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TMC Biodesign: The Design and Implementation of a Product Development Framework for Successful Innovation in the Healthcare Industry.

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TMC BIODESIGN: THE DESIGN AND IMPLEMENTATION OF A PRODUCT DEVELOPMENT FRAMEWORK FOR SUCCESSFUL INNOVATOION IN THE HEALTHCARE INDUSTRY

by

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ABSTRACT

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It is not uncommon to see both academic and industry institutions speed through, or even outright skip, the different stages of innovation. Industry often considers early stages of innovation, such as needs identification, to be too risky, or a waste of time and resources. They tend to focus more on improving validated solutions and creating incremental changes, resulting in products that lack innovation. Academia often considers aspects of the innovation process to be too commercial to consider during their research initiatives, which often results in the development of great technologies that cannot be implemented due to their lack of commercial viability, resulting in a great deal of wasted time and capital. There is a stark need to train everyone involved in the product development process to properly appreciate and implement all stages of the innovation cycle. Engineers, physicians, and business-minded people need to be taught how to come together to solve healthcare's biggest problems. They need to learn how to turn technological developments into commercially viable products that solve customer needs. In partnership with the Texas Medical center, I present in this research a framework for providing future medical technology leaders the experience required to create transformational solutions to healthcare's biggest challenges. I provide a structured process for innovating in the complex healthcare industry, beginning with first-hand observations of clinical needs and ending with a plan for commercializing a medical product. This thesis is intended to describe the proposed framework for medical device innovation and evaluate its potential for success through participation in the inaugural fellowship.

CHAPTER 1: INTRODUCTION

Healthcare product development is simply defined as the development of a drug or a biologic or medical device. However, this process is anything but simple. It is a long and complex undertaking that requires significant understanding of the stakeholders involved, of which there are often many. It also requires access to large amounts of capital and a strong understanding of how to navigate the complex regulations in place for medical devices. Due to the complex nature of the industry, there is an increasing need for innovation and a change in the way that product development is led and implemented.

Innovation can be defined as "the design, invention, development, and/or implementation of new or altered products, services, processes, systems, organizational structures, or business models for the purpose of creating new value for customers and financial returns for the firm" [1]. Typically, there are two types of innovations, as categorized by their impact on the stakeholders involved: incremental innovation and disruptive innovation. Over the past few decades, there have been many advancements made in healthcare thanks to advances in technology and pharmaceuticals. However, the majority of those innovations have focused on developing more targeted drugs or more precise surgical tools and diagnostic devices. While these inventions have been successful in significantly affecting medical treatment and have been used to save many lives, many of them have been relatively narrow in focus and incremental in nature [2]. With rising pressure to bring healthcare costs down while improving patient outcomes and quality of life, the need for innovation in the healthcare industry is stark. Healthcare organizations face unprecedented challenges compared to those in other industries, and a changing landscape is proving that innovation is increasingly necessary. The old method of fee-for-service medical care is changing to one that is increasingly focused on the patient and patient outcomes. More power is being given to the patients to allow them to take charge of their health, changes are being made to who has decision-making and purchasing power in hospitals, and lastly, there are significant changes being made in regulation and

reimbursement. All of these shifts are leading to new and complex challenges within the healthcare system, significantly increasing the need for innovation.

Due to the complexity of the healthcare industry, and the large number of stakeholders involved with a typical medical innovation, a user-centered design approach has become extremely important. User-centered design helps to guarantee "the development of high quality and well-designed devices that are in tune with the patient and user needs" [3]. It ensures that the design process comprehensively considers the setting in which the product will be used, the work flow of the users, and the specific needs of the individual users [4]. However, fully implementing a user-centered design approach, requires formal training in both human factors and engineering methodologies, as well as an understanding of business strategy and commercialization [5]. Therefore, it must be a team effort, involving people of cross-functional backgrounds.

The importance and value of focusing on user needs has been recognized by many, and research has shown that implementing a user-based approach in healthcare innovation can lead to a number of benefits, including improved patient safety, compliance, and health outcomes [6–7]. Additional studies have shown that adopting a more user-centered design approach in healthcare can also lead to higher levels of patient and physician satisfaction [8]. Lastly, adopting a more human-centered design approach can substantially reduce device development time by allowing usability issues to be identified and addressed prior to launch, avoiding costly design changes and product recalls [9-10].

However, simply focusing on user-centered design is not enough. The shift in demand for patient-centered healthcare, in addition to the other aforementioned changes, requires a complete change in the way we have been approaching innovation in the healthcare space. More focus needs to be placed on defining the right need, and implementing strategies that allow for quick and effective product development, as cost is becoming a larger factor and patient outcomes are becoming more important. It is necessary to consider and understand all potential risks associated with bringing a product to market before entering into the development and commercialization stages. Therefore, there is a growing need to develop a comprehensive framework that can be implemented to foster innovation and utilize proven design-thinking methodologies, user-centered

design, and needs-based innovation frameworks to ensure value and successful creation of a medical product. The framework needs to teach innovators how to identify and solve the real and complex problems that are arising in the ever-changing healthcare industry.

Although there has been more focus placed on using product development processes and user-centered design frameworks and applying them to healthcare in recent years, there has been relatively low success rates and low adherence due to the somewhat fragmented nature of the different frameworks. This brings into sharp and immediate focus the need for a better method for innovating in the healthcare industry, as well as a better understanding of how to successfully implement a comprehensive product development process for the healthcare industry.

1.1: Research Aims

1. This thesis aims to develop and launch a comprehensive framework that will teach and enable collaboration at all stages of the design process between interdisciplinary teams and end users in order to design a successful product in the healthcare industry.
2. I also aim to test the model by participating in and completing the proposed program and identifying the key factors for enabling success within the process.

1.2: Background

1.2.1: The challenge of innovating in the healthcare industry

The healthcare industry is consistently recognized as one of the most difficult industries to innovate in, primarily because of its complexity, significant regulations, and number of end-users or stakeholders [11]. In addition to all of the steps required in order to develop a product that will be accepted by customers, companies in the healthcare industry have to jump through multiple hoops to even get their product approved and on the market.

Additionally, medical companies have to develop products for consumers who are notoriously resistant to change. Specifically, in the healthcare sector, consumers

(physicians, nurses, healthcare administrators, etc.) are often against trying new products or ideas and are resistant to anything that disrupts their normal workflow, even if it could increase efficiency. Oftentimes innovators believe that their product is so good that they can overcome this issue and convince the customers to change their ways to fit the company's vision. However, this thinking is very unrealistic and often leads to failure.

Lastly, the healthcare industry is so large and complex that there are often multiple stakeholders that have to be considered, each with competing needs and interests. This significantly increases the challenges associated with developing a product that meets the customers' needs and will be accepted once on the market.

Due to the complex issues mentioned above, developing and commercializing a healthcare solution can be extremely challenging, and large amounts of time and money are spent each year developing solutions that are unable to succeed in this marketplace.

1.2.2: Reasons for the failure of healthcare products and startups

Each year, large healthcare companies spend significant amounts of time and money on projects possessing substantial amounts of uncertainty concerning technical feasibility, market fit and acceptance, and willingness to pay [12]. Similarly, many healthcare startups fail each year due to significant uncertainty in the same categories, taking millions in investment capital down with them.

These failures can often be attributed more specifically to a lack of understanding regarding the following: the need or problem, the product market fit, the competition and solutions on the market, the key stakeholders and their needs, the payment landscape in the healthcare industry, and the regulations in the industry. Although startups fail in other industries due to the same issues, the complexity of the healthcare system makes each of these issues much more challenging to address. For example, the healthcare industry has many stakeholders, often with conflicting needs, making innovating in this space much more challenging compared to other industries. Innovators often become trapped into thinking that they have to develop a product that meets the needs of all stakeholders rather than focusing on key stakeholders and tailoring the product to those key stakeholders. By attempting to please all stakeholders in the healthcare system, the innovator ends up

creating a generalized product that fails to address the needs of any of the stakeholders well enough to create value, and the company eventually fails due to lack of product market fit and a lack of willingness to pay.

Issues also commonly arise when developing business models for healthcare products. Reimbursement plays a large role in determining the pricing strategy for many healthcare products. Understanding the reimbursement landscape and how a product could be reimbursed can be very challenging, and oftentimes, healthcare startups overlook this during early stages of development and push it off until commercialization. This leads to issues when trying to commercialize the product, as the majority of hospitals and healthcare systems will not purchase products that increase their cost or are not highly reimbursed.

Due to these immense challenges faced by healthcare startups, developing and commercializing a solution can seem daunting and overwhelming without the help of a structured plan or framework to guide one through the design and development process.

1.2.3: Innovation frameworks in the healthcare industry

A number of frameworks and methodologies have been developed and applied to the healthcare sector over the past few years. However, success rates are low and implementation requires significant time, work, and capital. Additionally, different disciplines have focused significant attention on different stages of the product development cycle rather than the entire cycle. For example, engineering researchers typically focus on developing frameworks involved in engineering design decisions, while management researchers concentrate on the organizational issues and implementation strategies associated with product development. This approach, however, leads to segmented knowledge and the inability to evaluate a product's potential success from all angles (customer needs, technical feasibility, and commercial viability). For example, oftentimes, engineers are taught only how to evaluate a concept based on design inputs, and they possess limited knowledge as to what it would take to commercialize a solution; therefore, they cannot evaluate the concept based on its commercial viability. They are also often taught how to develop solutions based on given design inputs rather than being required to determine their own design inputs through first-hand observation of the

problem. This leads to a disconnect between the end users and the engineers, resulting in the development of solutions that fail to address the actual need, but instead address a subset of the need.

One of the earliest movements for applying an innovation framework to healthcare startups was the Lean LaunchPad. This was created by Steve Blank, and it took the methodologies of Eric Ries and applied them to healthcare. Ries created the idea of a "Lean Startup" and defined it as "an organization dedicated to creating something new under conditions of extreme uncertainty" [13]. This methodology focused on creating high value while keeping costs low and maintaining efficiency. He developed this methodology for managing technology and software companies, but it has since been applied to companies outside of the technology sector, including the healthcare industry. Steve Blank was the first to apply this methodology to the healthcare industry when he created a framework for his Lean LaunchPad class. This class aimed at teaching students from cross-functional backgrounds how to take their technology out of the research lab and into the real world. It emphasized the importance of testing a business idea before spending time and resources on launching it into a business, especially in the healthcare field [14]. Although the Lean LaunchPad is a great framework offering incredible insight into how to evaluate a business idea for commercial viability, it is still slightly segmented. The Lean LaunchPad focuses on what to do once an idea or concept has already begun to be developed, which is a stage too late. The first step of an innovation framework should be teaching people how to properly observe and identify needs in order to obtain a better understanding of customer requirements and develop a better solution. This way, pivoting (the act of changing a solution to fit a new or different market) can be avoided. The Lean LaunchPad teaches innovators how to pivot their idea after realizing there is not a strong product-market fit, but at that point, significant time, money, and resources could have already been used in developing the solution. By beginning the process with identifying a need, validating the need and potential market, and then developing a solution, significant risk and uncertainty can be eliminated early in the process and with minimal resources, thus eliminating the need for pivoting.

1.3 The Proposed Framework

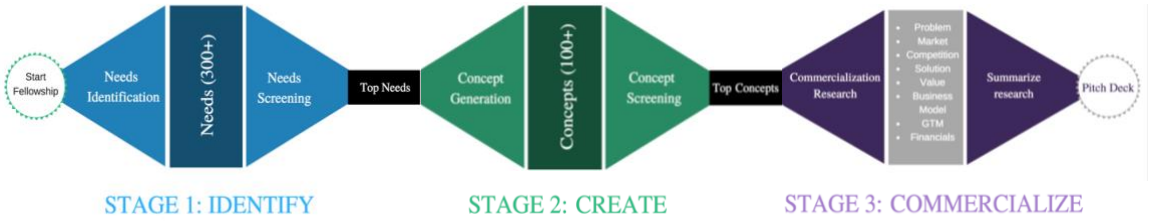


Figure 1: TMC Biodesign process overview.

As previously discussed, most frameworks focus only on teaching part of the innovation process. Although the insights gained from implementing those frameworks are beneficial and extremely important in starting a successful business, they are only small pieces of the overall process. When starting a venture, there is a great deal of risk associated with each step of the process, and those risks need to be evaluated and mitigated before moving on to the next step of the innovation process. Therefore, there is a need for a framework that encompasses all stages of product development to teach innovators how to efficiently evaluate a business idea and successfully create products that meet large healthcare needs. This thesis proposes such a framework.

As part of an initiative at the Texas Medical Center to bring healthcare entrepreneurship to Houston and utilize the abundant healthcare resources at the largest medical center in the world, I, in partnership with members of the TMC Innovation Institute, created the TMC Biodesign Fellowship. We created the framework used in this fellowship by combining the research initiatives of many other innovation processes (i.e., Lean Startup, Lean LaunchPad, user-centered design approaches, etc.), and we structured it very similarly to the fellowship created at Stanford University by Paul Yock and Josh Mackower.

The proposed framework adopts a broader perspective, focusing on the entire cycle of product development from identifying a need to developing a strategy for

commercialization. A much larger focus is placed on the initial stages of a project, aiming at making explicit the importance of considering not only design processes, but also the other processes that need to occur in the preliminary phases of innovation. Focusing on preliminary stages of the innovation process, such as observation and needs validation, has been proven crucial to the success of a healthcare product, since it is at this point during the cycle that significant risk and uncertainty can be eliminated relating to customer and market needs.

After significant research has been conducted to validate a need, the framework moves the fellows through a series of exercises to help them develop a viable solution that meets the identified user needs. Following that, the framework outlines a method for creating a commercialization strategy that encompasses everything from intellectual property and regulatory strategies to pricing and go-to-market strategies. Each stage of the process requires the fellows to look at a variety of aspects of the market and the solution, and with each stage, the research becomes more and more in-depth. This way, the fellows take into account the factors that lead to a successful business (market size, regulatory, competitive landscape, reimbursement pathways, etc.) from the early stages of the process rather than focusing on this only once a solution has been created, thus significantly mitigating risk.

This thesis outlines the structure of the framework and describes both the methods used throughout the inaugural year by the first medical device fellows and their results. It also summarizes some of the lessons I learned by participating in the program and details what key factors enable this program, or similar programs, to be successful.

The TMC fellowship is a 12-month training program that brings together four individuals from diverse backgrounds and emphasizes a needs-based approach to design. Its mission is to bring together the necessary people to solve healthcare problems and train innovators in how to innovate properly in the complex healthcare industry. The fellowship begins in September and finishes in the following September. After an initial week of onboarding, the fellows begin the first stage of the process: needs identification.

