifically done to serve a global marketplace, where these devices would serve the best purpose in low/middle resource countries. If the devices were to become mass manufactured and have widespread use in these countries though, there would be a degree of negative impact. Using these devices would only increase the waste and manufacture involved in the vaccination process, as these devices are meant to be used with a standard syringe that is disposed of after every use. If many of these devices were made and more vaccinations were administered, this would only cause an increase in energy consumption, carbon footprint, and filling of landfills. See section 4.5 for our estimates on the degree of this impact. The manufacturing and disposal of these devices could also serve a degree of negative societal impact, as more waste and an increased carbon footprint can have a harsh effect on the quality of life in the regions where it is developed and used. Yet we do believe the positive social impact from use of the devices through public health and safety outweighs the negative impact from the manufacturing and waste. Widespread manufacturing and use of these devices can also serve positive economic impacts, as the companies manufacturing and handling waste will see more business, and the communities using the devices will have a healthier workforce able to boost their economy.

To reach these conclusions regarding impacts of the device, a variety of tools was used. We started with stakeholder mapping to ensure we were considering all parties affected, and if they would generally be parties involved in, in support of, or against our solution. This was used to address public health as well as societal impacts. For the environmental impacts, a rudimentary analysis regarding the manufacturing was performed. Further explained in section 4.5, this was done mainly in regards to the prototyping of the device, with an acknowledgment to the mass manufactured version of the devices but limited by our capabilities of accurately modeling these processes. A much more in depth life cycle analysis could be performed, aided by an eco audit, to truly understand the numbers behind the impact from manufacture and disposal of market ready versions of our devices, yet was not performed by our group as we decided to focus our efforts on the development of the solution instead.

### 15.2 Team and Sponsor Dynamics

Cultural, privilege, identity, and stylistic differences among our team played a minimal role within our project. Although not every team member has the same background, there were no prevalent ways in which this seemed to negatively affect our work, as team members seemed to share similar views on how to approach the problem and the different stages of work. One positive impact from these differences was one of our team members' experience regarding vaccinations. They had previously administered vaccines, and so understood aspects of the

process which the other team members did not, providing valuable insight into how to approach this problem. The differences caused by this experience allowed us to better understand the needs of the patient and user of the devices, which served to guide some of our design decisions.

Cultural, privilege, identity, and stylistic differences between our team and our sponsor played a positive role within our project. Dr. Thiyag had much more experience regarding healthcare, low/middle resource countries, and vaccinations in general, serving as a great difference in backgrounds. These differences influenced our final design greatly, as we were able to better understand what would be needed to control injection depth and assist in locating the correct injection site. Constant communication and feedback from our sponsor served to improve our design process, as it would raise awareness of new things that needed iteration, and our final design would not be the same without the differences in background between our team and our sponsor. The power dynamics between us and our sponsor were minimal, but did play a role in the outcome of our project. Dr. Thiyag had visible power over our approach to the project, as we would directly follow our sponsor's guidance and input regarding the design, but we believe this has only positively affected the outcome of our work.

Within our project as a whole, the needs of the users had hidden power over the desires of the sponsor in our work. Our project attempted to create an invited space where stakeholders of all kinds can provide their input into our project and no power need override another group's power for the influence of our project, but we admittedly did have minimal stakeholder engagement as they were not easy connections to make within our time frame. When making decisions on the project, if there was any uncertainty, an approach would be taken to compare options fairly (tools like comparison charts or listing pros/cons of various options), instead of something like a majority vote when not all teammates saw eye to eye. Our decisions were then guided by what we knew would be in the best interest of our stakeholders, with key information coming from our sponsor. And our perspectives on these decisions were mainly shaped by our Michigan engineering background and information from our sponsor, which would be different from the end users perspective yet in an attempt to understand it.

**15.3 Ethics**

We did not feel as though we encountered any ethical dilemmas during our work. The goal we were aiming for was based on the ethics of helping people, and there were no points during our process in which we faced a situation where this goal must be adjusted, or any points that disagreed with common ethical practice. We acted honestly and reported our work honestly, with strong effort towards making our design as inclusive as possible. If our product entered the marketplace, the main ethical dilemma that would ensue would be the misuse of our product, as it could be used for various illegal and unsafe injections. This would need to be addressed by controlling the distribution of the product, and only allowing it to be sold to qualified health care institutions. As previously discussed, there would be some ethical debate over our product's negative environmental impact, but again, with the positive social and public health benefits involved we believe ethics would still drive this product to being adopted.

During our work, we believe our personal ethics and practices to have followed the ethics of University of Michigan engineering, as well as what would be expected from future employers

due to our societal awareness and honesty within our work, and we plan to uphold this for all of our future work.

# 16. RECOMMENDATIONS

Based on the feedback gathered from our sponsor and the participants of our usability study (**Table 10**), we recommend several design alterations to enhance the operation of the device as well as user confidence. Users felt that positive feedback during the insertion of the syringe into the cap would help them feel more comfortable with the syringe being accurately fitted to the cap. To address this, we suggest adding either a tactile detent or colour indicator to the cap which will allow the administrator to see that the syringe is correctly located. Improvements to the training manual may also include more explicit instructions regarding the twist-to-lock mechanism of the cap, particularly instructing the user to twist the syringe by its body as opposed to the rotating plunger, as most users were prone to do without additional instruction. The current design also assumes that the administrator will recap the syringe before disposing of it in a sharps container; we recommend that ideation be conducted around a design change that will allow the user to remove the syringe safely immediately after injection without recapping. Additionally, further development of the cap to accommodate a broader variety of syringes is necessary for more comprehensive implementation of the device across a diverse clinical setting.

# 17. CONCLUSION

## 17.1 Project Objective and Public Health Impact

This project aims to develop an intramuscular (IM) injection assistance device that will enable healthcare workers with less than nurse-level training to safely and effectively administer a variety of life-saving vaccinations in low-resource settings. Task shifting using this device will address critical shortages of healthcare workers with at least nurse-level training in low- and middle- income countries. Success in this project will directly benefit patients and their families by reducing complications due to improper vaccine injections and will decrease the likelihood of disease transmission within these communities. Beyond individual health benefits, the device may support local economies by increasing the health of the workforce and will contribute to vaccine manufacturers by increasing demand for their immunization product. To guide our goals for this device, we are centering our targets around the World Health Organization’s target of vaccinating 90% of girls in Ghana against HPV by the age of 15 to dramatically reduce the occurrence of cervical cancer.

## 17.2 Safety and Technical Standards

We seek to prioritize patient and provider safety by addressing key causes of injection related complications including the angle, depth, and site of the injection as well as the prevention of needle-stick injuries by ensuring the needle is not exposed immediately preceding and following the injection. Our specifications are grounded in CDC and WHO guidelines as well as ISO standards for sterile needles and sharps injury prevention.

## 17.3 Future Design Challenges and Sustainability: DR3

Analysis of our current design pool has shown that we are still lacking when it comes to designs addressing site selection and needle depth, requiring additional ideation and development in

these areas. A particular challenge of the site selection design is ensuring consistent performance across diverse body types and finding a method of guiding untrained individuals to the correct anatomical injection site. Additionally, in order to meet our universal IM vaccine compatibility requirement, additional research into the dimensions of different brands of syringes will be required. As there is no universal standard for syringe dimensions, developing an accurate range of sizes will likely take significant work. As we continue to develop our requirements and specifications, obtaining specific information regarding the available resources in the targeted low-resource setting continues to be a challenge. This is especially impactful for our sterility, durability, maintenance, and ease of use requirements and as such, will require continued research which is likely to include additional stakeholder interviews. As we aim to design for a sustainable device lifecycle, reusability and reparability are very important to consider with the local clinical setting in mind.

### 17.4 Next Steps: DR2

Our team is now moving towards finalizing our current designs and completing additional design ideation for site selection and depth control, in particular. As our designs develop, we will continue to prototype and test to address design worries. We also hope to conduct user testing with Michigan Medicine nursing students and staff to identify the usability of our designs. As several of our requirements and specifications are still in development, we will continue to conduct research to improve them. Finally, we will continue to engage with our stakeholders as we aim to gain a better understanding of the healthcare centers where this device will be used. In particular, we plan to work with Dr. Thiyag, Dr. Asah-Opoku, and Michigan Medicine staff.

### 17.5 Next Steps: DR3

Based on our team's perspectives as well as feedback from the project sponsor, we believe we have fully explored the idea space and are confident in our current designs (both the injection device and the shoulder placement device). Therefore, as we move towards DR4, we plan to prototype both devices and conduct rudimentary usability testing on ourselves and classmates. To do this, we plan to use 3D printing materials available in the x50 shop as well as materials that we have begun to source (syringes, spring, velcro straps). Although full usability testing and verification is outside the scope of this semester, we will continue to research and develop plans for this to be conducted in the future. Finally, we will continue to address our anticipated challenges such as finding the dimensions of our placement device base plate and finding participants for testing through continued research and communication with stakeholders and helpful contacts.

### 17.6 Solution Assessment

Overall, we believe that we have successfully met the goals set by both our sponsor and ourselves for this semester. We have created a prototype device consisting of two parts: one to aid in site selection and the other to prevent needle-stick injury and control the injection angle, depth, and speed. Based on our verification tests which included proxy usability testing, we are confident in the quality of our solution and believe that it should continue to be developed. In total, 13 specifications passed their verification tests, 3 were inconclusive, and 4 failed. Of the failed specifications, only the shoulder injection site was ranked as high priority. To address this, we recommend further development of the training guide, additional user testing with a wider range of participants, and further design if necessary. As the current design will likely require

additional work to address issues such as syringe compatibility, we encourage further ideation to ensure the device is an effective solution for as many people as possible. If this project is continued, we recommend focusing on achieving universal syringe compatibility and completing additional user testing with healthcare workers with less than nurse-level training.

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# 20. APPENDIX A - Individual Concept Generation

<u>Jake</u>

A - Create way to get vaccine into muscle through inhalation

B - Use electronic waves to push vaccine through skin into muscle

C - Patch to put on body, algorithm lights up patch to where needle should be injected

D - Thing to strap onto body, sits flush with body and only allows 90 degree injection

E - Scanning device that tells you where to inject needle

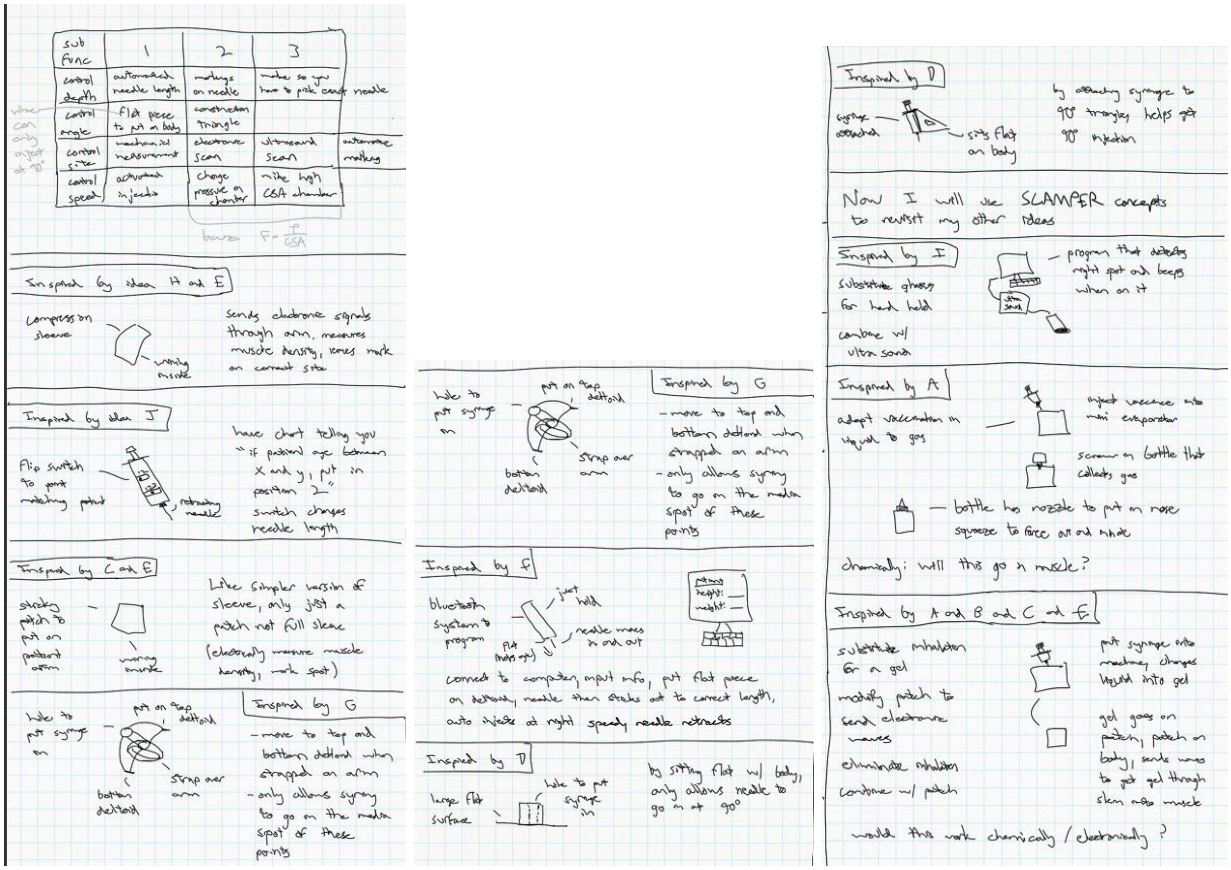
F - Automated injection system, only goes in so far and injects at right speed

G - Something to strap on body, uses mechanical system to find median spot based on "checkpoints" of shoulder

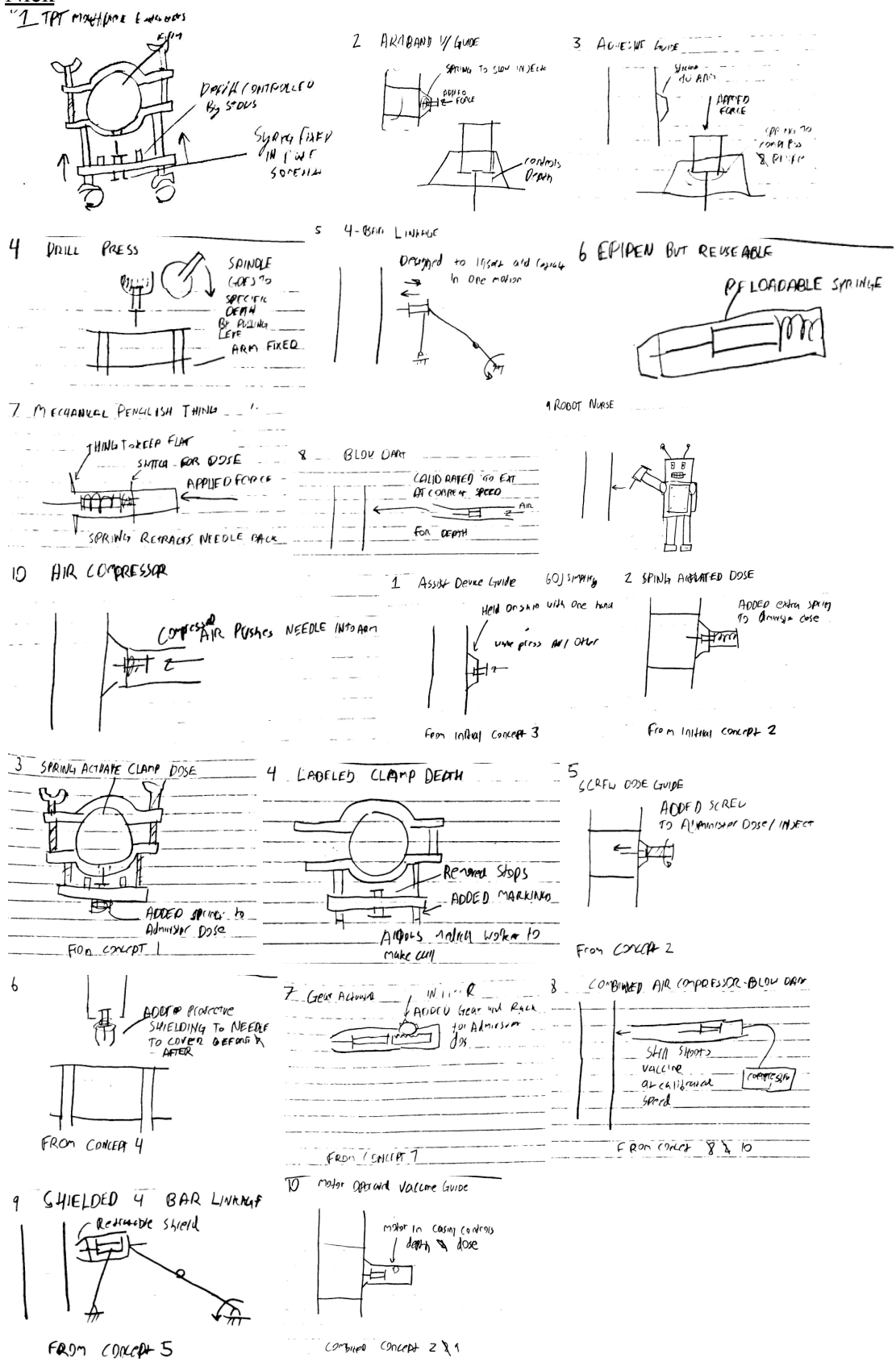
H - Compression sleeve that injects into muscle

I - Use “Meta” glasses to identify correct site

J - Create device where you input information on patient, than auto extends needle to be the correct depth needed

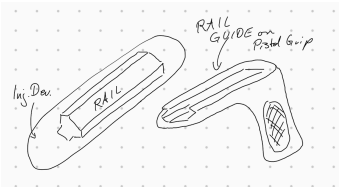


Nick

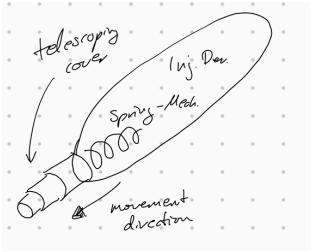

1 TPT Mouthpiece Extractors
Depth controlled by stops
Spring fixed in place somewhere
2 Armband w/ Guide
Spring to slow injects
Applied force
Controls depth
3 Adhesive Guide
Applied force
4 Drill Press
Spindle goes to specific depth by pulling lever
Arm fixed
5 4-Bar Linkage
Designed to insert and retract in one motion
6 Epipen but reuseable
Reloadable spring
7 Mechanical Pencilish Thing
Thing to keep flat
Switch for dose
Applied force
Spring retracts needle back
8 Blow Dart
Calibrated to exit at correct speed
Air
For depth
9 Robot Nurse
10 Air Compressor
Compressed air pushes needle into arm
1 Assist Device Guide
60J simplify
Hold on skin with one hand
Wake press air / other
From initial concept 3
2 Spring Activated Dose
Added extra spring to administer dose
From initial concept 2
3 Spring Activate Clamp Dose
Added springs to administer dose
From concept 1
4 Labeled Clamp Depth
Removed stops
Added markings
Allows medical worker to make call
5 Screw Dose Guide
Added screw to administer dose / inject
From concept 2
6
Added protective shielding to needle to cover before & after
From concept 4
7 Gear Actuator
Added gear and rack for administer dose
From concept 7
8 Combined Air Compressor-Blow Dart
Still shoots vaccine at calibrated speed
From concept 8 & 10
9 Shielded 4 Bar Linkage
Retractable shield
From concept 5
10 Motor Operated Vaccine Guide
Motor in casing controls depth & dose
Combined concept 2 & 9