Summary of the framework

Stage 1: Identify

1. **Needs identification:** During the needs identification stage, the fellows participate in a number of activities to help them identify needs in the healthcare system. They are partnered with clinical mentors in their clinical focus areas who will help them set up rotations for clinical observations. The fellows also conduct research and clinical interviews to help identify potential needs, in addition to attending industry conferences in order to better understand the current problems being highlighted in the different healthcare settings. They begin to turn their observations and research into simple need statements that capture the problem, the stakeholders affected, and the desired outcomes.
2. **Needs screening:** After identifying a large number of needs, the fellows focus on gaining a deeper understanding of the needs and define criteria to determine the importance of a need. They work to determine whether the need actually exists and its scope. The fellows conduct multiple rounds of needs screening, and with each stage of screening, they dive deeper into their research surrounding the need. They present their top 12–15 needs to a panel of clinical experts for feedback before settling on a list of top 3 needs to move forward with into Stage 2: Create.

Stage 2: Create

1. **Concept generation:** After screening and selecting their top three needs, the fellows begin the concept generation stage where brainstorming occurs. The fellows are provided access to a prototyping space that contains multiple materials intended to spark creativity and enable brainstorming, such as whiteboards, sticky notes, markers, and so on, as well as a variety of low-fidelity prototyping material (i.e., clay, paper, pipe cleaners, glue, etc.).
2. **Concept screening:** Once the fellows have participated in a variety of brainstorming sessions for each need and have developed a list of potential solutions, they begin the filtration process once again, this time with a focus on intellectual property, regulatory and reimbursement hurdles, timeline to launch, technical feasibility, team interest, and other criteria that they define. They conduct

multiple rounds of concept screening before determining a concept to move forward with into Stage 3: Commercialize.

Stage 3: Commercialize

1. **Commercialization strategy & pitch deck:** During this stage, the fellows spend a great deal of time developing strategies for intellectual property, regulatory and reimbursement, R&D, and business development, in addition to crafting the elements of their pitch. They enlist the help of experts during this stage to aid them in finalizing their business strategies and reaching a point where they can pitch to angel investors and apply for business plan competitions.
2. **Investors, accelerators, and competitions:** The fellows are required to apply to at least two startup accelerators and to apply to pitch to at least one angel group as part of the completion of the fellowship. They are also encouraged to apply to as many business plan competitions as they can. So, during the final stage of the fellowship, the fellows create a pitch deck summarizing their need, solution, and commercialization plans.

After the fellowship ends, the fellows are not required to continue working on the product. However, if there is a great deal of interest and potential for commercial success, the fellows are encouraged to continue.

To our knowledge, this is the first fellowship program that is not associated with a specific university and that aims to train multidisciplinary teams on how to innovate in the healthcare industry.

The most distinctive features of this program are the intensive focus on the needs identification and user research aspect of the design cycle, the access to a variety of clinical institutions (clinical immersion in multiple different hospitals and healthcare systems rather than ones only associated with a specific university) and clinical mentors, and the length of the program.

CHAPTER 2: METHODS

2.1: Stage 1: Identify

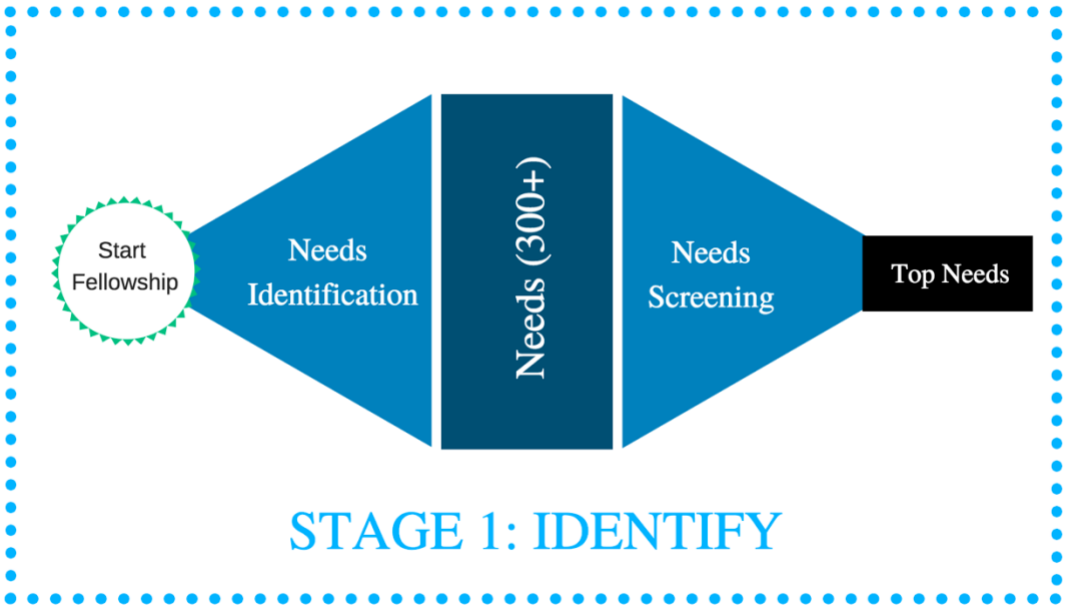


Figure 2: Overview of the first stage of the fellowship.

Identifying a compelling clinical need is arguably the most important step in the innovation process. There are many unsolved clinical problems just waiting to be identified; however, doing so is not as easy as it sounds. It takes hours of observation, research, and clinical interviews to identify a real unmet clinical need. Many innovators have found that the best way to identify real unmet clinical needs is to witness them first hand by observing both the people who encounter them every day as well as the situations in which these needs take place. Often times, people become so used to performing tasks in the manner in which they were originally taught that they forget to stop and ask why such a method is used, or they fail to see the inefficiencies in their processes. This is why simply adding a pair of fresh eyes can lead to uncovering significant opportunities for innovation.

By blending in as part of the team and observing the day-to-day operations, one can really understand how the procedures are currently performed, as well as the difficulties that arise with the current techniques. Only with a deep understanding of the difficulties and hurdles that need to be overcome can an innovator design something that truly solves the problem. This section outlines a method for identifying compelling clinical needs and provides pointers for determining the best need with which to move forward.

2.1.1 Needs Identification

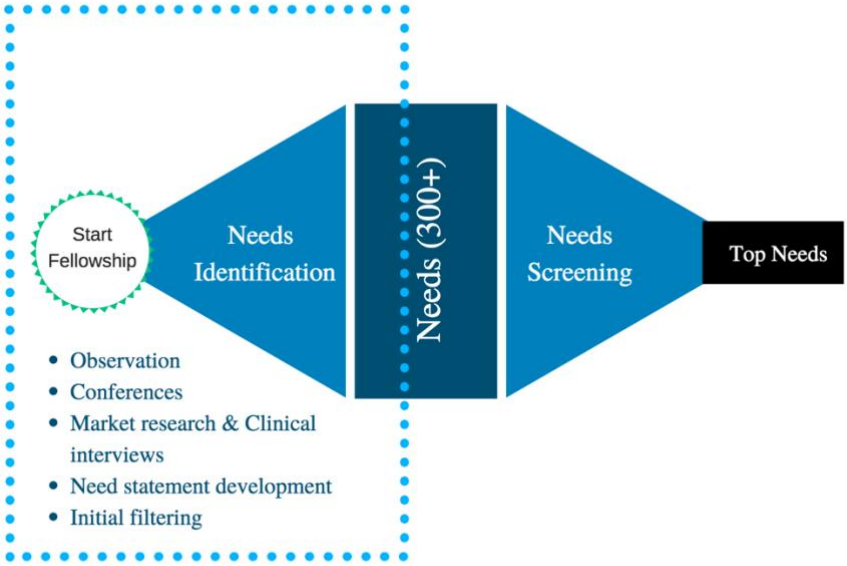


Figure 3: Overview of the needs identification process.

The fellows are encouraged to use a variety of methods for identifying potential needs during the initial stage of the fellowship. The majority of needs identification should be spent in clinical observations and shadowing healthcare providers in a variety of clinical settings. Outside of clinical rotations, fellows are encouraged to study disease state fundamentals and market trends, as well as to attend conferences intended to provide the opportunity to learn more about emerging technology and the problems that are important to thought leaders in the industry. All of the observations and problems identified through

clinical rotations and research should be documented and eventually turned into need statements. The development of a need statement will be an iterative process that should end with a well-defined need specification. This will be the guiding document throughout the innovation process and will be extremely important in designing a device that truly addresses a need. A process for identifying compelling clinical needs and translating them into need statements is described in detail below.

2.1.1.1: Observations

Observation is the most important and efficient method of identify needs. The goal of observation is to become a part of the team and observe problems through the eyes of the different stakeholders, and to see them from different perspectives. Fellows should begin by setting up their clinical rotations with the mentors they have been introduced to through the fellowship. As they shadow and meet new clinicians, they should continue to set up rotations to ensure that they observe in a variety of settings with a variety of clinicians of varying skill levels. For each clinical rotation, the fellows should document the date and time of the rotation, the procedures observed, the physicians and clinical staff shadowed, and the amount of time they shadowed, in addition to any observations they make during their rotation. Below are some tips for how to prepare for and what to look for while rotating.

1. **Preparing for observation:**

   Once the fellows have set up clinical rotations, they need to perform initial research into the procedure they are observing. This will help them understand what is being done in the procedure, what the outcomes should be, and what type of providers they will be observing. This allows them to ask educated questions and focus on the problems associated with the procedures rather than spending time trying to understand what is happening during the procedures. Fellows should purchase small bound notebooks that can fit in the pockets of their scrubs to bring into the OR or clinic in order to document their observations during their shift. They should always ask the physicians with whom they are rotating if it is okay for them to bring the notebook in and take notes.

2. Observation techniques:

During clinical rotations, the fellows should split up to cover more ground and observe a variety of procedures. If possible, for observations in the OR, one fellow should be on the floor with the surgical team while another observes from upstairs in an observation room. This allows more of the procedure to be documented and different vantage points to be recorded.

During each procedure, the fellows should time-stamp every step that is performed and take as detailed of notes as possible regarding the steps of the procedure and who did what during the procedure. This will make it easier to determine the inefficiencies in the procedures, which steps take the longest, and how many times specific tasks are done or repeated. Fellows are encouraged to look for steps that require multiple hands or seem cumbersome, require extreme precision or skill, require a great deal of time, or actions that, when asked why they are performed in a certain way, elicit such responses as, “That is the way we were taught,” or, “That is just how it is done,” and so on. Often times, these are signs that there is opportunity for innovation. It is important for the fellows to observe everyone involved in the procedure or process and understand the needs of each stakeholder, including the patient, provider (physician, nurse, tech, assistant, etc.), and the system. **Figure 4** provides examples of what to look for and what questions to ask during observation in order to identify potential needs based on the different types of stakeholders.

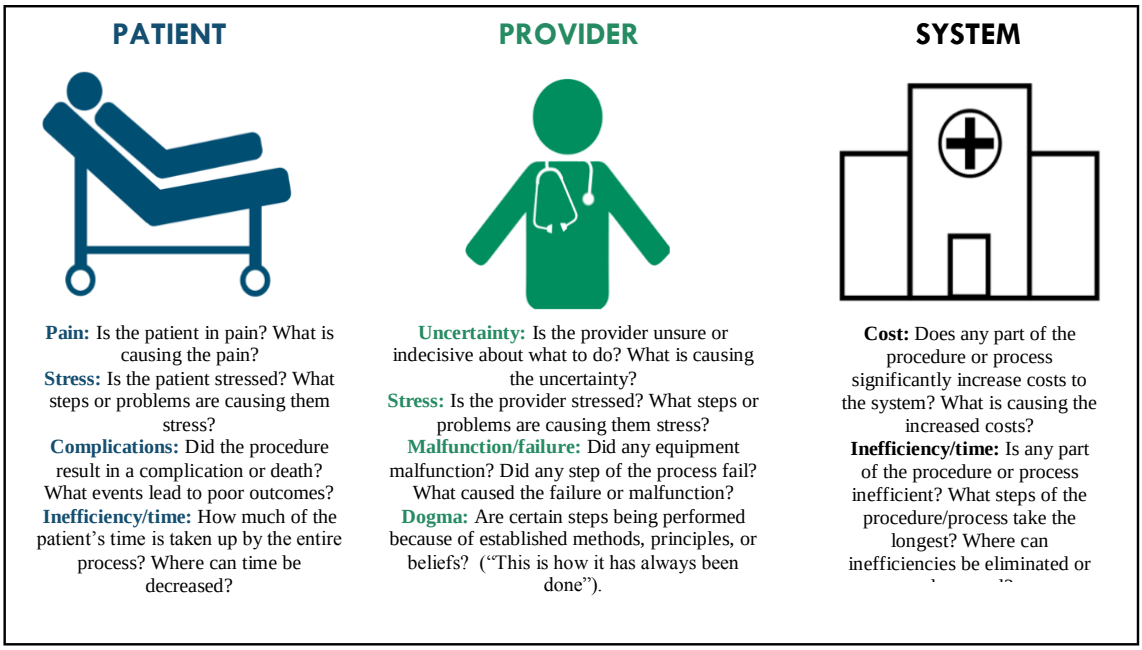


Figure 4: Examples of what to look for during observation for each stakeholder involved in the procedure or process.

It is important for the fellows to document every observation, even ones they do not think are relevant. A great deal goes on during a procedure, which makes it difficult to remember everything that happened and know what information might be useful later; if the fellows have detailed notes from their observations, they can go back to them later for reference.

When observing surgeries specifically, the fellows should always try to set up a time to debrief with the surgeon or surgical team after the procedure if possible, as they will most likely be unable to ask questions during the procedure. Many surgeons like their OR quiet, or would prefer not to be distracted during the procedure, so if the fellows have a question regarding a certain step or why something was performed a certain way, they should make a detailed note regarding when in the procedure it happened and the circumstances surrounding the step or event, and then ask the clinician about it in a post-surgery interview or debrief.

After every rotation, the fellows should review the notes they made during the shift and document all of the problems or needs identified during that shift. They

should create a shared spreadsheet that includes the problem, the procedure in which it was identified, the date it was identified, the stakeholder(s) affected, and any notes or observations surrounding it. This will be helpful when it comes time for them to translate their observations into need statements.

2.1.1.2: Industry Conferences

Another great way to identify potential needs is to attend conferences related to the focus area. This will help fellows to understand the issues that the key opinion leaders (KOLs) in their clinical focus area see as important. Attending conferences is also a great way for the fellows to network with potential stakeholders and KOLs who might be interested in becoming clinical mentors or advisors. Additionally, conferences serve as a great place to develop an understanding of the emerging technologies that address some of the needs in the industry, as well as new techniques that are being implemented in practice. The fellows should document the problems they identified through conference panels and presentations, as well as the emerging technologies or techniques that are related to the problems, if any, and prepare a presentation to share with their team upon their return.

2.1.1.3: Clinician Interviews and Market Research

Another great way to identify potential needs is to talk with clinicians and determine their pain-points or frustrations. It is important to understand that stakeholders sometimes do not see the entire need, and are instead aware of only a small part of the problem, so it is important to listen to them while also being able to take a step back and understand what is truly driving their frustration. In addition to interviewing clinicians and other stakeholders, market research is another great way to identify some of the major issues associated with a clinical focus area. Fellows should look into diseases that cost the healthcare system a great deal of money or result in serious complications or death, and then dive deeper into the diseases or procedures in order to understand the problems associated with them.

2.1.1.4: Need Statements

It is often easy to understand the broad nature of the clinical problems observed or identified, but it can be extremely difficult to define the actual clinical need. Often, needs are either too broad or too specific, solution dependent, or simply inaccurate due to lack of information, research, or understanding of the problem. After compelling clinical problems have been identified through observation, research, industry conferences, interviews, and so on, the next step is to translate the identified needs into clear need statements. A need statement is a one-sentence description of the clinical need that includes the problem or opportunity, the stakeholder or population affected, and the desired outcome (Figure 5).

Figure 5: Components of a good need statement.

Determining the perfect need statement will require a significant amount of work and trial and error, but this activity is extremely important, because it will help to scope the problem definition and the specifications associated with the need, and eventually, the parameters that the solution will have to satisfy [15]. The need statements will start out as very broad, rough versions of a need statement and, through iteration, scoping, and validation, will be shaped and refined into a more descriptive need statement.

It is important for the fellows to note that often times, there are multiple desirable outcomes associated with a need. However, it is important to include only the most important outcome in the need statement. This will ensure that the fellows are focused on the most important results, and will keep them from thinking that a solution only addresses the need if it addresses all of the desired outcomes, which is usually impossible. Three

examples of potential need statements can be seen in **Figure 6**. Once the fellows have created need statements for each of the problems identified through observation, it is time for them to perform an initial needs screening.

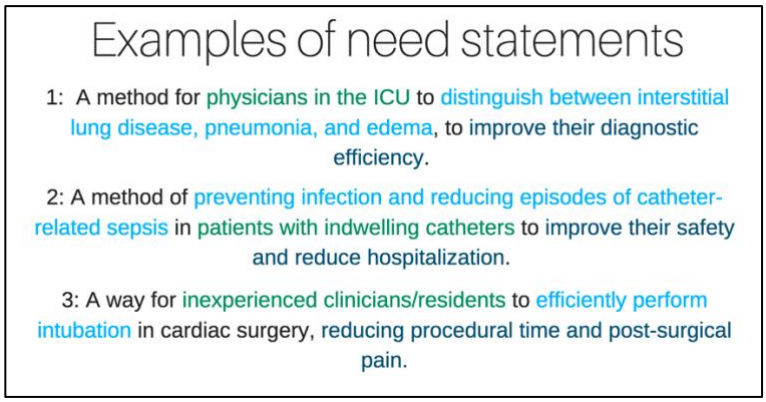


Figure 6: Need statement examples highlighting the problem/observation, stakeholder/population affected, and the desired outcome.

2.1.1.5: Initial Needs Screening

The fellows should have identified over 250 needs during their time in the needs-identification stage. The needs will be of varying clinical importance, and depending on the fellows' goals for their type of solution (i.e. blue sky vs. incremental), their team enthusiasm, and potential impact/market size, they should consider performing a preliminary needs screen. It is unrealistic to do in-depth research for all 250+ needs, so a preliminary screen could be very beneficial in helping the fellows choose which needs to dive deeper into. Through the exercises performed to develop the need statements and the preliminary research and validation performed during needs identification, fellows should already have a basic understanding of the need and be able to determine whether or not a need is worth looking into with more detail.

2.1.2: Needs Screening

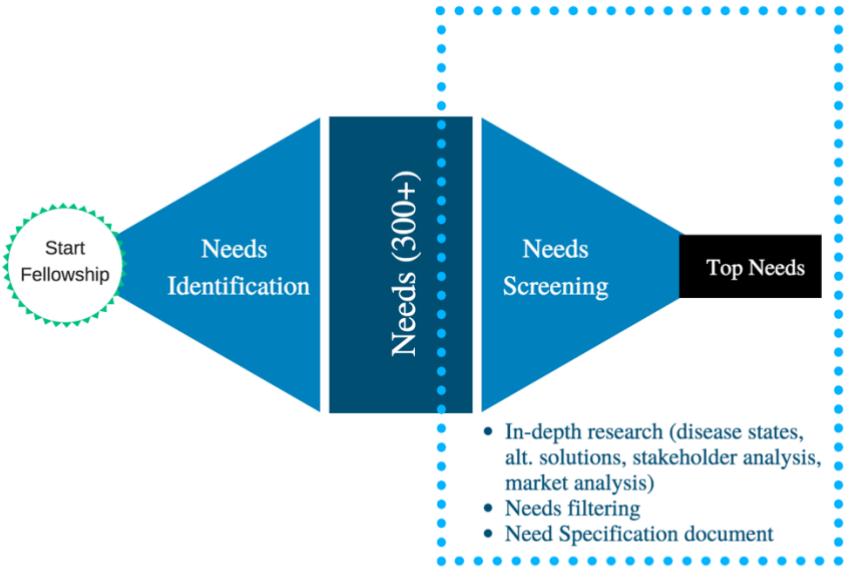


Figure 7: Overview of needs screening activities.

Once the fellows have turned all of their observations into need statements, scoped and validated them with preliminary stakeholder interviews, and performed an initial round of filtering, it is time for them to begin researching the needs in more detail.

The types of research that fellows should be performing for their needs are described in detail in this section. It is important to note that in the beginning, this research will be broad because of the large number of needs being researched. However, as needs continue to pass through the different screening stages, this research will become more in-depth.

2.1.2.1: Disease State Fundamentals

Like many other steps in this process, disease state research is iterative and becomes more refined as it is used throughout different steps of this stage. It starts out as background research performed prior to observation, and it becomes slightly more in-depth when

creating a need statement, but it becomes more important after the need statement has been crafted and refined. This research will help the fellows to compare multiple needs against each other during the screening processes, and is therefore a critical step. It is important that the fellows do not skip this step, even though it may seem tedious. This research does a great deal to help the fellows understand every aspect of the need, which can help them scope the problem and focus on the most important aspects of the need. After needs are defined, fellows should begin research into the diseases associated with the needs. This research is intended to provide the fellows with a deep understanding of the diseases and aspects of the conditions that are relevant to the clinical needs they have identified. As specific need statements are developed and refined, this research becomes more focused on the disease surrounding the specific aspect of the need identified. The fellows should understand the mechanism of action for the condition in question. They should focus on the anatomy and physiology associated with the need, pathophysiology, clinical presentation, clinical outcomes, epidemiology, and economic impact. In the beginning, this research is very high level. However, as the fellows continue through the different rounds of screening, this research becomes more in-depth.

2.1.2.2: Existing Solutions

As part of the initial needs identification research, as well as participating in observations and interviewing clinicians, the fellows should have gained insight into some of the treatment options that are currently on the market, as well as some opportunities for improvement. Now it is time to dive deeper into the current solutions that relate to the specific problem and desired outcome included in the need statement. The point of this is for the fellows to understand not only what solutions are currently on the market, but also the solutions that are emerging. This information will be crucial in ranking needs and determining whether or not a need should move on through the screening process. Therefore, it is important to not rush through this research. It is important to understand that there are multiple types of solutions, not just devices, that could be addressing a problem, and fellows are encouraged to research all types of solutions. Types of solutions include, but are not limited to, diagnostics, percutaneous treatments, minimally invasive

treatments, open surgery/invasive treatments, pharmacologic treatments, lifestyle treatments, services, and disease management [16]. During this research, it is important to also note what type of stakeholder is involved in providing the treatment. For example, there are a variety of different treatments available for damaged heart valves. Two types of the many solutions include open-heart valve replacement and trans-catheter valve replacement. Although the desired outcome is the same for both of these procedures, the stakeholders involved and the facilities required are different. For the open-heart procedure, a cardiothoracic surgeon would most likely be performing the procedure in an OR, whereas in the trans-catheter procedure, an interventional cardiologist would most likely be performing the procedure in a catheterization lab. Understanding the different stakeholders involved with each available treatment will help during the next step: Stakeholder Analysis.

2.1.2.3: Stakeholder Analysis

Stakeholder analyses are extremely important, especially in the medtech field due to the complex nature of the healthcare system. Unlike many other industries, healthcare has multiple stakeholders that drive adoption and possess decision-making power, and often times, their needs conflict. By collecting and analyzing data on all stakeholders involved with a need, one can develop an understanding of how they make decisions and what they require in a solution. It is important to note that it is common for stakeholders to have conflicting perspectives—solving the need may benefit some stakeholders while negatively affecting others. For example, a new device or technology that improves the accuracy of a procedure, but also significantly increases the cost, might be very desirable to the surgeon who cares most about outcomes, but not be as appealing to the hospital due to the increased costs. Another example could be a new device that allows procedures to be performed in a cardiac catheter lab rather than a cardiac OR; this might be appealing to the interventional cardiologists, but unappealing to the cardiothoracic surgeons because it could result in less procedures coming their way. Understanding how the need affects each different stakeholder is vital to creating a value proposition that resonates with all of the stakeholders.

A stakeholder analysis aims to identify the stakeholders involved with the need and understand their individual perspective and how they are affected by the need. It also stands to help the innovator determine the relevance of each stakeholder, as well as their potential to drive adoption.

The first step of the stakeholder analysis is to identify the important stakeholders associated with the need. This can be done through research and clinical interviews with known key stakeholders focused on identifying other important stakeholders. Due to the large number of stakeholders often involved in the healthcare industry, it is impractical, if not impossible at times, to please every stakeholder, so it is important to focus on the most critical stakeholders. Hospital—or medical—stakeholders can be defined as "individuals, groups, and organizations who have a stake in the decisions and actions of the hospitals and who may attempt [or have the power to] influence those decisions and actions" [17]. They can be characterized as primary stakeholders, who are essential to the adoption and survival of the product, and secondary stakeholders, who the company might interact with or who might be directly affected by the need, but do not possess decision-making power, or are not essential to the adoption and survival of the product and company [18]. There can also be external stakeholders, such as other companies, who might contribute to, compete with, or have something to gain from a product. These stakeholders are frequently categorized as potential collaborators or threats [19].

In order to understand and properly categorize each stakeholder, user profiles should be created for each identified stakeholder. A user profile should include general information about the person (age, gender, education level, job title, etc.), as well as their needs, interests, expectations, and behaviors. Much of this information will already have been gathered during clinical observations, but the fellows will most likely need to go back and observe and interview the stakeholders again, this time focusing specifically on aspects that will help them create a user profile rather than identifying needs.

Once the fellows have a strong understanding of each of the stakeholders, how they are affected by the need, and their influencing power, they can begin to categorize each stakeholder. One way to do this is to create a plot of the stakeholders, taking into account their level of interest and their level of power (Figure 8). The stakeholder's location on the

plot will help the fellows to understand if they are primary or secondary stakeholders and the best way to engage them.

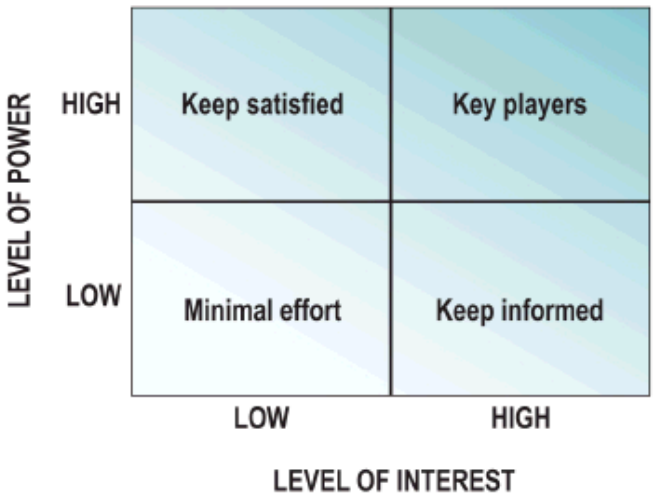


Figure 8: Stakeholder analysis plot. Reprinted from *Understanding stakeholder analysis: the key steps*, by State Services Commission (2009). Retrieved from: http://www.ssc.govt.nz/node/6253.

As the fellows continue throughout this process and learn more about their need and, eventually, design a solution, the user profiles and stakeholder analyses will become more detailed, and this will be extremely valuable during the concept generation and commercialization phases.

2.1.2.4: Market Analysis

One of the most frustrating aspects of this process is identifying a real need that, if addressed, could save lives and make an impact, but realizing that the market is not large enough for it to be commercially viable. This will likely occur during the screening process, and it is important for fellows to determine this early on in the process, rather than moving forward and wasting time and money pursuing a need that is not commercially viable. This is not to say that fellows cannot address a need that has a small initial market, but if the

target market is small, then there must be other markets that are associated with the need to make it a worthwhile need to pursue. The fellows will need to define what makes a market viable based on feedback from stakeholders and potential investors. Performing a market analysis is extremely important and will provide valuable information for refining the need statement and eventually developing a need specification. The insight gained from performing a market analysis will also help the fellows better understand the different requirements associated with each market associated with the overall need. Performing a good market analysis includes multiple steps, which are explained in more detail below.

1. **Market mapping and segmentation:** As discussed earlier, it is not realistic to perform a detailed market research on every need. Therefore, fellows are encouraged to initially perform a high-level overview of the broad markets associated with each need and then continue to dive deeper into the market landscape as they move through the screening process. The fellows should begin by identifying the overall market for the diseases associated with their needs and then narrow the market size down to the specific conditions, patients, symptoms, and so on that their need targets. Often times, fellows will have already developed a broad understanding of the market size through the course of the disease state fundamentals research.

   Fellows should also use the information gathered from the existing solutions research they conducted to map out how well the needs are being met in the overall market. This should help the fellows identify where there are opportunities in the market for new solutions. Fellows should also look into growth opportunities for the overall market and market trends. They should be aware of whether a market seems to be shrinking or growing and understand what factors are affecting this growth or shrinkage. All of this information should be documented and used during needs screening to evaluate the viability of the need.