Florian

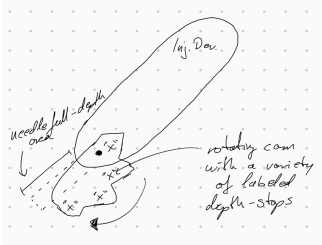
1. Pistol grip for ease of handling
2. Push out tube shield for needle that collapses into injector and is pushed out by some sort of spring system
3. Print out deltoid guide made of a cheap material like paper
4. Adjustable caliper depth gauge with calculations for different depths based on patient demographics
5. Tripod system for positioning and correct injection angle
6. Circle system for positioning and correct injection angle, that could match up with the print out guide
7. Slap bracelet deltoid guide
8. Laser guidance, projecting a crosshair onto the skin that only comes into complete focus when the angle and such are accurate
9. 90 degree wall to lean against with a shoulder pocket and vaccine location cut out
10. Suction cup guide that aligns the device to the injection site and keeps it in the correct position while pulling the tissue up to the needle
11. Modular handle system (iterated from 1 - pistol grip)
    a. Heuristic: 9 - allow users to customize
    b. A rail system that would allow workers to swap between different grips for different workers or scenarios




12. Telescopic shield for needle (iterated from 2 - push out shield)
    a. Heuristic: 48 - nest
    b. Telescoping the shield would make it take up less space laterally inside the injector

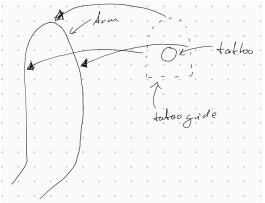



13. Scan and 3D print deltoid guide (iterated from 3 - print out deltoid guide)
    a. Heuristic: 20 - change geometry
    b. Instead of a flat or even foldable guide, this would be custom made for each patient, ensuring maximum accuracy for each injection
14. Depth Cam (iterated from 4 - caliper depth gauge)
    a. Heuristic: 6 - adjust functions for specific users
    b. Instead of needing calculations and a specific depth being set, a cam could be set to specific heights for a few different demographics
15. Cuff for tripod to rest against (iterated from 5 - tripod system)
    a. Heuristic: 15 - attach product to user
    b. By attaching the product to the user using a cuff that interlocks with the injector at 3 different points, the accuracy of the IM injection can be increased.



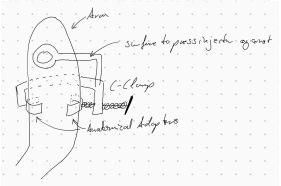

16. Sharpie and Ruler Geometry Guide: A system of instructions to draw lines on the patient with a ruler and sharpie to determine the correct injection area

17. Temporary Tattoo Guide: A placeable temporary tattoo that shows the exact location of the IM injection site after being applied relative to the patient's bone structure



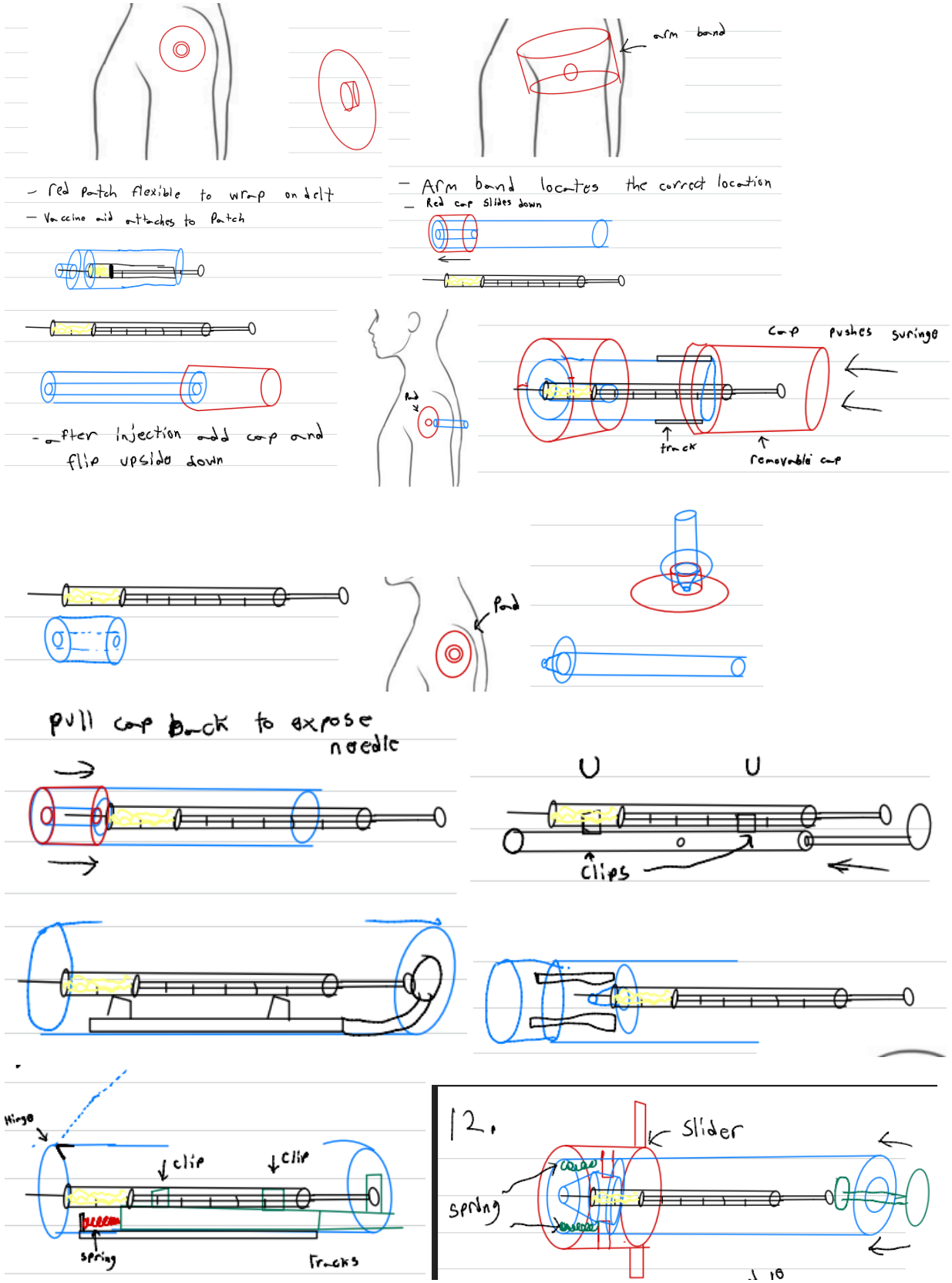

18. Arm C-Clamp: This would have parts that make it anatomically fit a patient's arm and ensure it does not move relative to the injection device

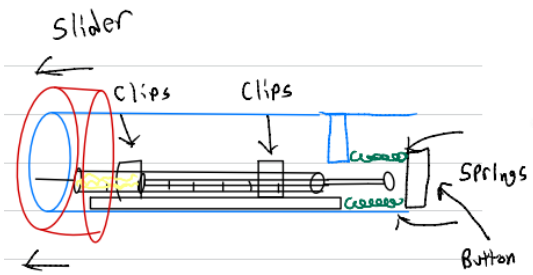
19. Temporary Zip Tie: A reusable zip tie with a place for the injection device to mount, ensuring they cannot move relative to one another

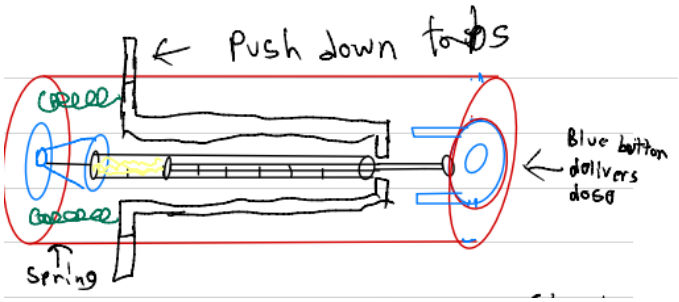


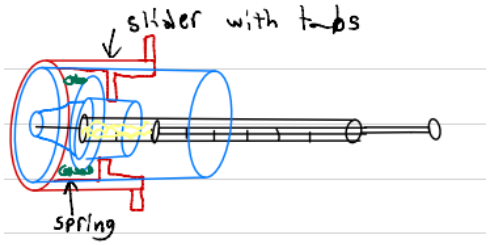

20. Spring Loaded Needle Retraction: This would pull the needle up inside the device after injection completion, likely triggered by the plunger of the syringe bottoming out.
21. Spring Loaded Hinged Needle Cover: This would flip a Cover over the exposed needle from the side of the device after the needle is being pulled from the patient's arm.