   After a broad understanding of the overall market is established, it is important for the fellows to break the market up into segments. Market segmentation refers to the aggregation of stakeholders into groups that possess common needs and respond similarly to the identified need [20]. It is unlikely that

a solution will address the needs of all stakeholders associated with a broad market, so it is important to understand the requirements of stakeholders in different market segments and to determine which segments have needs that are not being met by current solutions. There are multiple ways to segment a market in the medical field. Four of the most common types of market segmentation can be seen in Table 1.

Table 1: Types of market segmentation

Segmentation Type	Description
Geographic	Geographic segmentation divides markets based on geographic criteria such as Country, Region, Population Density, Climatic Zone, City or Town size, etc. This type of segmentation would be helpful for deciding which country a solution might bring the most value to.
Demographic	Demographic segmentation divides markets based on variables such as age, income, family size, professional experience, etc. In the medical device industry, demographic segmentation might be based on patient age or physician skill-level/training, or by the type of payer, such as Medicare or out-of-pocket payer.
Psychographic	Psychographic segmentation divides markets based on the activities, interests, and opinions of potential customers. It focuses on which external influences they respond to, and how they make decisions for which products they use or buy.
Behavioral	Behavioral segmentation divides markets based on observed behaviors. This could include benefits sought (quality, low-cost, convenience, etc), brand loyalty (loyal, switcher, non-loyal, etc), buyer readiness, or adopter status. In the medical field, adopter status is a popular way to segment markets. For example certain specialties are known for being innovative, or having clinicians that are considered early adopters of new technology.

Specifically for segmenting healthcare markets, it can be beneficial to start with basic patient-based analysis and then build from that by adding in more complex factors to eventually account for the different stakeholders [15]. A more detailed approach to market segmentation will be taken once a final need has been selected,

a concept has been chosen, and the fellows are entering the commercialization stage.

2. **Target market identification:** After the fellows have spent some time segmenting the markets associated with each of their needs, they can begin identifying potential target markets. The fellows will spend more time looking into potential target markets during the commercialization stage. To choose a potential target market for each need, the fellows should use all of the information found during the initial market analysis process to determine the segment for which a solution could bring the most value. Fellows need to take into account market size, market dynamics, the needs of the market segment, willingness to pay, and market enthusiasm. The target market, and the analysis surrounding the target market, should be used to help filter needs during the needs screening process

The market analysis process can seem very daunting and time-consuming. However, it is important to realize that this information is necessary to evaluate the different needs. More detailed research will be performed as the final needs are determined and a final concept is selected. The research performed during this stage of the process is preliminary, and it is unrealistic for the fellows to have detailed market analyses for all of their needs. The extent of the research performed during this stage should only be as in-depth as necessary to evaluate the viability of the needs in question.

2.1.2.5: Needs Screening and Selection

Once the fellows have a preliminary understanding of the disease state fundamentals, existing solutions or treatment options, the stakeholders, and the market landscape, it is time for them to perform needs screening. Multiple rounds of needs screening will be required to select the top three needs that will move forward into Stage 2: Create. Each stage of needs screening will require more information and research than the last. Figure 9 depicts a general approach for the different stages of needs screening.

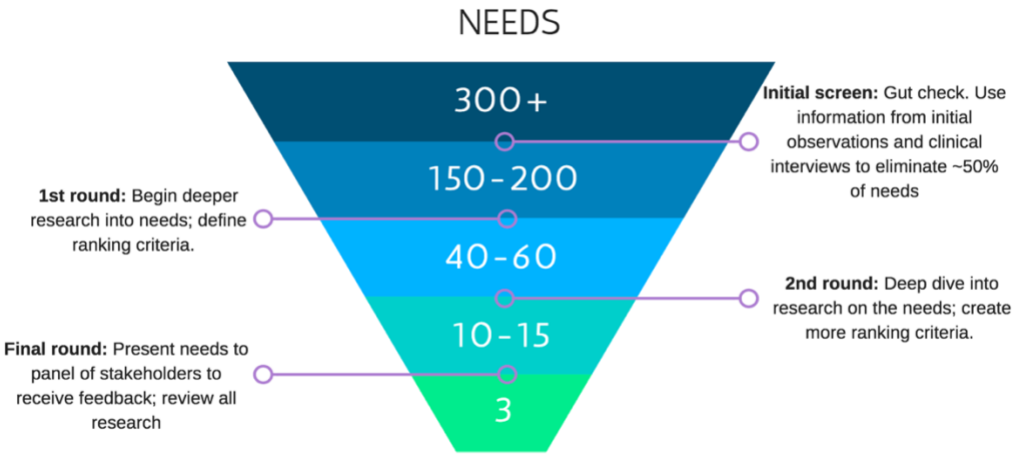


Figure 9: The different needs screening and the number of needs in each round.

At the end of this phase, fellows will draft a need specification document—a document that summarizes all of the important information gathered throughout the identification stage and the filtering stage, which is explained in more detail in later sections of this thesis. This document will serve as a starting point for initial concept generation.

Needs filtering is an inherently subjective process, so it is important to develop a framework for assessing and comparing needs that ensures that all of the data and information gathered throughout this process is taken into account. An approach for filtering and selecting needs can be seen in Figure 10.

Figure 10: Process for needs screening and selection.

As seen from the figure above, this process is iterative and will most likely be performed multiple times before the fellows arrive at their final needs.

2.1.2.6: Need Specification Document

Once the fellows have identified their top 10–15 needs, they should begin developing a need specification document, also known as an opportunity specification document, for each of their top needs. This document will be essential for guiding concept generation and selection, and will be constantly revised throughout this innovation process. The need specification document is a detailed document that summarizes the market need and the information gathered surrounding the market opportunity. It should include the need statement, a summary of the information and data gathered throughout the needs identification and needs screening processes, and the need criteria. The need criteria are the stakeholders' key requirements for any solution relating to the need. These are often grouped by "must-have" and "nice-to-have" criteria. Must-have criteria are essential to the solution and are required in order to fully address the need. They are often related to function and safety, and are the key requirements for creating value for the stakeholders. Nice-to-have criteria are not essential to solving the problem, but they increase the solution's value and desirability. These criteria should be defined based on the research with key stakeholders performed throughout this process, and they should be validated with stakeholders before moving forward into Stage 2: Create.

Breaking the criteria into must-haves and nice-to-haves will help the fellows to remain focused during concept generation and selection, and prevent them from spending extra time or energy developing nice-to-have features that don't add much value. It is important for them to focus their time and effort on developing the most imperative features of a solution first (must-have criteria).

It is important to realize that, although need specification documents have to be created in order to move forward with the innovation process, those are living documents,

and will most likely evolve over time as the fellows learn more about the need they are addressing and begin generating concepts and gathering feedback concerning them.

2.1.2.7: Final Selection

After the need specification documents have been created, fellows should arrange for a feedback session with a group of key opinion leaders associated with each of their top needs, in addition to their mentors and advisors. They should present the need specifications to the group and gather feedback on the top needs. The input from the stakeholders and business advisors should serve as the last screening round before choosing the top three needs with which to move forward. Fellows should ask the clinicians and advisors to rank their needs and provide feedback on the need statements and specification documents. This information, along with all of the information gathered throughout the needs screening process, should be used to choose three top needs that will continue on to Stage 2: Create.

2.2: Stage 2: Create

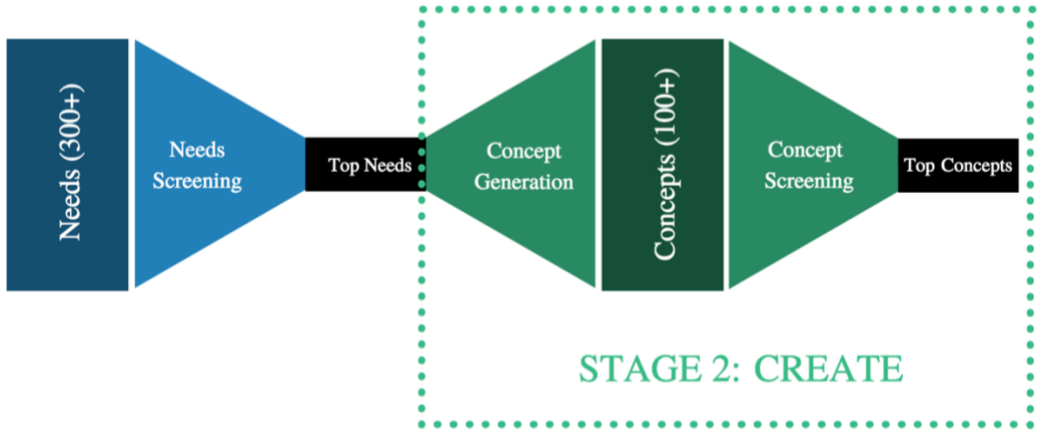


Figure 11: Overview of the second stage of the fellowship.

Inventing a medical device is a much more complex process than inventing products in many other industries due to the number of stakeholders involved and regulations required.

Just as there are a number of steps to complete during the initial stage of this process related to the need, stakeholder interest, and market opportunity, there are multiple activities the fellows need to partake in during this second stage of product development. During this stage, it is extremely important for fellows to understand not only how to translate user needs into product functions, but also the very complex pathways to reimbursement and regulatory approval. The hurdles associated with regulations and payments in the healthcare system can be very complicated, making innovating within this industry extremely challenging. This means that great attention must be placed on understanding the regulatory and reimbursement pathways associated with the concepts that are being generated, in addition to the requirements necessary to create an innovative product in other industries, such as the IP landscape, business model, and feasibility. This section will describe techniques the fellows should use throughout concept generation and concept screening.

2.2.1: Concept Generation

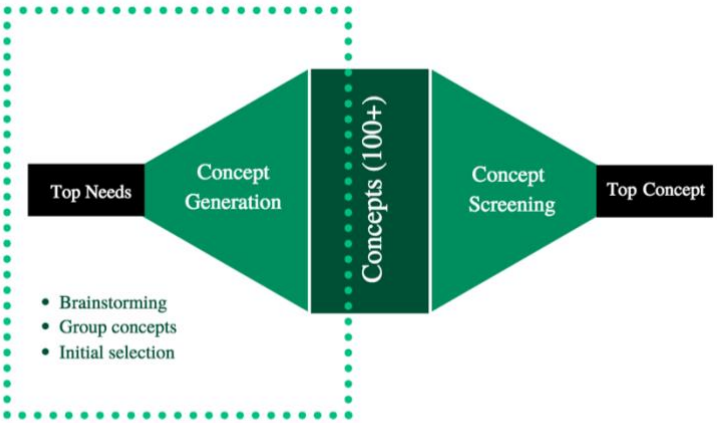


Figure 12: Activities included in concept generation.

Once the top three needs are chosen, fellows can begin the brainstorming and concept generation process. It is important to understand that concept generation requires a very different mindset than any other stage in the product development cycle—one that is

neither critical nor judgmental. As there are many different, and often conflicting, theories around the best way to brainstorm, fellows should implement a variety of techniques to see which ones work best for the individuals on the team. A process for brainstorming is described in detail below.

1. **Establish rules before beginning brainstorming:** The fellows should establish general rules for the brainstorming sessions so that everybody feels safe sharing their ideas during the sessions, and so that the sessions can be as productive as possible.
2. **Break needs down into smaller problems, causes, or functions:** Hosting brainstorming sessions on general needs can often be overwhelming and intimidating, and can lead to unproductive and frustrating sessions. It is often advantageous for fellows to break down their overall needs into smaller needs or causes for the problem, and then have brainstorming sessions on each sub-need or sub-problem.
3. **Implement different brainstorming techniques:** The fellows should implement multiple brainstorming techniques throughout this stage to spark creativity and determine which brainstorming styles work best for the different individuals on their team. There is an abundance of brainstorming techniques utilized today, and the fellows are encouraged to determine which ones work best for them. It is important to host multiple brainstorming sessions, implementing a variety of brainstorming techniques for each sub-problem or sub-function identified as part of the overall need. This is important in order to make sure that all aspects of the problem have been addressed, and looking at smaller pieces of the overall problem can help the fellows generate ideas when they previously though they had exhausted all possibilities.
4. **Capture and organize the results:** It is very important to capture all ideas that come out of a brainstorming session. During a session, ideas should be documented on paper, post-its, white boards, or even explained using low-fidelity prototypes. The ideas generated should be documented immediately after the session has ended. This allows any confusion to be addressed while the idea is still fresh in the

inventor's mind. A process for capturing and organizing the results from a session is detailed below:

a. Name each idea/concept: After a brainstorming session, review each generated concept and give it a label and short description in order to make it easily remembered. The person associated with the concept must also be documented so that, if clarification is desired, it can be acquired through follow-up with the person who came up with the idea.
b. Photograph all sketches/lo-fidelity prototypes: If the concept is complicated or has a sketch or lo-fidelity prototype associated with it, it should be photographed, and its image should accompany its name and description.
c. Group and cluster ideas: As mentioned throughout this section, concept generation is about quantity. As such, it is important that multiple ideas are generated before settling on a specific solution. However, it is unrealistic for the fellows to prototype and research every concept that is generated. In order to move from an overwhelming number of concepts to a more manageable number of realistic concepts, it is important for fellows to organize and group their solutions into categories or types of concepts (**Figure 13**). This is an effective method for seeing how the solutions are related to each other and the overall need, as well as seeing if there are any gaps in the solutions identified. This also helps the fellows organize their concepts in preparation for concept screening.

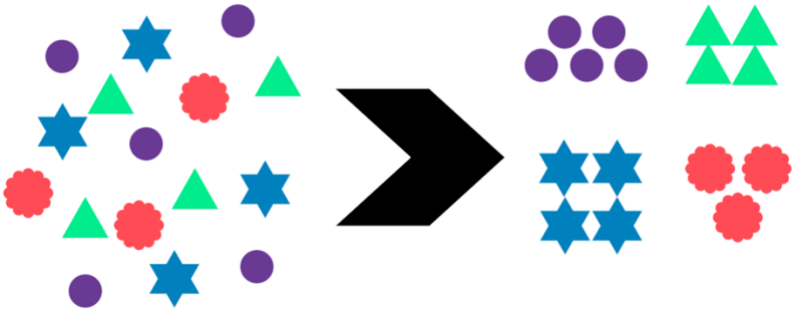


Figure 13: Visual representation of grouping concepts based on organizing principles.