Zakaria


arm band
- red patch flexible to wrap on dolt
- Vaccine and attaches to Patch
- Arm band locates the correct location
- Red cap slides down
- after injection add cap and flip upside down
cap pushes syringe
track
removable cap
pull cap back to expose needle
clips
Hinge
clip
clip
spring
Tracks
12.
slider
spring

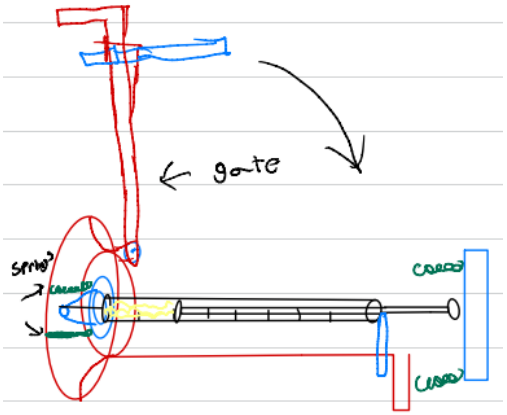


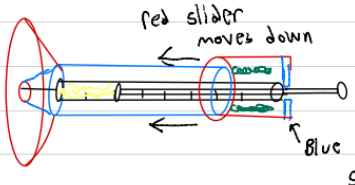



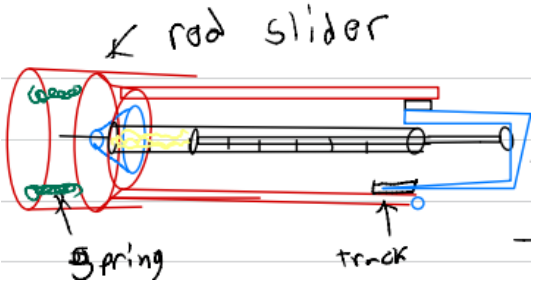

-slider guides injection

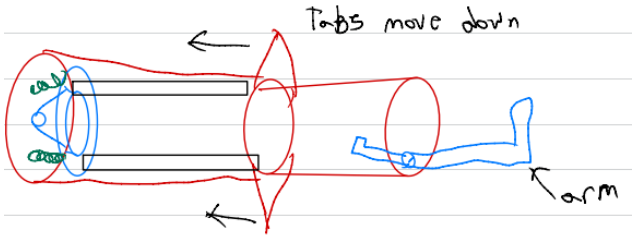
- springs brings needle back up

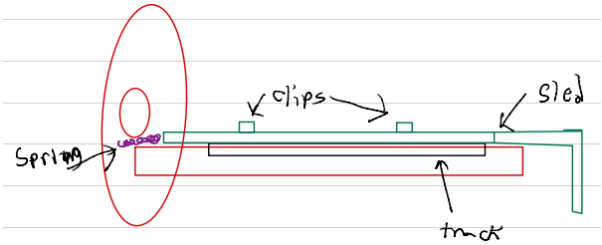



Blue tabs move in and out so you are able to put in vaccine

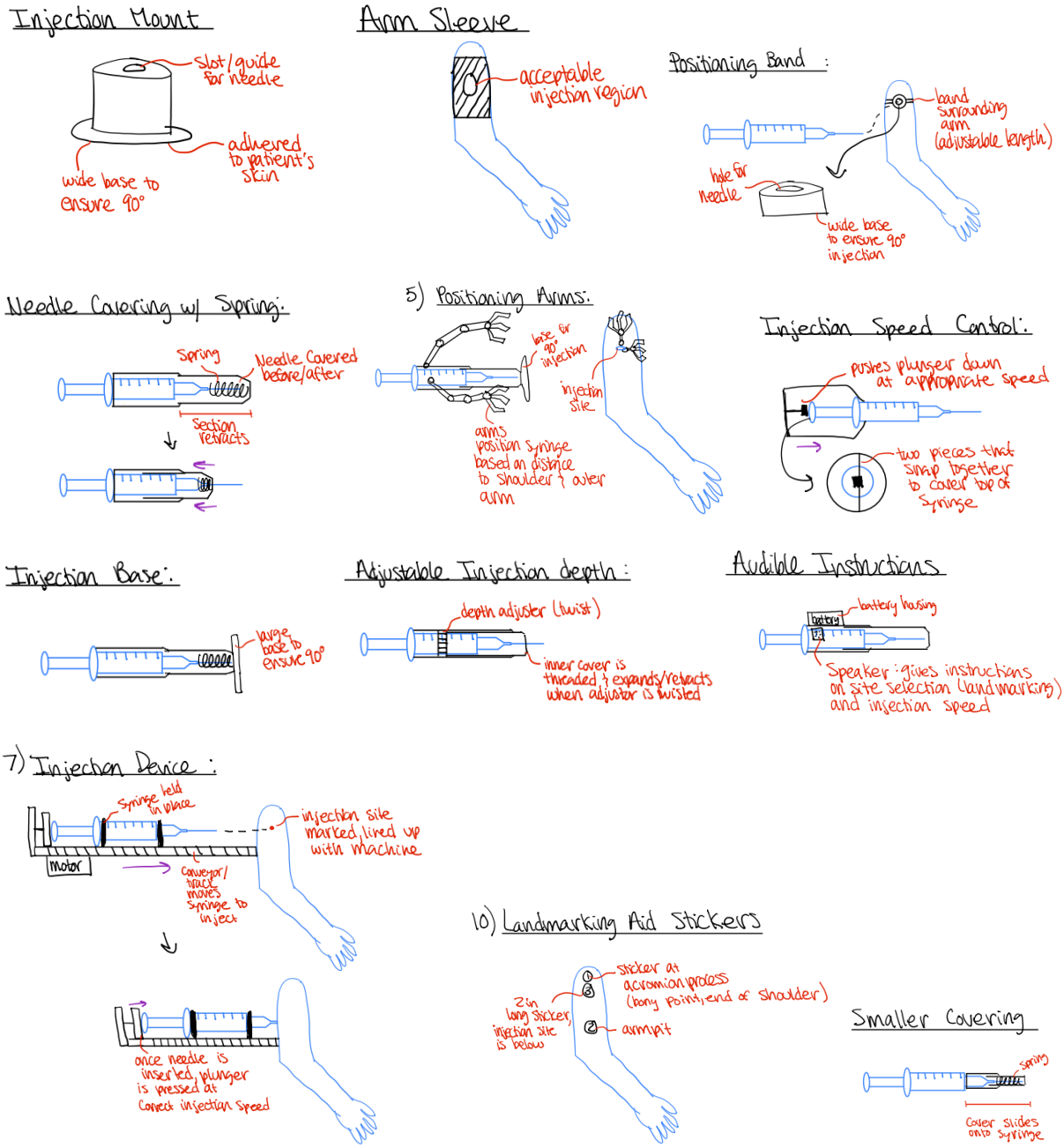


Emma

1- Device that gives audible instructions to guide injection
2 - Stencil to put on the arm, use marker to mark injection site
3 - Tattoo stencil that is placed on the arm and shows the site
4 - Computer aided site selection that uses image/scan of arm to identify injection site
5 - Retractable needle covering
6 - Wide injection base to ensure correct angle
7 - Practice injection site (synthetic skin) before actual injection
8 - Injection depth stop
9 - 20:



## 21. APPENDIX B - Team Bios

Zakaria Benchbana

I'm a 5th year Mechanical Engineering student from Rochester Hills MI, planning to graduate in Summer 2026. I've been interested in engineering from a young age, starting with LEGO sets that used gears and moving parts. I entered the College of Engineering undecided, and building a rover in my ENGN 100 section led me to mechanical engineering. I enjoy understanding how systems work and designing components with motion, and after graduating I plan to work in manufacturing or renewable energy.

Emma Cavalli

I am a 4th year Mechanical Engineering major planning to graduate in the fall of 2026, originally from Portage, Michigan. My dad is a professor of Mechanical Engineering at Western Michigan University and as a kid, I spent a lot of time doing random projects with him, visiting his office/lab, and attending various STEM camps. Because of these experiences, I knew I wanted to do some kind of engineering and originally applied to U of M for biomedical because I really liked biology in high school. After my freshman year, I quickly realized that I preferred physics to biology/chemistry and mechanical engineering felt like the natural choice. This summer I will be completing a manufacturing internship at Steelcase in Grand Rapids and hope to go into something manufacturing related after graduation. Random fun fact: I was on a jury for a three day trial last summer.

Nick Ferguson

I am in my 5th year of studying Mechanical Engineering, with plans to graduate in Summer 2026. I am from Livonia, MI, attending Churchill High School, where I decided to pursue engineering after enjoying the design projects associated with my physics classes. I have interned at DiClemente-Siegel Design Inc. for the past 3 summers and hope to work there after graduation in the mechanical building systems field. A fun fact about me is that I played the trumpet in the Michigan Marching Band up until last semester.