After each brainstorming session, the concepts should be labeled and photographed (if necessary), and the concepts should be grouped according to some organizing principle, such as function, technical feasibility, resources required, and so on. Once clustered or grouped, the concepts should be visually organized into something like a mind-map. A mind-map, or concept map, visually represents how ideas relate to one another and the overall need. They are used to help the fellows cluster their ideas and recognize patterns, as well as to identify gaps in the solutions they have generated. An example of a mind map can be seen in Figure 14. This mind-map breaks down a need relating to empyema and pleural effusions. The organizing principles identified in this example are (1) removing fluid and (2) removing the peel/rind. These principles are further broken down into sub-principles when the mind-map is generated. For example, "Removing the peel/rind" is broken down into mechanical, biomimetic, and mechatronic ways to remove the peel, and then the solutions or ideas are placed where they best fit within these organizing principles and sub-principles. By looking at the number of ideas in each sub-group, it is easy to see that some concepts or ideas are well defined and thought out, while other solutions are more generalized ideas or approaches. Creating a mind-map helps fellows to identify what their next steps need to be and to

determine if they are ready to move on to concept screening and selection, or if they need to spend more time generating new ideas.

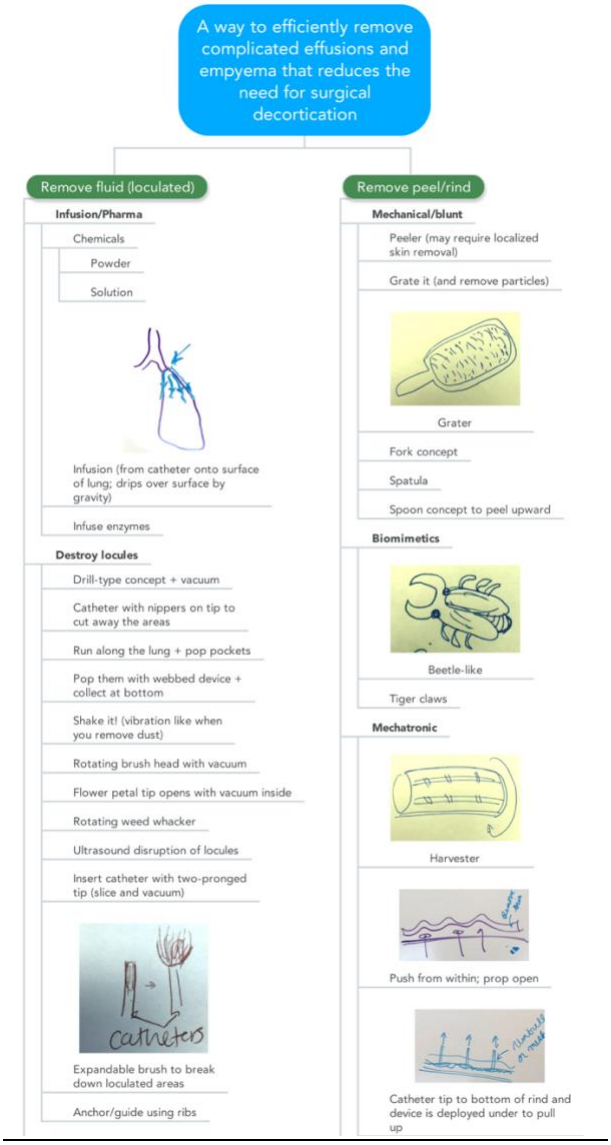


Figure 14: An excerpt from a simple mind-map for the need: A way to efficiently address complicated effusions and empyema that reduces the need for surgical decortication. Courtesy of inagural TMC Biodesign team: Jessica Traver, Nicole Moskowitz, Yashar Ganjeh, and Xavier Garia-Rojas.

5. **Initial concept screening:** Similarly to when the fellows had to perform an initial needs screening to eliminate a large number of needs so that they could focus on a smaller number of needs that they could research in detail, the fellows now need to perform an initial screening of their concepts so that, moving forward, they can

reduce the number of concepts to research to a more manageable number. At this stage, it might be helpful to engage with experts in the field in order to stay objective and ensure that the solutions are addressing the actual need statement. Speaking with individuals who have diverse backgrounds and experiences can be helpful in evaluating the solutions on the different criteria assigned for screening. Two methods that should be used during the initial concept screen are explained below:

a. Compare concepts to needs specification: Once all of the concepts are grouped and the fellows have a strong understanding of the concepts generated, the proposed solutions should be compared against the need and the requirements set forth in the needs specification document created during the identification stage. Concepts should be evaluated relative to the need criteria, as well as the defined "must haves" and "nice-to-haves." Concepts that do not meet the "must haves" and the need criteria should be set aside or removed, while the ones that do should then be compared against the nice-to-have criteria.
b. Perform initial "gut check" and feasibility screen: After comparing the concepts to the needs specification documents, the fellows should perform a simple concept screen based on criteria of their choice (similarly to what was done for initial needs screening). This could either be a "gut check" based on feasibility or it could be based on criteria surrounding team skillsets, team enthusiasm, clinical enthusiasm, timeline to proof-of-concept, and so on. After the initial concept screening, fellows should have between 10–20 concepts with which to move forward.

2.2.2: Concept Screening and Selection

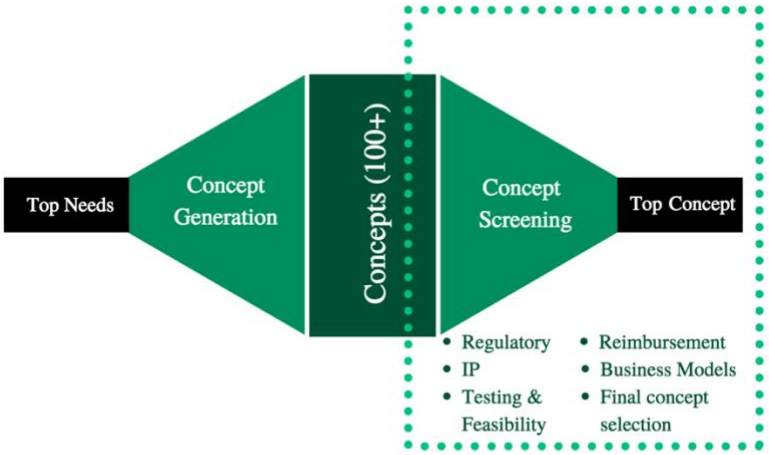


Figure 15: Summary of activities in concept screening.

After brainstorming hundreds of potential concepts and performing an initial concept screen, it is time to begin narrowing down the list of potential solutions to just one or two. It is common to see fellows hesitate during this stage and not want to make a decision due to lack of information or uncertainty concerning whether a solution could work or not. It is important to realize that it is impossible to seriously consider multiple concepts at the same time. The phrase "fail fast" is important to keep in mind during this stage. By choosing one or two concepts and moving forward with them quickly, fellows can gain valuable insights into the concept and can move on to other potential solutions quickly if they find that a solution was not feasible. The goal during this stage is to prove/disprove the top solutions as quickly as possible. However, there is a balance between thorough research and failing fast that the fellows must find.

It is important to understand the pathway of medical device innovation and how reimbursement, regulations, intellection property, business models, and feasibility of a solution are all vital to creating a successful device. Understanding the potential strategies and pathways for the solutions in review is necessary and should be a large part of the

concept selection process. The type of research that should be performed for each of the concepts at this stage is described below. The fellows should use the findings from this research to rank concepts and determine their top one or two in order to move forward into the commercialization stage.

2.2.2.1: Intellectual Property (IP) Basics and FTO

It is important to research similar technologies and review existing patents that are related to the concepts that have been generated. A patent gives the inventor the right to exclude others from commercial use of the invention, so understanding existing patents related to a concept under review is extremely important. *Biodesign: The Process of Innovating Medical Technologies* [15-16] describes the importance of understanding the patent landscape well when they say that "the presence of patents with similar technology to the concept in question can complicate or even derail the fellows' ability to launch a new company or product. However, on the other hand, having a strong patent landscape can add tremendous value to an invention" [16]. Therefore, understanding the IP landscape early in the concept screening stage is important to determining the commercialization potential for a solution.

Another thing to be aware of is that a patent gives one the right to exclude others, but it does not give one the right to practice, which is why it is important to understand freedom to operate. Freedom to operate (FTO) is only established if the features of the new invention are "free and clear of valid claims from patents that are still in force in the country of question" [16] There should not be any claims in a prior patent that describe the features of the new invention and nothing else, meaning if there is a patent that has claims on features that are not part of the new invention, or if the new invention has some features that are not covered by the prior claims, then FTO is preserved [16].

Fellows should begin understanding the IP landscape by performing prior art searches and documenting any patents that seem similar to the concepts being assessed or have claims that cover features of the concept being assessed. It is important to determine if prior art exists for a concept being pursued as soon as possible, because if prior art is identified, it can either save the fellows a significant amount of time and money by allowing

them to move forward with a different concept, or it can give them the opportunity to redesign the concept into something that is patentable and has FTO.

Prior art searches will require a lot of time and will be an ongoing process, as new patents and patent applications are released every Tuesday and Thursday in the US. In order to begin a prior art search, the fellows need to have a clear understanding of the concept they are researching and its potential claims. This will help them to determine key search terms for identifying potential prior art. While reviewing similar patents, it is important to understand what claims are important and how they relate to the concept in question. In order to do that, it is important to understand what makes an invention patentable. There are three things an invention is judged on to determine if its patentability: utility, novelty, and obviousness [21]. "Utility" means that the invention has to do something that is useful, which is easiest to prove in the medical device field. "Novelty" means that the invention must be in some way different than other patents or products known to the public anywhere in the world. This is relatively easy to prove, because any difference between a new invention and a prior invention will suffice. Fellows can determine if their concept will meet the requirements for novelty by performing a prior art search. However, it is important to remember that just because an invention is considered novel and a patent is issued, it does not mean that there is FTO. The last, and hardest, criterion upon which an invention is judged is "obviousness." The patent reviewer has to believe that the new invention is non-obvious, meaning that any skilled person working in the given field with the technology in question would not think the invention to be obvious in light of prior patents [21].

Fellows should use this understanding of what a concept requires to be patentable to help them determine which existing patents could exclude them from receiving a patent on their concept. All relevant patents and claims should be documented and ranked according to perceived risk, and they should be used as selection criteria for the final concept.

2.2.2.2: Regulatory

Regulatory issues play a critical role in the success of a new medical device. As such, understanding the regulatory landscape or necessary regulatory pathway for a solution is extremely important and should be taken into consideration during concept screening. Often, fellows will seek help from a regulatory consultant at some point during development, but at this early stage, it is important to understand the basics of the regulatory pathway that a concept would require, and the costs, timeline, and clinical data associated with the different pathways. In the US, there are three different classes of devices, each requiring different requirements to receive FDA clearance. Table 2 explains the different FDA classifications. Fellows are encouraged to research the different classes in more detail and understand what class each of their solutions would be considered a part of.

Table 2: Medical device classification and requirements.

Class	Description	FDA Pathway/Requirements	Examples
Class I	Class I devices are considered low risk, and therefore present minimal potential harm to the patient.	Class I devices are only subject to general controls, including registering the medical device, proper branding and labeling, and proper manufacturing techniques. The company must notify the FDA prior to marketing the device.	Elastic bandages, tongue depressors, exam gloves, handheld dental instruments, dental floss.
Class II	Class II devices are considered moderate risk devices. They are more complex than Class I devices, and therefore, companies must prove that the device does not cause harm to the user or the patient. The majority of medical devices are considered Class II.	Class II devices are subject to general and special controls, including special labeling requirements, mandatory performance standards, design controls, and post-market surveillance. These devices generally require a 510(k) pathway. However, certain Class II devices without clear predicate devices may be required to take a De Novo 510(k) pathway.	Ultrasound devices, infusion pumps, powered wheelchairs, surgical needles, suture materials.
Class III	Class III devices are high risk devices, and have the highest chance of causing potential harm to the patient. These devices are usually implantable, therapeutic, or life-sustaining.	Class III devices must meet all requirements for Class I and II devices, in addition to strict requirements relating to gathering evidence proving the safety and efficacy of the device before being able to be used in humans. Typically, Class II devices must take the PMA pathway for regulatory approval.	Implantable pacemakers, heart valves, breast implants, bone cement.

A great way to determine the class under which a concept might be categorized, as well as to understand they type of testing that would be required to receive FDA clearance, is to research predicate devices. Predicate devices are devices that are substantially equivalent to the product in question. According to the FDA, "Substantial equivalence is established with respect to: intended use, design, energy used or delivered, materials, performance, safety, effectiveness, labeling, biocompatibility, standards and other applicable characteristics" [22]. Fellows should use this information to help determine whether or not a device they are researching can be used as a predicate for the concept they are assessing.

2.2.2.3: Reimbursement

In industries outside of healthcare, a product will usually be successful if there is high enough demand from the customer or end user. However, in healthcare, things are not that simple. In the healthcare industry, payers (private or public insurance companies) are responsible for making the decisions surrounding whether or not a device will be paid for or reimbursed. This is taken into serious consideration by hospitals and healthcare facilities before introducing a new medical device into their practice, because it can significantly affect the cost burden to the facility and its physicians, as well as their profit margins. Securing reimbursement can be one of the most challenging hurdles for a new medical device to overcome, so it is important for the fellows to understand the basics of how their solution might be reimbursed.

Many factors are taken into account in order to determine the amount that is reimbursed for each procedure, including the location of the procedure, the costs associated with the procedure, and the codes associated with the procedure. Physicians and facilities submit bills to insurers using standardized codes to document what procedures were performed. Depending on the setting (inpatient or outpatient), different types of codes are used to determine what needs to be billed. The different type of codes, when they are used, and who gets reimbursed (facility or physician) are described in Table 3.

Table 3: Types of reimbursement billing codes.

Type of code	Description/Use	Setting	Facility or Physician Reimbursement
ICD-9	Used to document both diagnoses and procedures for facility bills in the inpatient setting.	Inpatient setting	Facility bill
HCPCS Level 1 (aka CPT)	Used to document procedures and services provided by physicians and medical staff.	Outpatient setting	Facility & Physician bill
HCPCS Level II	Used to document products, supplies, and services that are not included in the CPT codes that were used outside of the physician's office.	Outpatient setting	Facility bill

Simply submitting a properly coded bill to an insurance company does not guarantee that the facility or physician will be reimbursed for their work. Procedures are only covered under specific conditions, and the policies surrounding when a procedure is covered is not uniform across all payers, so fellows are encouraged to reach out to payers, as well as to speak with reimbursement specialists in order to better understand the type of reimbursement they can expect for their solutions. A flow diagram of how billing and reimbursement typically works depending on setting and codes used can be seen in Figure 16. Fellows are encouraged to map out the reimbursement process for the procedures their solutions are associated with, or to document the setting, applicable codes, reimbursement rates, and other pertinent information into a table for analysis.

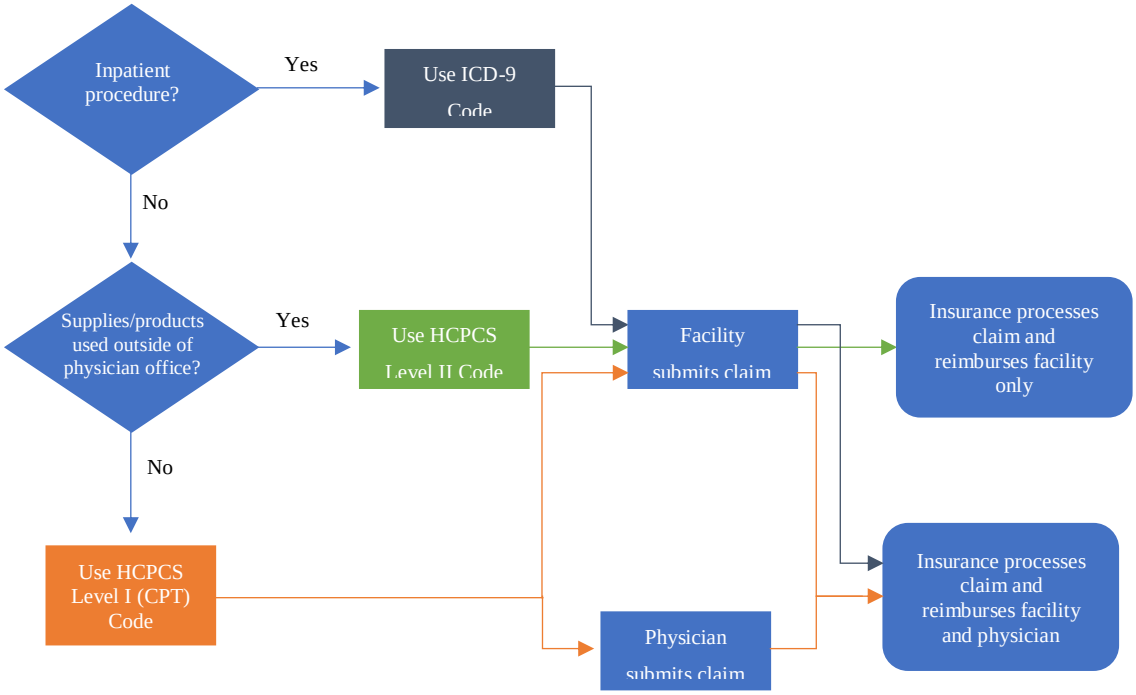


Figure 16: A diagram of how billing and reimbursement works based on the setting and type of code used.

2.2.2.4: Business Models

In general, a business model is how an organization, product, or service will generate revenue and create and deliver value to customers. It is just as important to consider the business model that will be employed as it is to consider the IP, reimbursement, and regulatory strategies that will be required for a device.

In the medical device industry, a variety of business models are commonly used, including, but not limited to, reusable products, disposable products, implantable products, and capital equipment. Each of these business models are briefly discussed below. Fellows are encouraged to research other business models in addition to the ones listed below.

1. **Disposable Products:** Disposable products are low-cost, single-use products. They can be coupled with capital equipment or reusables, or they can be stand-alone products. They are usually sold through distribution channels, require little to no training, and require high sales volumes in order to make up for the low margins.

Disposables generate constant revenue, but they are also very commoditized goods, and therefore, competition is usually very high. *Examples include needles, collection tubes, ultrasound covers, sterile draping, and surgical sponges.*

2. **Reusable Products:** Reusable products are products that can be used multiple times but have a relatively short life-span (when compared to capital equipment). These products have higher costs than disposable products, but are much cheaper than capital equipment. These products tend to have no recurring revenue, except for when a device breaks and needs to be replaced. Consequently, they cannot support a sales force. Sales margins can be high for these products, but due to lack of recurring revenue, businesses opportunities around only reusable products tend to be smaller. *Examples include clamps, forceps, endoscopes, stethoscopes, surgical trays, and surgical shavers.*
3. **Implantable Products:** Implantable products tend to be high-cost products, ranging anywhere from $1,000–$5,000+, and they require the most clinical validation. They also carry the most liability to the company that manufactures and markets them. Due to the high risk of the device, implantable products require a large sales force. However, a benefit of implantable devices is that they provide an ongoing revenue stream due to the direct link between the number of products sold and the number of procedures performed each year. *Examples include pacemakers, artificial joints, stents, breast implants, and nerve stimulators.*
4. **Capital Equipment:** Capital equipment are reusable products that have much longer shelf lives and must be sold at much higher costs than reusable products in order to offset the lack of recurring revenue. The decision to purchase a capital equipment product is usually made by a team of people at the facility, and therefore, sales cycles can be much longer than other products. A benefit of capital equipment is that there is usually strong brand loyalty once purchased—it is extremely costly for a facility to switch to another provider after they have already purchased a capital equipment product from another. *Examples include ultrasound devices, MRIs, X-Ray machines, and CT Scanners.*

A great tool for developing a business model is the business model canvas developed by Alexander Osterwalder. The fellows are encouraged to fill out the canvas in order to identify a business model that works best for their product or service. The business model canvas (Figure 17) is broken up into nine building blocks that can help break down how a company plans to make money, focusing on the four main areas of a business: customers, offer, infrastructure, and financial viability [23].

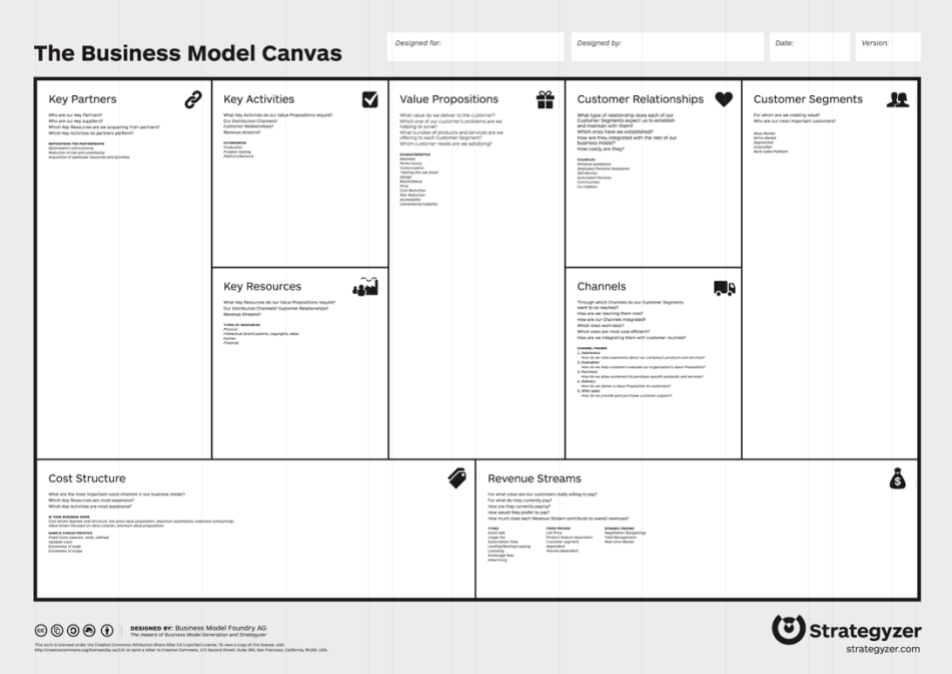


Figure 17: Business model canvas. Reprinted from *The Business Model Canvas*. Osterwalder, Pigneur & al. (2010). Retrieved from https://strategyzer.com/canvas/business-model-canvas.

The nine building blocks, as seen in the canvas above, are customer segments, value propositions, channels, customer relationships, revenue streams, key resources, key activities, key partnerships, and cost structure. Each block has a set of questions the fellows should be asking, which are described in more detail below. For more detailed information on how to fill out the business model canvas, fellows should refer to the book *Business Model Generation* by Alex Osterwalder and Yves Pigneur. It is important to note that fellows should continue to revisit the business model canvas and make changes as they

learn more about their business opportunity. They should also fill out multiple versions for each concept in order to see how different business models could affect their business.

1. **Customer Segments:** Fellows should start with this section, because without customers, a company cannot survive, which makes understanding them crucial to developing a successful business model. This section defines the different groups of people that a product aims to reach or serve. It is important to categorize and group customer segments and then determine which segments will be focused on and which will be ignored. At this stage, fellows should already possess a very strong understanding of the customers they are focusing on and their specific needs. Important questions to ask for this section are as follows: *For whom are we creating value? Who are our most important customers?*[23]
2. **Value Propositions:** After defining the customer segments, fellows should move on to the value proposition box. The value proposition is the reason that a customer chooses one product over another; it solves the customers' problem or satisfies their need. At this stage, fellows should also possess a very strong understanding of their value proposition, which should make filling out this section easy for them. Important questions to ask for this section are as follows: *What value do we deliver to the customer? Which one of our customers' problems are we helping to solve? Which customer needs are we satisfying? What bundles of products and services are we offering to each customer segment?* [23]
3. **Channels:** Channels constitute the company's interaction with customers and the way in which the customer will purchase the product. Questions to ask for this section are as follows: *Through which channels do our customer segments want to be reached? How are our channels integrated? Which ones work best? Which ones are most cost-efficient? How are we integrating them with customer routines?* [23]
4. **Customer Relationships:** This block helps to determine the type of relationship a company will establish with each customer segment and how they will go

about establishing that relationship. The questions to ask for this section are as follows: *What type of relationship does each of our customer segments expect us to establish and maintain with them? Which ones have we established? How costly are they? How are they integrated with the rest of our business model?* [23]

5. **Revenue Streams:** This is where the fellows should define how their product will generate revenue from each customer segment. The questions to ask for this section are as follows: *For what value are our customers really willing to pay? For what do they currently pay? How are they currently paying? How would they prefer to pay? How much does each revenue stream contribute to overall revenues?* [23]
6. **Key Resources**: Key resources are the resources needed to make the business model work. Key resources can be financial, physical, human, or intellectual, and they can be owned by the company or acquired by key partners [23]. Questions to ask for this section are as follows: *What key resources do our value propositions require? Our distribution channels? Customer relationships? Revenue streams?* [23]
7. **Key Activities:** Key activities are the most important actions a company needs to take in order to make the business model work. Questions to ask for this section are as follows: *What key activities do our value propositions require? Our distribution channels? Customer relationships? Revenue streams?* [23]
8. **Key Partnerships:** Key partnerships describe the network of partners that are required in order to successfully introduce the product to the market. Questions to ask for this section are as follows: *Who are our key partners? Who are our key suppliers? Which key resources are we acquiring from partners? Which key activities do partners perform?* [23]
9. **Cost Structure:** This section should include all of the costs required to operate the business model. All of the costs associated with creating and delivering value, maintaining customer relationships, and generating revenue can easily be determined after defining the key resources, activities, and partnerships.

> Questions to ask for this section are as follows: *What are the most important costs inherent in our business model? Which key resources are most expensive? Which key activities are most expensive?* [23]

Fellows should create multiple versions of the business model canvas for each concept and iterate on them in order to determine the best business models possible for each solution. The top business model canvas for each solution should be documented and be taken into consideration during final concept selection.

2.2.2.5: Prototyping and Feasibility Testing

A prototype allows a concept to be transformed into a form so that insights can be gained, feedback can be given, and adjustments can be made. Prototyping is extremely important in the design stage and is vital to the concept screening process. Fellows should be encouraged to fail fast and fail early during this process, meaning low-fidelity prototypes should be created often during this stage. Having a methodology or process for creating prototypes efficiently can be very beneficial during this stage. Figure 18 demonstrates a process fellows should use to efficiently assess concepts and mitigate risk by developing different types of prototypes.

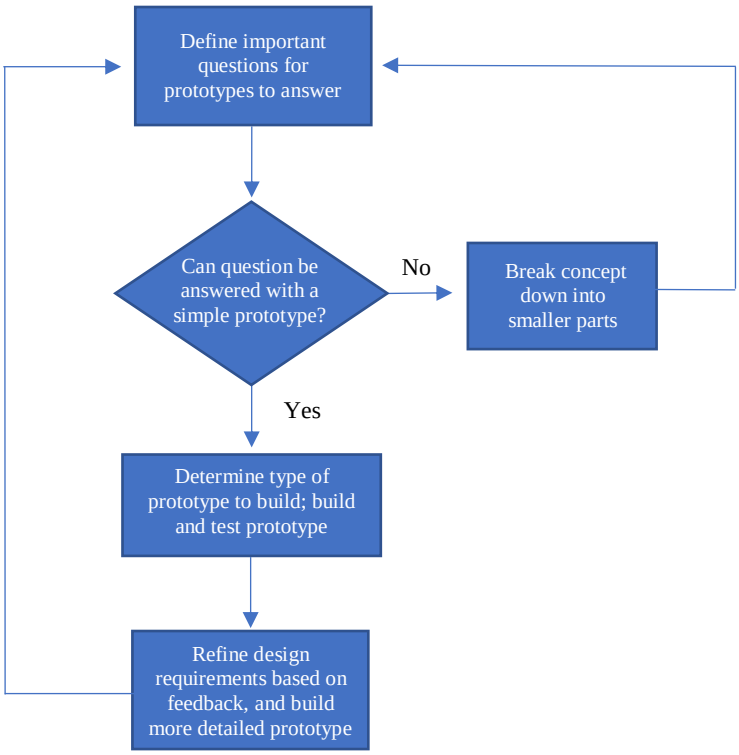


Figure 18: Process for developing prototypes to mitigate risk quickly.

1. **Define the core questions that need to be answered for each concept to mitigate risk:** To prototype effectively, it is important to understand the most important questions that need to be answered about a potential solution. The issues the fellows should be focusing on are ones that, if addressed by a prototype, will significantly mitigate risk moving forward. The goal of this stage is to mitigate risk as quickly as possible and with the simplest test possible. Fellows should focus on designing the least complex model possible that can still adequately address the key issue or question, also known as a minimum viable product (MVP). An MVP is a product that has the smallest number of features that will work as a standalone product while still solving at least one of the user's core needs and demonstrating value [24]. This is a great tool for maximizing customer feedback and learning in a short period of time, in addition to being a great way to create a product that one can get into early-

adopters' hands as soon as possible. Having a clear understanding of what the MVP should contain (refer to the need specification documents) is extremely beneficial, because it keeps the fellows on track and does not allow them to waste time focusing on building and testing "nice-to-have" features rather than the critical features that bring value to the user.