Florian W Lautenschlager

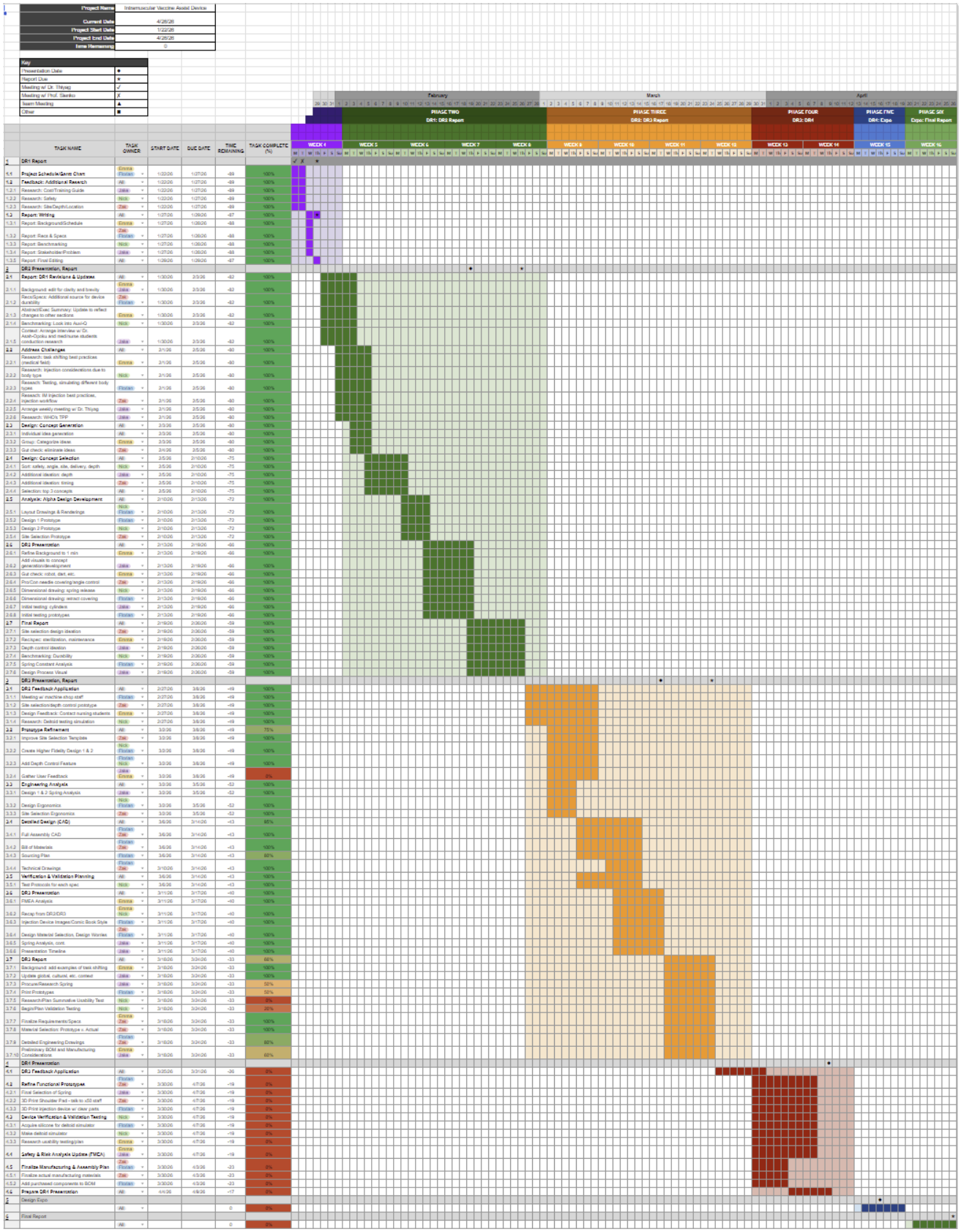
I am a senior Mechanical Engineering student graduating at the end of the Winter 2026 semester. I am from München, Germany and have lived both in Germany and Michigan throughout my life. After high school, I graduated from a program in which I received degrees in Aviation Maintenance Technology. I then trained as a pharmacy technician, a profession in which I administered vaccinations including the COVID-19, Flu, Hepatitis, and Shingles. Following the pandemic, I enrolled at the University of Michigan Dearborn as a Mechanical Engineering student before matriculating to the University of Michigan Ann Arbor where I continue to pursue the same degree. I have worked as a calculus tutor and in the Undergrad Machine Shop and have had an internship as a Process Engineering Internship at Fusion Coolant Systems. This experience has given me insight into process and manufacturing engineering that I look forward to applying in my career following my graduation.

Jake Schornak

I am from Petoskey, MI, and in my 4th year of Mechanical Engineering studies, planning to graduate in the Fall 2026 semester. I knew I wanted to become an engineer, as I enjoyed learning how things worked and applying math and science skills to solving a problem, but I couldn't

decide what branch to pursue. After taking courses from many curricula, I found Mechanical Engineering to best fit the general set of knowledge I wanted, and liked how it did not force me into any one industry. After graduation I will plan to work in industry, but am not sure under which concentration yet as there are just too many that are interesting and exciting to me.

# 22. APPENDIX C - Gantt Chart



| Project Name | Intramuscular Vaccine Assist Device |
|---|---|
| Current Date | 4/28/26 |
| Project Start Date | 1/22/26 |
| Project End Date | 4/28/26 |
| Time Remaining | 0 |

| Key | |
|---|---|
| Presentation Date | ● |
| Report Due | ★ |
| Meeting w/ Dr. Thiyag | ✓ |
| Meeting w/ Prof. Sienko | ✗ |
| Team Meeting | ▲ |
| Other | ■ |