2. **Break concepts down into smaller, essential sub-concepts to test:** Similarly to the concept generation and brainstorming stage, where it can be overwhelming to brainstorm on an entire need, trying to prototype an entire concept can also be overwhelming and might take up more time than necessary to answer the basic questions surrounding the solution. Fellows are encouraged to break a concept down into smaller parts, or sub-concepts, that represent different functions of the solution, and to prototype those parts. By doing this, fellows can quickly prototype the smaller, essential components of the concepts in order to test their feasibility and mitigate risk quickly. Once the smaller parts have been prototyped and their feasibility proven, the fellows can begin to mix and match prototypes to create a more cohesive solution.
3. **Determine the best type of prototype to answer the questions surrounding the concept:** There are a variety of different types of prototypes that can be built in order to test different theories or answer different types of questions. It would be inefficient to design a prototype with human factors in mind just to prove technical feasibility in a lab, just as it would be to receive feedback on the look and feel of a design using a prototype that also functions technically. It is important to gain answers to the questions surrounding the top concepts as quickly as possible, and in order to do so, it is necessary to determine what types of prototypes should be built to best attain those answers. As explained in *Biodesign: The Process of Innovating Medical Technologies*, picking the right prototype is extremely important [16]:

> Just as developing a prototype that is unnecessarily complex can be distracting to the innovators, it can also be distracting to users when asked to give their feedback… if an early works-like prototype looks too much like a finished product, users may

> concentrate on how the device looks and feels instead of focusing on critical issues related to its fundamental functionality. The level of the prototype must match the question or issue being considered an only incorporate as much complexity as is needed to find this answer.

Generally, there are three types of prototypes that are commonly used to address different questions surrounding a concept: a "works-like" prototype, a "feels-like" prototype, and a "looks-like" prototype. During later stages of prototyping, these models can also be combined to answer more specific questions surrounding the concept. The types of prototype and the types of questions they should be used to answer are explained in Table 4.

Table 4: Types of prototypes and their purpose.

Type of Prototype	Description	Purpose
Works-like prototype	• Demonstrate technical feasibility • May not look or feel like the end product • Gather feedback about what stakeholders like/dislike about the *functional aspects* of the concept	Should be used to answer questions related to *technical feasibility*
Feels-like prototype	• Demonstrate ergonomics, weight, size, etc. • Created from final material or material similar to final material • Gather feedback about what stakeholders like/dislike about the *usability* of the concept	Should be used to answer questions related to *user experience and usability*
Looks-like prototype	• Demonstrate shape, color, size, packaging, etc. • Used to demonstrate a "finished looking" prototype to show to investors or potential customers • Often created during later stages of development • Gather feedback about what stakeholders like/dislike about the *form factors* of the concept	Should be used to gather feedback surrounding *marketing*, as well as to communicate the design to *investors and customers*

After feedback has been received and questions have been answered using the types of prototypes described in Table 4, fellows should begin combining the types of prototypes to answer more specific questions and move closer to a final prototype. For example, a works-like/looks-like prototype might start to incorporate some of the feedback surrounding form factors into a working prototype, allowing fellows to use the device in more detailed testing in order to better understand how stakeholders interact with the device as a whole and gather feedback on how the form of the device might change the effectiveness of the technology.

4. **Refine design requirements and design more detailed prototypes:** Once a prototype has been developed and can demonstrate a concept in working form, it becomes easier to gather specific feedback from stakeholders that can guide improvements for the solution. Once the original need specifications have been built into a prototype and tested, additional criteria can be defined based on what has been learned from the prototyping and testing that was completed, as well as the feedback gathered using those prototypes. Future prototypes should incorporate the feedback gathered from earlier stages of testing and the new design requirements. Through the process of developing more and more detailed prototypes, fellows will start to understand the technical specifications necessary for each design, in addition to the trade-offs necessary between technical specifications and design requirements.

2.2.2.6: Define Ranking Criteria and Perform Final Concept Screen

After creating, testing, and gathering feedback on multiple prototypes, diving deeper into IP, regulatory, and reimbursement strategies and looking into different types of business models, it becomes time to decide which solution to move forward with into the implementation stage. During research into the IP landscape, the regulatory pathway required, reimbursement options, and potential business models for each concept, fellows will automatically eliminate some of the concepts based on killer risks or problems that are so important that it is clear to the fellows that the concept cannot move forward. Then,

during the prototyping and testing stage, fellows should be able to eliminate the majority of the leftover concepts based on feasibility. That way by the time they reach the final selection stage, there should only be a small number of concepts left to evaluate, if they were not already able to select a top concept through the activities performed during this stage. At this point, it is time to define criteria to rank each concept against and evaluate the risks associated with each leading concept. Fellows are encouraged to speak with their advisors and mentors during this stage to help them evaluate the concepts without bias.

2.3: Stage 3: Commercialize

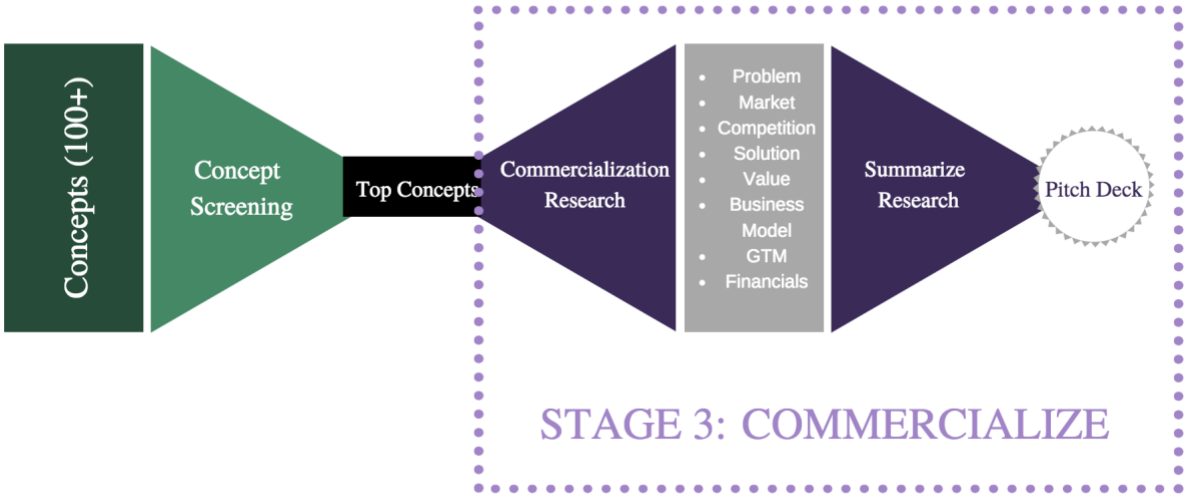


Figure 19: Summary of activities in the commercialization stage.

Now that the fellows have identified a viable need and proven their concept, it is time to begin the commercialization process. Although this is the final stage of the fellowship, it is really just the beginning of the company's journey. After the fellowship is over, if the fellows decide to move forward with their idea, they will continuously be iterating on what comes out of this stage.

During this stage, the fellows will build off of everything they have learned over the last two stages relating to their need and concept. They will focus on refining strategies related to every aspect of their company, including IP, regulatory, reimbursement, product development, business models, and finances. The fellows will rely heavily on their advisors and will begin to engage with consultants during this stage. It is imperative for them to work with people who have a deep understanding of the areas they are researching. Any money that is left in their budget after prototyping should be used to hire consultants or bring on part-time advisors. If all of the allotted budget was used during prototyping, they can discuss other forms of payment with potential collaborators. Commonly, law firms will defer payments until a funding round, or advisors will help in exchange for equity rather than money. Often, founders will even use their own funds to help move a project forward. The payment methods are up to the fellows to negotiate and determine on a case-to-case basis; what is important is that they find a way to work with experts during this stage to develop the best strategies they can for moving forward.

2.3.1: Strategy and Pitch Deck Development

At the end of the fellowship, the fellows should possess enough information surrounding their business and their path forward to pitch to angel investors for seed funding, compete in business plan competitions, and apply to startup accelerators. The deliverable for this stage, and therefore the fellowship, should be a complete pitch deck that can be used for such applications and pitches. A pitch deck is a presentation that consists of 15–20 slides used to showcase a product or technology and describe the business plan for the company. It is typically used in place of a formal business plan document, which startups rarely prepare at this early stage.

I suggest the approach of building the pitch deck as a way to prepare for implementation, as this helps to identify any gaps in the knowledge and helps the fellows focus on getting the help they need to fill in those gaps. Once the fellows have a pitch deck, I would suggest that they pitch to advisors and any investors that they know, not for money, but to see what questions they ask, where they lose focus, and what they don’t understand.

This will help the fellows identify where they need more information and help them to understand what does and does not resonate with their audience.

Throughout this section, I will break down the aspects of the pitch and all that needs to be included. In doing so, I will explain in more detail the strategies that need to be developed further during this stage in order to prepare the team to begin the fundraising process. The steps below are listed in the suggested order for presenting in a pitch deck. However, gathering the information for these sections will most likely be done in parallel, as much of the information gathered for one section will also help in another.

2.3.1.1: The Problem

The key questions that need to be answered in this section are as follows: What is the procedure associated with the problem; what are the problems with the current method/procedure; why are they important; how important are they; and who are they important to? At this point, the team should possess a very strong understanding of the problem(s) associated with current methods of a procedure, but now it is the fellows' job to determine which problems are important to which stakeholders, and to tailor their message to each of them. For this section, the fellows have to go through all of the issues associated with the current procedure and determine which are the most important to highlight to their audience.

This section should align very closely with what is presented in later in this section: The Value. In both sections, there will be a large focus on the stakeholders and what they value most, so it will be advantageous for the fellows to revisit the user profiles and stakeholder analyses created previously and dive even deeper into them. They should conduct even more stakeholder interviews, this time with the prototype and the knowledge they possess regarding the functionality/potential functionality of their device. They should gather feedback concerning what problems associated with the overall need are the most important to the different stakeholders. Again, the fellows should already have a strong understanding of this due to the extensive research they have performed throughout the fellowship; now, they should be gathering additional data to substantiate their claims and summarizing the data they have gathered.

2.3.1.2: The Market Size

The key questions that need to be answered in this section are as follows: How big is the market for the problem being addressed; how many procedures are performed each year, or how many patients are affected; what is the cost of the current procedures; and what is the total addressable market? Fellows should possess a basic understanding of the market size based on the initial research performed during in the previous stages. However, now it is time to for them to evaluate the market based on their solution and develop a better understanding of the cost associated with the current procedures. Fellows should already know how many procedures are being performed or how many patients are affected by the need they are addressing. At this point, they need to focus on the market segments the device could actually be applied to, in addition to the different sub-populations or procedures the solution addresses. Segmenting the market in this way will aid the fellows when it comes time to evaluate what their launch market will be. Once the fellows have gained a better understanding of the number of procedures or patients that their solution could potentially address, they can begin calculating their total addressable market. The total addressable market is the amount of revenue that a business would earn if they captured 100% of their market. This number needs to be large enough that, if they are able to capture a small amount of it, their business would still be profitable and attractive to investors. There are two main methods of calculating the total addressable market: a top-down approach and a bottom-up approach.

1. **Top-down approach:** A top-down analysis is usually conducted by first determining the overall market and then applying filters related to the specific solution in order to narrow the market down to what the solution can address in order to estimate the share of the market that the company could capture. For example, assume a company is developing a device for patients with late-stage COPD (stage 4–5) who are not candidates for lung-volume reduction (LVR) surgery. The number of patients with COPD in the country—or world, depending on what market is being evaluated (national or global)—would need to be determined. It is estimated that currently there are over 11M people with COPD in the in the US [25]. Next, a filter would be added for the stage of the disease.

Assuming 5% of patients have late stage COPD (Stage 4–5), the market would be narrowed to 550,000 patients. Lastly, a filter would be applied for patients that are not candidates for LVR surgeries. Assuming that only 25% of late-stage COPD patients are candidates for LVR procedures, then the market would be 412,000 patients. This example is represented in Figure 20.

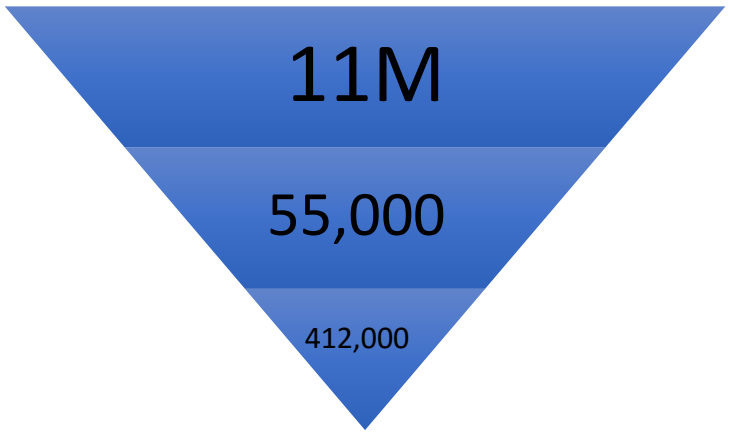


Figure 20: Example of the top-down approach for a device that targets patients with late-stage COPD who are not candidates for LVR surgeries (Filters are based on assumptions; therefore, end market value is not accurate and should not be taken as such).

The cost of similar procedures or devices would then be determined and multiplied by the market size in order to determine the total addressable market. For example, assuming the average LVR alternative procedure costs approximately $35,000 per patient, the total addressable market would be 412,000 x 35,000 = $14.42B.

2. **Bottom-up approach:** A bottom-up approach sizes a market based on estimates related to small, defined segments of the market. One would start by identifying the customer segments the device is intended to reach, the settings or places in which the product could be sold, and how the customer segments are expected to grow based on comparable products on the market and expected adoption rates. For example, assume a technology company is entering a new market to provide health and fitness data through a wearable device. Through research, the company

determines that there are two customer segments that are likely to adopt the product: Women ages 22–45 in urban centers, and married men ages 35–50 in urban centers. In this case, the company would look at other devices on the market addressing similar market segments to determine acceptable estimates for growth and adoption rates. They would take into consideration where tech accessories such as wearables are typically sold, how many locations sell wearable technologies, and how many of these places would be willing to sell their wearable. This would require a mix of stakeholder interviews and research into similar devices and the places they were able to sell their products. They could then look at how many places sell devices similar to their wearable each year in order to estimate the market size for their product. This method is usually more time consuming and requires more research than the top-down approach, but it is typically more accurate.