| | TASK NAME | TASK OWNER | START DATE | DUE DATE | TIME REMAINING | TASK COMPLETE (%) |
|---|---|---|---|---|---|---|
| 1 | DR1 Report | | | | | |
| 1.1 | Project Schedule/Gant Chart | Emma Flotari | 1/22/26 | 1/27/26 | -89 | 100% |
| 1.2 | Feedback: Additional Research | All | 1/22/26 | 1/27/26 | -89 | 100% |
| 1.2.1 | Research: Cost/Training Guide | Jake | 1/22/26 | 1/27/26 | -89 | 100% |
| 1.2.2 | Research: Safety | Nick | 1/22/26 | 1/27/26 | -89 | 100% |
| 1.2.3 | Research: Site/Depth/Location | Zak | 1/22/26 | 1/27/26 | -89 | 100% |
| 1.3 | Report: Writing | All | 1/27/26 | 1/28/26 | -87 | 100% |
| 1.3.1 | Report: Background/Schedule | Emma | 1/27/26 | 1/28/26 | -88 | 100% |
| 1.3.2 | Report: Race & Space | Zak Flotari | 1/27/26 | 1/28/26 | -88 | 100% |
| 1.3.3 | Report: Benchmarking | Nick | 1/27/26 | 1/28/26 | -88 | 100% |
| 1.3.4 | Report: Stakeholder/Problem | Jake | 1/27/26 | 1/28/26 | -88 | 100% |
| 1.3.5 | Report: Final Editing | All | 1/28/26 | 1/28/26 | -87 | 100% |
| 2 | DR2 Presentation, Report | | | | | |
| 2.1 | Report: DR1 Revisions & Updates | All | 1/30/26 | 2/3/26 | -82 | 100% |
| 2.1.1 | Background: edit for clarity and brevity | Emma Jake | 1/30/26 | 2/3/26 | -82 | 100% |
| 2.1.2 | Race/Space: Additional source for device durability | Zak Flotari | 1/30/26 | 2/3/26 | -82 | 100% |
| 2.1.3 | Abstract/Exec Summary: Update to reflect changes to other sections | Emma | 1/30/26 | 2/3/26 | -82 | 100% |
| 2.1.4 | Benchmarking: Look into Aavi-Q | Nick | 1/30/26 | 2/3/26 | -82 | 100% |
| 2.1.5 | Context: Arrange interview w/ Dr. Aadi-Oziku and med/nurse students conduction research | Jake | 1/30/26 | 2/3/26 | -82 | 100% |
| 2.2 | Address Challenges | All | 2/1/26 | 2/5/26 | -80 | 100% |
| 2.2.1 | Research: task shifting best practices (medical field) | Emma | 2/1/26 | 2/5/26 | -80 | 100% |
| 2.2.2 | Research: Injection considerations due to body type | Nick | 2/1/26 | 2/5/26 | -80 | 100% |
| 2.2.3 | Research: Testing, simulating different body types | Flotari | 2/1/26 | 2/5/26 | -80 | 100% |
| 2.2.4 | Research: IM injection best practices, injection workflow | Zak | 2/1/26 | 2/5/26 | -80 | 100% |
| 2.2.5 | Arrange weekly meeting w/ Dr. Thiyag | Jake | 2/1/26 | 2/5/26 | -80 | 100% |
| 2.2.6 | Research: WHO's TPP | Jake | 2/1/26 | 2/5/26 | -80 | 100% |
| 2.3 | Design: Concept Generation | All | 2/3/26 | 2/5/26 | -80 | 100% |
| 2.3.1 | Individual idea generation | All | 2/3/26 | 2/5/26 | -80 | 100% |
| 2.3.2 | Group: Categorize ideas | Emma | 2/3/26 | 2/5/26 | -80 | 100% |
| 2.3.3 | Gut check: eliminate ideas | Zak | 2/4/26 | 2/5/26 | -80 | 100% |
| 2.4 | Design: Concept Selection | All | 2/5/26 | 2/10/26 | -75 | 100% |
| 2.4.1 | Sort: safety, angle, site, delivery, depth | Nick | 2/5/26 | 2/10/26 | -75 | 100% |
| 2.4.2 | Additional ideation: depth | Jake | 2/5/26 | 2/10/26 | -75 | 100% |
| 2.4.3 | Additional ideation: timing | Zak | 2/5/26 | 2/10/26 | -75 | 100% |
| 2.4.4 | Selection: top 2 concepts | All | 2/5/26 | 2/10/26 | -75 | 100% |
| 2.5 | Analysis: Alpha Design Development | All | 2/10/26 | 2/13/26 | -72 | 100% |
| 2.5.1 | Layout Drawings & Renderings | Nick Flotari | 2/10/26 | 2/13/26 | -72 | 100% |
| 2.5.2 | Design 1 Prototype | Flotari | 2/10/26 | 2/13/26 | -72 | 100% |
| 2.5.3 | Design 2 Prototype | Nick | 2/10/26 | 2/13/26 | -72 | 100% |
| 2.5.4 | Site Selection Prototype | Zak | 2/10/26 | 2/13/26 | -72 | 100% |
| 2.6 | DR2 Presentation | All | 2/13/26 | 2/19/26 | -66 | 100% |
| 2.6.1 | Refine Background to 1 min | Emma | 2/13/26 | 2/19/26 | -66 | 100% |
| 2.6.2 | Add visuals to concept generation/development | Jake | 2/13/26 | 2/19/26 | -66 | 100% |
| 2.6.3 | Gut check: robot, dart, etc. | Emma | 2/13/26 | 2/19/26 | -66 | 100% |
| 2.6.4 | Pro/Con needle covering/angle control | Zak | 2/13/26 | 2/19/26 | -66 | 100% |
| 2.6.5 | Dimensional drawing: spring release | Nick | 2/13/26 | 2/19/26 | -66 | 100% |
| 2.6.6 | Dimensional drawing: retract covering | Flotari | 2/13/26 | 2/19/26 | -66 | 100% |
| 2.6.7 | Initial testing: cylinders | Jake | 2/13/26 | 2/19/26 | -66 | 100% |
| 2.6.8 | Initial testing prototypes | Flotari | 2/13/26 | 2/19/26 | -66 | 100% |
| 2.7 | Final Report | All | 2/19/26 | 2/26/26 | -59 | 100% |
| 2.7.1 | Site selection design ideation | Zak | 2/19/26 | 2/26/26 | -59 | 100% |
| 2.7.2 | Recipes: sterilization, maintenance | Emma | 2/19/26 | 2/26/26 | -59 | 100% |
| 2.7.3 | Depth control ideation | Jake | 2/19/26 | 2/26/26 | -59 | 100% |
| 2.7.4 | Benchmarking: Durability | Nick | 2/19/26 | 2/26/26 | -59 | 100% |
| 2.7.5 | Spring Constant Analysis | Flotari | 2/19/26 | 2/26/26 | -59 | 100% |
| 2.7.6 | Design Process Visual | Jake | 2/19/26 | 2/26/26 | -59 | 100% |
| 3 | DR2 Presentation, Report | | | | | |
| 3.1 | DR2 Feedback Application | All | 2/27/26 | 3/6/26 | -49 | 100% |
| 3.1.1 | Meeting w/ machine shop staff | Flotari | 2/27/26 | 3/6/26 | -49 | 100% |
| 3.1.2 | Site selection/depth control prototype | Zak | 2/27/26 | 3/6/26 | -49 | 100% |
| 3.1.3 | Design Feedback: Contact nursing students | Emma | 2/27/26 | 3/6/26 | -49 | 100% |
| 3.1.4 | Research: Deltoid testing simulation | Nick | 2/27/26 | 3/6/26 | -49 | 100% |
| 3.2 | Prototype Refinement | All | 3/3/26 | 3/6/26 | -49 | 75% |
| 3.2.1 | Improve Site Selection Template | Zak | 3/3/26 | 3/6/26 | -49 | 100% |
| 3.2.2 | Create Higher Fidelity Design 1 & 2 | Nick Flotari | 3/3/26 | 3/6/26 | -49 | 100% |
| 3.2.3 | Add Depth Control Feature | Flotari Nick | 3/3/26 | 3/6/26 | -49 | 100% |
| 3.2.4 | Gather User Feedback | Jake Emma | 3/3/26 | 3/6/26 | -49 | 0% |
| 3.3 | Engineering Analysis | All | 3/3/26 | 3/5/26 | -52 | 100% |
| 3.3.1 | Design 1 & 2 Spring Analysis | Jake | 3/3/26 | 3/5/26 | -52 | 100% |
| 3.3.2 | Design Ergonomics | Nick Flotari | 3/3/26 | 3/5/26 | -52 | 100% |
| 3.3.3 | Site Selection Ergonomics | Zak | 3/3/26 | 3/5/26 | -52 | 100% |
| 3.4 | Detailed Design (CAD) | All | 3/6/26 | 3/14/26 | -43 | 85% |
| 3.4.1 | Full Assembly CAD | Flotari Zak Flotari | 3/6/26 | 3/14/26 | -43 | 100% |
| 3.4.2 | Bill of Materials | Zak | 3/6/26 | 3/14/26 | -43 | 100% |
| 3.4.3 | Sourcing Plan | Flotari | 3/6/26 | 3/14/26 | -43 | 80% |
| 3.4.4 | Technical Drawings | Flotari Zak | 3/10/26 | 3/14/26 | -43 | 100% |
| 3.5 | Verification & Validation Planning | All | 3/6/26 | 3/14/26 | -43 | 100% |
| 3.5.1 | Test Protocols for each spec | Nick | 3/6/26 | 3/14/26 | -43 | 100% |
| 3.6 | DR2 Presentation | All | 3/11/26 | 3/17/26 | -40 | 100% |
| 3.6.1 | FMEA Analysis | Emma | 3/11/26 | 3/17/26 | -40 | 100% |
| 3.6.2 | Recap from DR2/DR3 | Emma Nick | 3/11/26 | 3/17/26 | -40 | 100% |
| 3.6.3 | Injection Device Images/Comic Book Style | Flotari | 3/11/26 | 3/17/26 | -40 | 100% |
| 3.6.4 | Design Material Selection, Design Worries | Zak Flotari | 3/11/26 | 3/17/26 | -40 | 100% |
| 3.6.5 | Spring Analysis, cont. | Jake | 3/11/26 | 3/17/26 | -40 | 100% |
| 3.6.6 | Presentation Timeline | Jake | 3/11/26 | 3/17/26 | -40 | 100% |
| 3.7 | DR3 Report | All | 3/16/26 | 3/24/26 | -33 | 66% |
| 3.7.1 | Background: add examples of task shifting | Emma | 3/16/26 | 3/24/26 | -33 | 100% |
| 3.7.2 | Update global, cultural, etc. context | Jake | 3/16/26 | 3/24/26 | -33 | 100% |
| 3.7.3 | Procure/Research Spring | Jake | 3/16/26 | 3/24/26 | -33 | 50% |
| 3.7.4 | Print Prototypes | Flotari | 3/16/26 | 3/24/26 | -33 | 50% |
| 3.7.5 | Research/Plan Summative Usability Test | Nick | 3/16/26 | 3/24/26 | -33 | 0% |
| 3.7.6 | Begin/Plan Validation Testing | Nick | 3/16/26 | 3/24/26 | -33 | 20% |
| 3.7.7 | Finalize Requirements/Specs | Emma Zak | 3/16/26 | 3/24/26 | -33 | 100% |
| 3.7.8 | Material Selection: Prototype v. Actual | Zak | 3/16/26 | 3/24/26 | -33 | 100% |
| 3.7.9 | Detailed Engineering Drawings | Flotari Zak | 3/16/26 | 3/24/26 | -33 | 80% |
| 3.7.10 | Preliminary BOM and Manufacturing Considerations | Emma Jake | 3/16/26 | 3/24/26 | -33 | 60% |
| 4 | DR4 Presentation | | | | | |
| 4.1 | DR3 Feedback Application | All | 3/25/26 | 3/31/26 | -26 | 0% |
| 4.2 | Refine Functional Prototypes | Flotari Zak | 3/30/26 | 4/7/26 | -19 | 0% |
| 4.2.1 | Final Selection of Spring | Jake | 3/30/26 | 4/7/26 | -19 | 0% |
| 4.2.2 | 3D Print Shoulder Pad - talk to s50 staff | Zak | 3/30/26 | 4/7/26 | -19 | 0% |
| 4.2.3 | 3D Print injection device w/ clear parts | Flotari | 3/30/26 | 4/7/26 | -19 | 0% |
| 4.3 | Device Verification & Validation Testing | Nick | 3/30/26 | 4/7/26 | -19 | 0% |
| 4.3.1 | Acquire silicone for deltoid simulator | Flotari | 3/30/26 | 4/7/26 | -19 | 0% |
| 4.3.2 | Make deltoid simulator | Nick | 3/30/26 | 4/7/26 | -19 | 0% |
| 4.3.3 | Research usability testing/plan | Emma | 3/30/26 | 4/7/26 | -19 | 0% |
| 4.4 | Safety & Risk Analysis Update (FMEA) | Emma Jake | 3/30/26 | 4/7/26 | -19 | 0% |
| 4.5 | Finalize Manufacturing & Assembly Plan | Zak Flotari | 3/30/26 | 4/3/26 | -23 | 0% |
| 4.5.1 | Finalize actual manufacturing materials | Zak | 3/30/26 | 4/3/26 | -23 | 0% |
| 4.5.2 | Add purchased components to BOM | Flotari | 3/30/26 | 4/3/26 | -23 | 0% |
| 4.6 | Prepare DR4 Presentation | All | 4/4/26 | 4/9/26 | -17 | 0% |
| 5 | Design Expo | All | | | 0 | 0% |
| 6 | Final Report | All | | | 0 | 0% |

# 23. APPENDIX D - Verification and Validation Traceability Log

| Requirement ID | Requirement | Priority | Specification ID | Specification Description | Verification ID | Verification method | Verification testing owner | Verification testing stage | Verification testing date | Verification results summary | Verification test conditions | Verification test limitations and uncertainties | Verification evidence | Verification Results | Validation ID | Validation method | Validation question (plain language) | Validation testing owner | Validation testing stage | Validation testing date | Validation test metric + results | Validation test conditions | Validation test limitations and uncertainties | Validation evidence | Validation results |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A | Prevent needle-stick injuries. | High | A-01 | After completing an injection, the needle shall be fully covered within ≤ 1 s. | A-V-01 | Observing prototype over 10 trial to ensure needle is covered in ≤ 1 s after injection. | Emma Cavalli | Data Processed | 4/14/2025 | Over 10 trials, the needle was covered in the required time 10 times | silicone proxy skin used for injection | Test takes place with a new spring, which may not mimic conditions | Guidelines for the proper and safe use of needles | Pass | A-VA | User testing with med/nursing students or other x30 students (users with limited medical training) | Are users safe from needle-stick injury while using the device? | unassigned | Method Chosen | TBD | Metric: user testing trials | TBD | Uncertain if the test subjects we could contact will truly be representative of all of even the average user, limited by our available test subjects | TBD | TBA |
| A-02 | The device shall have 0 mm of exposed needle when the device is not actively performing an injection (before and after use). | A-V-02 | Met by design intent | N/A | Data Processed | N/A | The specification is met by design intent | N/A | N/A | Guidelines and studies for sanitization of medical devices. | Pass | | | | | | | | | | | | | | |
| B | Ensure correct intramuscular injection speed. | High | B-01 | The device shall allow the vaccine to be administered at the rate of 10 seconds/mL. | B-V-01 | Met by design intent | N/A | Data Processed | N/A | The specification is met by design intent | N/A | N/A | CDC and WHO guidelines | Pass | B-VA | User testing with med/nursing students or other x30 students (users with limited medical training) | Does the device allow for a safe injection speed? | unassigned | Method Chosen | TBD | Metric: user testing trials | TBD | Uncertain if the test subjects we could contact will truly be representative of all of even the average user, limited by our available test subjects | TBD | TBA |
| C | Ensure correct IM injection angle | High | C-01 | Device constrains angle to 90±3° relative to skin surface | C-V-01 | Measure angle of injection across test trials | Florian Lautenschlager | Data Processed | 4/14/2026 | Over 5 trials each by 5 participants, the angle reached was within the tolerances in 100% of trials | University student volunteers using device with no needle attached | Limited by participants education level and device being used with no needle | CDC and WHO guidelines, independent study | Pass | C-VA | Usability testing: Have non-nurse trained individuals use and rate how confident they are in achieving and maintaining... | Is the injection angle correct? | unassigned | Method Chosen | TBD | Metric: user testing trials | TBD | Uncertain if the test subjects we could contact will truly be representative of all of even the average user, limited by our | TBD | TBA |
| D | Ensure correct intramuscular injection depth. | High | D-01 | Maintain desired depth ±2 mm during use | D-V-01 | Trial injections into synthetic skin, measure depth across various points of injection | Florian Lautenschlager | Data Processed | 4/14/2026 | Over 10 trials, the needle reached the required depth into synthetic skin 100% of times | silicone proxy skin used for injection | Limited by not having advanced equipment that could provide real-time injection depth information across all points of injection | interview with sponsor, CDC guidelines | Pass | D-VA | Use silicone to mimic skin, test several different depths. | Does the device insure the correct injection depth? | unassigned | Method Chosen | TBD | [insert here] | [insert here] | [insert here] | [insert here] | TBA |
| D-02 | Includes adjustable depth feature | D-V-02 | Test different settings of device to see if correctly limits depth. | N/A | Data Processed | N/A | The specification is met by design intent | TBD | Limited by realistically only designing for some injection depths, leaving gaps in between the different settings. Need to ensure that these gaps are small enough to not make an impact on IM vaccine delivery. | interview with sponsor, CDC guidelines | Pass | | | | | | | | | | | | | | |
| E | Ensure correct injection site for IM injection in shoulder. | High | E-01 | In simulated-use testing, ≥ 90% of users shall place the device such that the needle is within ±10 mm of the center of an approved deltoid injection. | E-V-01 | Trial ones of location assist device using training materials | Florian Lautenschlager | Data Processed | 4/14/2026 | In user trials, the correct location was found 80% of the time | University student volunteers using device with no needle attached | Limited by participants education | CDC guidlines | Fail | E-VA | [insert here] | Is the injection location correct? | unassigned | Metric Chosen | TBD | Metric: user testing trials | [insert here] | [insert here] | [insert here] | TBA |
| F | Be durable | Medium | F-01 | The device shall withstand ≥ 300 use cycles without functional failure. | F-V-01 | The spring will be compressed and uncompressed 300 times | Nick Ferguson | Method Chosen | TBD | TBD | TBD | situation not representitive of use conditions | Durability guidlines for medical devices | Pass | F-VA | Accelerated Life Testing (ALT)? | [insert here] | unassigned | Metric Chosen | TBD | [insert here] | [insert here] | [insert here] | [insert here] | TBA |
| G | Be universally compatible with IM syringes. | Medium | G-01 | The device shall accommodate standard 0.3 mL, 1 mL, and 3 mL syringes from multiple manufacturers. | G-V-01 | Met by design intent | unassigned | Data Processed | N/A | The device was not designed for multiple syringe sizes | N/A | N/A | research into commonly used vaccine syringes | Fail | G-VA | User testing: Test if device functions with all IM syringes | Does the design accomodate multiple syringe sizes? | unassigned | Metric Chosen | TBD | [insert here] | [insert here] | [insert here] | [insert here] | TBA |
| G-02 | The device shall support intramuscular injections using standard needle lengths of 16–38 mm. | G-V-02 | Met by design intent | unassigned | Data Processed | N/A | The device was designed to accomodate the required needle lengths | TBD | N/A | Interview with sponsor | Pass | | | | | | | | | | | | | | |
| H | Be easy to use with minimal training. | Medium | H-01 | A user with ≤ 15 minutes of training shall successfully complete a simulated injection task. | H-V-01 | Usability testing by intended users. | unassigned | Data Processed | 4/14/2026 | Over 5 trials, participants were able to complete the task in 100% of trials | University student volunteers using device with no needle attached | Usability testing cannot be conducted on the true users (healthcare workers in Ghana) so results may not be indicative of reality. | Usability guidlines | Pass | H-VA | User testing. | Is the device easy to use with limited training? | unassigned | Method Chosen | TBD | [insert here] | [insert here] | [insert here] | [insert here] | TBA |
| H-02 | The device shall require ≤ 5 discrete steps to complete use. | H-V-02 | Usability testing and analysis of steps required for use. | unassigned | Data Processed | N/A | The specification is met by design intent | N/A | Real use may require more steps than we intend. | Usability guidlines | Pass | | | | | | | | | | | | | | |
| H-03 | System Usability Scale (SUS) score of ≥ 80 when tested by targeted users. | H-V-03 | Usability testing by intended users. | Florian Lautenschlager | Data Processed | 4/14/2026 | The SUS score of all users was greater than 80 | University student volunteers using device with no needle attached | Usability may not accurately reflect real use. | Usability guidlines | Pass | | | | | | | | | | | | | | |
| I | Be easy to repair in low-resource environments. | Medium | I-01 | The device does not require access to a reliable power supply. | I-V-01 | Analysis of device to ensure reliable power is not required. | unassigned | Data Processed | N/A | N/A | N/A | N/A | Interview with sponsor | Pass | I-VA | [insert here] | Can the device be easily repaired with limited resources? | unassigned | Metric Chosen | TBD | [insert here] | [insert here] | [insert here] | [insert here] | TBA |
| I-02 | Device can be repaired in ≤ 15 minutes by an average user. | I-V-02 | Brainstorming potential issues and how long the fixes would take. | unassigned | Metric Chosen | TBD | TBD | TBD | We may not consider every possible fix that could be required in the future. | [insert here] | TBA | | | | | | | | | | | | | | |
| I-03 | Device can be repaired using ≤ 3 basic tools. | I-V-03 | Brainstorming potential issues and the number of tools fixing it would require. | unassigned | Metric Chosen | TBD | TBD | TBD | We may not consider every possible fix that could be required in the future. | [insert here] | TBA | | | | | | | | | | | | | | |
| J | Be easy to appropriately sanitize. | Medium | J-01 | Materials are non-porous and durable, allowing for repeated sanitization with low- to intermediate-level disinfectants. | J-V-01 | Design for no-porous and durable materials. | unassigned | Data Processed | N/A | The specification is met by design intent | N/A | After work is done to ensure materials are chosen meeting these attributes, there are no worries. | Guidelines and studies for sanitization of medical devices. | Pass | J-VA | User testing: Test if users can appropriately sanitize the devices. | Can the devices be readily sanitized? | unassigned | Method Chosen | TBD | Metric: user testing trials | Can be made resonably similar to real use conditions by providing equivalent sanitization materials to hat would be expected in these settings. | An uncertainty is that different people will operate at different paces, and so the results of this can be largely dependant from person to person. | [insert here] | TBA |
| J-02 | Device design allows for sanitization of all surfaces that contact the patient in less than 2 minutes. | J-V-02 | Timed runs of necessary sanitization. | unassigned | Method Chosen | TBD | TBD | TBD | An uncertainty is that different people will operate at different paces, and so the results of this can be largely dependant from person to person. | Guidelines and studies for sanitization of medical devices. | TBA | | | | | | | | | | | | | | |
| K | Minimize cost. | Low | K-01 | The device shall have a production cost of less than $15. | K-V-01 | Calculations as to mass manufacturing costs. | unassigned | Method Chosen | TBD | TBD | TBD | Will be limited by the amount of information we can gather of manufacuring prices and necessary assumptions, can not be completely accurate to the outcomes of true mass manufacturing. | Dr. Thiyag interview. | TBA | K-VA | [insert here] | Is the cost low enough to become a reasonable market option? | unassigned | Method Chosen | TBD | Metric: cost per unit in mass production | N/A | Uncertainty will be in the fact that we can't account for the exact situation and rates of a manufacturing plant and will vary depending on the company outsourced for manufacturing. | [insert here] | TBA |
| L | Ensure correct injection site for anterolateral thigh injection. | Low | L-01 | In simulated-use testing, greater than 90% of users shall place the device so it would inject within 30mm of the approved anterolateral thigh injection site. | L-V-01 | Trial injections into thighs, measure how far the needle has would be from the deal site. | unassigned | Data Processed | Not preformed | The device was not designed for the thigh location | Not preformed | Will be limited by the amount of participants we can gather, with a larger test the results may shift notably from what we see on small scale. | CDC guidelines. | Fail | L-VA | Usability testing: see if users can find the correct thigh injection site with use of device. | Can users inject the correct spot on the thigh. | unassigned | Method Chosen | TBD | Metric: user testing trials | Can be made very similar to real use situations. | Limited by the participants that can be gathered for testing, resuts can be dependant from person to person and too small of a group will not represent this variability. | [insert here] | TBA |

## 24. APPENDIX E - Training Guide

# Intramuscular Vaccine Administration Assistance Device: **Training Guide**

## Contents

Materials.....1
Prepare the Vaccine Dose.....2
Prepare the Injection Site.....3
Perform Injection.....4
Sanitization Procedure.....5
Recommendations and Knowledge Check.....6

Materials.

**a)** 1 pair sterile gloves
**b)** 1 alcohol swab stick
**c)** 2 alcohol swab pad
**d)** 1 adhesive bandage
**e)** 1 injection dose, prepared
**f)** 1 injection device
**g)** 1 location device
**h)** 1 vaccine syringe
**i)** 1 vaccine needle
**j)** 1 sharps container

**a)**



**b)**



**c)**



**d)**




**e)**



**f)**



**g)**



**h)**



**i)**



**j)**



[1]

1

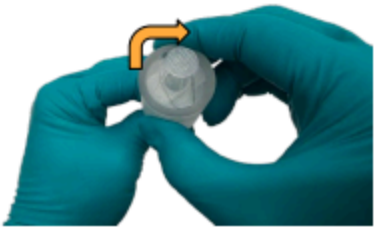
## Prepare Vaccine Dose.

**1.** Pull dose according to manufacturer guidelines.

**2.** Slide syringe and needle into cap.



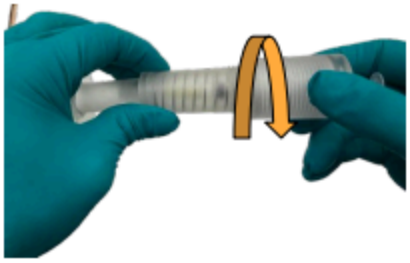
**3.** Twist syringe right to lock in place.



**4.** Slide syringe into body of the device.

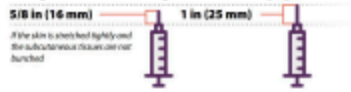


**5.** Thread cap onto body of the device.

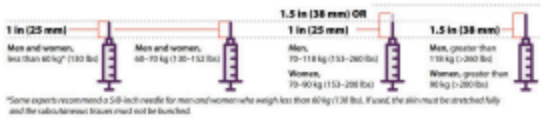


**6.** Thread cap to appropriate needle length, selected from the chart below.

**For youth, 7-18 years old** [2]:




**For adults, 19+ years old** [3]:




2

## Prepare Injection Site.

**1.** Roll up patient's sleeve to fully expose their shoulder and armpit.

**2.** Ensure patient's arm remains relaxed at their side for the duration of the injection.

**3.** Using two fingers, locate the acromion (top of the shoulder bone).



[4]

**4.** Place the device so the shoulder strap passes under the armpit and over the top of the shoulder.



**5.** Align the acromion pad so it sits flush over the acromion bone.

**6.** Tighten the shoulder strap to secure the device in place.



**7.** Confirm the device is stable and properly aligned.

**8.** Sanitize the indicated injection area using an alcohol swab.



## Perform Injection.

**1.** Push the outside of the baseplate down, exposing the needle cap.



**2.** Remove the needle cap.



**3.** Place the injection device against the injection site on the location device.



**4.** Depress the device smoothly and evenly.



**5.** Count aloud to actuate the syringe plunger smoothly at a rate of 10 seconds/mL.



**6.** Gently and smoothly remove the device from the patient's arm.

**7.** Carefully replace the needle cap by pushing down on the outside of the baseplate and placing the cap opening first onto the needle before pushing down.



**8.** Remove the syringe by unthreading the cap from the device body, twisting left, and pulling the syringe out.



**9.** Safely dispose of the syringe and needle in a designated sharps container.

## Sanitization Procedure.

**1.** Swab the inside of the needle guard with an alcohol swab stick.



**2.** Swab the bottom of the base plate with an alcohol swab pad.



**3.** Swab the location device guide with an alcohol swab pad.



## Recommendations and Knowledge Check.

**Practice**

- We encourage you to practice putting the location device onto a colleague's arm to ensure you are comfortable using this to find the correct injection site.
- Practice inserting a syringe into the injection device and adjusting the cap to get a better feel for how to set up the injection device (do not remove the needle guard from the syringe during practice).
- Without a syringe in the injection device, push it into a flat surface a couple of times to get a feel for the spring action inside the device, and a better understanding of what it feels like to push it until the needle guard of the device is fully retracted.

We strongly encourage following these practice steps to ensure you and your patient's safety during an injection.

**Knowledge Check**

Q: What syringes can be used with this device?

A: 3 mL BD Luer-Lok only

Q: Should you remove the needle guard from the syringe before inserting it into the device cap?

A: No. Wait until the device cap has been adjusted to the desired depth before removing the syringe guard to minimize risk of accidental needle sticks.

Q: Should you only push the injection device forward by 16 mm if you are doing a 16 mm deep injection?

A: No. After the device cap is adjusted to have the end of the needle at the correct depth marking, the device should always be pushed all the way until the guard can no longer retract during injection.

**References**


[1] "Mountainside Medical," Mountainside Medical. Accessed: Apr. 14, 2026. [Online]. Available: https://www.mountainside-medical.com

[2] "Vaccine Administration: Intramuscular (IM) injections: Children 7 through 18 years of age." Accessed: Jan. 15, 2026. [Online]. Available: https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-injection-children.pdf?utm_

[3] "Vaccine Administration: Intramuscular (IM) injections: Adults 19 years of age and older." Accessed: Mar. 16, 2026. [Online]. Available: https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-adult.pdf

[4] "Acromion," Wikipedia. Feb. 16, 2026. Accessed: Apr. 14, 2026. [Online]. Available: https://en.wikipedia.org/w/index.php?title=Acromion&oldid=1338627462

# 25. APPENDIX F - User Testing Results

| Participant | Angle (tested on silicone analog) | | | | Depth (tested on silicone analog) | | | | Site Selection (measured on simulated patient) | | | | Training Time (min) | SUS Score | Any pain/ discomfort when using the device? | Previous experience with IM injections? | Do you feel the device allowed you to perform the task more easily? |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Needle insertion angle relative to skin | | | | Injection depth (mm) [Target: 25mm] | | | | Needle distance from center of injection area (mm) | | | | | | | | |
| | *Trial 1* | *Trial 2* | *Trial 3* | *Avg* | *Trial 1* | *Trial 2* | *Trial 3* | *Avg* | *Trial 1* | *Trial 2* | *Trial 3* | *Avg* | | | | | |
| 1 | 90 | 90 | 90 | 90 | 22 | 22 | 23 | 22.33 | 0 | 1 | 0 | 0.33 | 4:37:00 | 87.5 | Yes | Yes | Yes |
| 2 | 90 | 90 | 90 | 90 | 23 | 22 | 23 | 22.67 | 1 | 1 | 0 | 0.67 | 4:37:00 | 77.5 | No | No | Yes |
| 3 | 90 | 90 | 90 | 90 | 23 | 23 | 23 | 23.00 | 0 | 1 | 0 | 0.33 | 4:37:00 | 85 | No | No | Yes |
| 4 | 90 | 90 | 90 | 90 | 23 | 22 | 23 | 22.67 | 20 | 20 | 20 | 20.00 | 4:37:00 | 92.5 | No | No | Yes |
| 5 | 90 | 90 | 90 | 90 | 23 | 23 | 23 | 23.00 | 1 | 1 | 0 | 0.67 | 4:37:00 | 90 | No | No | Yes |
| 6 | 90 | 90 | 90 | 90 | 23 | 23 | 22 | 22.67 | 5 | 6 | 8 | 6.33 | 4:37:00 | 77.5 | No | No | Yes |
| AVG | | | | 90 | | | | 22.72 | | | | 4.72 | 4:37:00 | 85 | | | |

# 26. APPENDIX G - Bill of Materials

## ME450 Team 22 Bill of Materials (BOM)

*Add all finalized parts necessary for mfg and assy.*

*Please adress any discrepancies with the Team.*

| Part # | Name | Description | Material & Dimension | Vendor | Part Number | Qt | Cost | Purchase/Specs Link |
|---|---|---|---|---|---|---|---|---|
| *0* | *(Example) Flood Light* | *Example part, not part of BOM* | *n/a, 5" Diameter* | *McMaster-Carr* | *1635K56* | *1* | *$18.50* | *https://www.mcmaster.com/1635K56/* |
| | Injection Device | | | | | | | |
| 1 | Compression Spring | Internal spring to extend needle guard | OD 0.845 in, FL 2.25 in, Stainless Steel | Lee Springs | LP 035P 06 S31 | 5 | 13.03 | https://www.leespring.com/product/compression-spring-lp035p06s316-stainless-steel-type-316 |
| 2 | Base Plate (Inj Dev) | Ensure 90deg inj angle | Formlabs Clear v4.1 | Team #22 | T22_1 | 1 | - | N/A |
| 3 | Needle Guard (Inj Dev) | Ensure patient and admin safety | Formlabs Clear v4.1 | Team #22 | T22_2 | 1 | - | N/A |
| 4 | Body (Inj Dev) | Core of inj device | Formlabs Clear v4.1 | Team #22 | T22_3 | 1 | - | N/A |
| 7 | Spring Stop (Inj Dev) | Hold internal spring in place | Formlabs Clear v4.1 | Team #22 | T22_4 | 1 | - | N/A |
| 8 | Cap (Inj Dev) | Secure syringe and adjust injection depth | ABS | Team #22 | T22_5 | 1 | - | N/A |
| | Smooth-On Dragon | | | | | | | |
| 9 | Skin 10 Medium | Develop muscle testing analog | Silicone | Amazon | B00NH0RHBK | 2 | 39.92 | https://www.amazon.com/dp/B00NH0RHBK?th=1 |
| 10 | Arm Strap | Attach to patient arm | Nylon Strap | ME Shop | MES_1 | 1 | - | N/A |
| 11 | Side Strap | Attach location plate to arm strap | Nylon Strap | ME Shop | MES_2 | 2 | - | N/A |
| 12 | Acromion Pad | Secure location device to correct landmark | TPU | Team #22 | T22_6 | 1 | - | N/A |
| 13 | Rivet Buttons | Securearm strap to side strap | Stainless Steel | ME Shop | MES_3 | 2 | - | N/A |
| 14 | Location Plate | Indicate correct injection site | PLA | Team #22 | T22_7 | 1 | - | N/A |