It is important to understand that market sizing in general requires a fair amount of guesswork and estimations, and it will never be perfectly accurate. The goal is to make educated assumptions based on a mix of research into the potential markets, comparable devices, and stakeholder adoption rates so that one can better estimate how much money a business could make when on the market.

2.3.1.3: The Competition

The key questions that need to be addressed in this section are as follows: How is this product better than the competition; how will this invention be protected; and how can competitors be kept from copying this product?

2.3.1.3.1: Understanding the Pros and Cons of Existing Products or Emerging Products

It is extremely important for the fellows to possess a strong understanding of how their product differs from others on the market, and to be able to explain the benefits of their product. This will be important not only for investors, but also for marketing strategies in the future. There are typically three categories companies use to differentiate their product on the market: Functional positioning, i.e., “Our device disinfects the tool 5x better than

the leading brands;" symbolic positioning, i.e., "Our device reduces disposable waste generated in the OR," which appeals to a symbolic position that the consumer may value; and experiential positioning, i.e., "Our bone saw is quieter than the competition," therefore making some steps of the procedure less annoying, loud, uncomfortable, etc. for the physician.

The fellows should break down each of their competitor's products and look at how their product differs, focusing on the three different categories of positioning explained above. They should determine a set of criteria to compare their product against based on feedback from stakeholders regarding what aspects of the product the stakeholders value.

There are two main methods for visually demonstrating the competitive landscape and how the solution being presented stacks up against competition: a graph or a table. If displaying competition in the form of a graph, the fellows should choose two important factors for comparison, which would become the axis of the plot. Then, they should plot their competition, and themselves, on the graph, ideally showing that their product is a better choice than that of their competition. An example of a competition graph for the popular technology startup, Airbnb, can be seen in Figure 21. This option is beneficial if there are few important factors that stakeholders consider when purchasing a product. If there are multiple pieces of criteria to rank products with, the fellows should display their product and competition as a table.

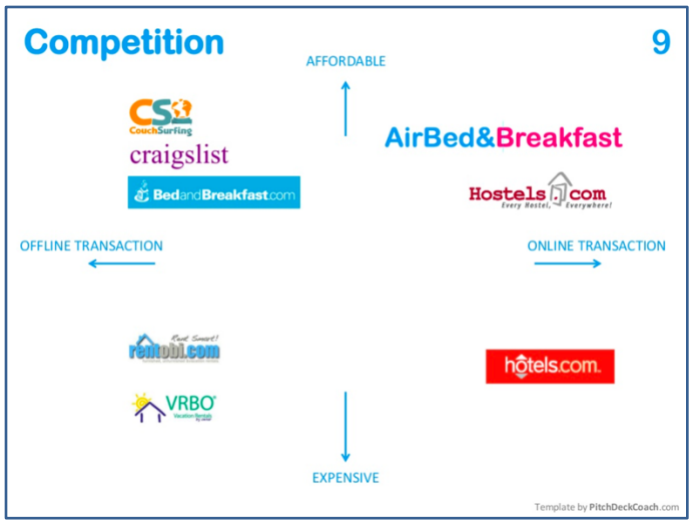


Figure 21: Competition graph for Airbnb. Reprinted from *Slideshare.* PitchDeckCoach (2015*).* Retrieved from https://www.slideshare.net/PitchDeckCoach/airbnb-first-pitch-deck-editable.

If the fellows choose to display their competition as a table, they should pick the most important criteria that stakeholders are interested in when purchasing a product and list them in the rows of the table. They should then develop a visual ranking system (i.e., red, yellow, and green dots, or simply ‘x’s and check marks) to demonstrate how well each product meets each criterion. An example of a competition table for a company called Vidinterest, who claims to be “the Pinterest for video,” can be seen in Figure 22.

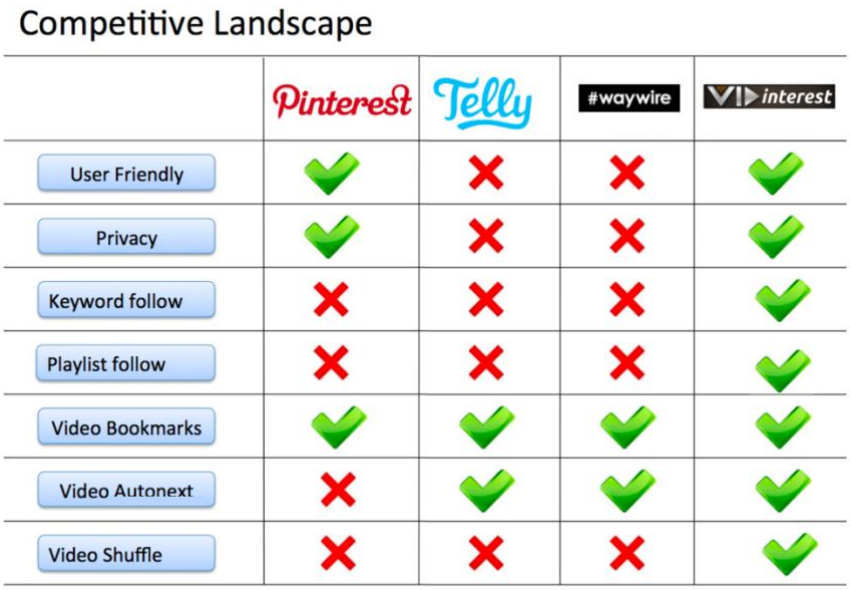


Figure 22: Competition chart for Vidinterest. Reprinted from *Pitch Club: The Competition Slide in Your Startup Pitch Deck.* StartupsHK (2013). Retrieved from http://www.startupshk.com/pitch-club-the-competion-slide-in-your-startup-pitch-deck/.

Both methods for displaying the competitive landscape are acceptable and widely used, so the fellows should choose whichever method works best with their product.

2.3.1.3.2 : Protecting Against Competition

Understanding how a product compares to its competitors, and proving that the product being developed is superior to them, is only half of the competition strategy. Another extremely important factor is related to the company’s intellectual property (IP). Having a strong IP strategy is particularly important in the medical device field. A strong IP strategy

can cause significant barriers to entry for potential competitors, as well as help to avoid any costly lawsuits down the line. In order to have a strong IP strategy, the fellows need to be consistently reviewing the patent landscape related to their solution and working with patent experts to help create a patent portfolio that makes sense for them.

During this stage, fellows should consult with legal counsel to determine what IP they should be filing at this stage and what they should think about filing in the near future. Usually, this will result in the fellows filing one, or many, provisional patents on their solution.

Fellows should also discuss with their attorneys whether or not it is a good time for them to have an FTO search completed. It is commonly assumed that receiving a patent means individuals are allowed to commercialize their product, but this is incorrect. There are frequently situations where a device may have a patentable feature, but other features of the device infringe on other patents. Therefore, it is very important to evaluate FTO.

The FTO searches performed by big law firms can cost anywhere between $10–20k, so if the fellows cannot afford that, or their firm will not agree to defer the costs, they should begin attempting a search themselves. This will most likely be sufficient for a friends and family or seed round of funding, but once they raise money, they need to have an official FTO search performed.

Often, startups will not include their IP landscape as an entire slide, but it is useful to have this information on hand, or as a backup slide in case someone asks. Some investors will want to see the FTO, as well as any patent applications as part of their due diligence process, so it is wise to have these available.

2.3.1.4: The Solution

The key questions that need to be answered for this section are as follows: How does your solution work; what are the features of your product; and how do you plan to test and develop your product? This should be one of the easier sections to complete at this point. After the concept generation and selection stage, the fellows should possess a strong understanding of the different functions of their device and the features that their stakeholders care most about. This section should be a general overview of the technology

and the features of the proposed solution. It is very important that if a provisional patent is not yet in place for any aspects of the design, drawings of those parts should not be included in a pitch deck for public display. It is common for investors to decline signing a non-disclosure agreement, so it is sometimes acceptable to share details with investors before a provisional is in place. However, the fellows should always consult their legal counsel before disclosing any confidential information.

Below are two examples of acceptable solution slides for a deck (Figure 23 and Figure 24). Figure 23 is for a technology company called Intercom, which developed a platform that brings more of an engaging and personal experience to customer communication and support.

Figure 24 is an example taken from the pitch deck for a company called LastBite, which developed a mobile app to sell perishable food to last-minute consumers. Although both examples are outside of the medical device industry, the same template can be applied for a medical device.

Figure 23: Example of a solution slide for a company called Intercom. Reprinted from *Pitch Deck Examples: Intercom Pitch Deck.* (2016). Retrieved from https://pitchdeckexamples.com/startups/2016/11/4/intercom-pitch-deck.

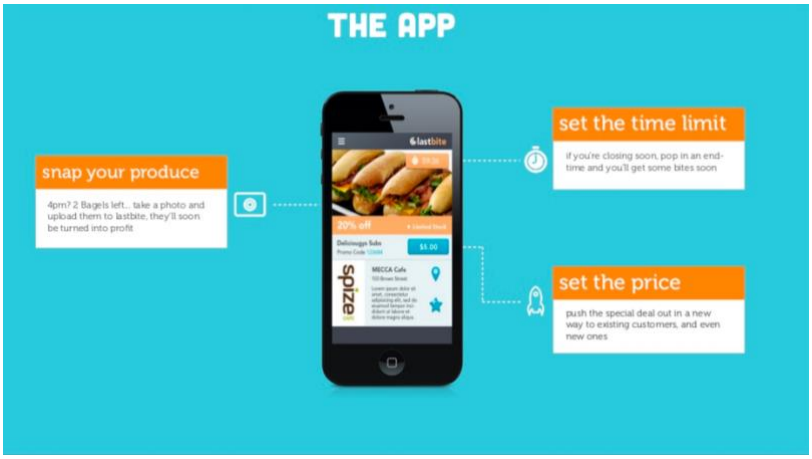


Figure 24: LastBite's solution slide from their pitch deck. Reprinted from *Pitch Deck Examples: LastBite Pitch Deck.* (2016). Retrieved from https://pitchdeckexamples.com/startups/last-bite-pitch-deck.

The purpose of this section is to tell the audience about the features of the proposed device. It should focus on the features that are the most important to the stakeholders and that best address the need. This will allow for an easy transition into the value section, in which how the product creates value is explained.

In addition to focusing on the features of the solution during this stage, the fellows should think about developing their strategy for moving the product forward through R&D. They should create a development timeline and a testing timeline, as well as strategies to accompany them. They need to think about the types of activities they need to complete before moving onto the next stage of development. Working with engineering mentors will be extremely beneficial for this. Having a strong path forward is extremely important, and it will allow the fellows to understand what it will take from an R&D standpoint to get the product market ready. They should focus on what their product will need to prove and the most efficient way to acquire the necessary data. This includes, but is not limited to, bench-top testing, usability testing, animal studies, cadaver studies, human studies, sterility testing, and biocompatibility testing.

2.3.1.5: The Value

The key questions that should be answered for this section are as follows: How is your product creating value for each stakeholder and why should stakeholders care about your solution? It is extremely important to test assumptions surrounding value with stakeholders before presenting to investors. Preparing this section will require a great deal of research and numerous interviews, and this section will constantly change throughout commercialization as the fellows continue to learn more and more about their stakeholders and markets. Determining the of value a solution is a very complex process and utilizes a mix of understanding what each stakeholder wants, how their needs differ, and how a solution could affect them. Value can be emotional, physical, or monetary, and the fellows have to determine which type of value their solution brings to each stakeholder and how to quantify that value.

It is important that the points in this slide mimic the points presented in the need statement slide. However, simply saying that a product addresses each of the major issues defined in the need slide will not suffice. The fellows need to include numbers and data with their value propositions in order to make them convincing and interest stakeholders. The fellows should begin by determining the metrics that are most important to each key stakeholder. For example, an ER physician might care most about efficiency and throughput because the more patients he can see during his shift, the better. A hospital administrator might be more focused on reducing complications and readmission rates. A patient might care most about wait time, pain, and recovery time. Each stakeholder has different priorities, so it is important to understand what they are and to develop a value proposition for each of them. Some factors that fellows should research include, but are definitely not limited to, average procedure times; costs of time in the OR/ER/Fluoroscopy suites, etc.; readmission and complication rates and the costs associated with those; and the number of physicians/staff required to perform a procedure and the hourly costs for each staff member. This could be a very time-consuming activity depending on the product, and it should be a huge priority for all fellows. It may be beneficial to enlist the help of a healthcare economics specialist if public data is not readily available for the procedure in question.

It is important to understand that emotional values can be quantified as well. They usually just take a little bit more time and creativity to determine how to quantify them. For example, simply stating that a device improves patient satisfaction may not gain the attention of hospital procurement staff. However, many hospitals are moving towards a value-based healthcare system, and having poor patient satisfaction scores can result in a hospital losing up to 2% of Medicare reimbursement payments. So, when pitching to a hospital administrator or procurement director, rephrasing the value as "the unnecessary suffering of the patient caused by the current procedure can lead to negative patient satisfaction scores, undermining your hospitals' ability to capture up to 2% of at-risk Medicare payment," for example, might make them more interested in that value proposition.

For another example, assume a company is developing a device that improves the emergency C-section procedure, reducing stress on the mother and recovery time. Both of those are emotional values for the mother, and at first look could be hard to quantify and generate interest from stakeholders other than the patient. However, women tend to be decision makers when it comes to their family's healthcare and where they are treated, so their experiences can directly affect the number of customers a hospital has. A new tool that promises to reduce recovery time and stress for a soon-to-be mother requiring a C-section might be a great marketing tool for a hospital to attract the decision makers of the household, and thus grow their customer base.

This process will be very iterative, and similarly to market sizing and pricing, will require a great deal of guesswork and assumptions. It is important to meet regularly with advisors and stakeholders to evaluate the different value propositions and the assumptions made in order to ensure that they make sense and resonate with the targeted stakeholders.

It is not required to present the numbers associated with each value proposition during a pitch or presentation. However, the fellows must have this information available in the event that it is brought up in a meeting or during due diligence with investors. Fellows should create back-up slides, memos, or, at the very least, basic calculations for how they have quantified each value proposition.

2.3.1.6: The Business Model

The key questions that should be answered in this section are as follows: How can the product make money; how will the product be delivered to the customers; and how much will the product cost? The fellows should possess a strong understanding of potential business models for their device from the work they performed with the business model canvas. At this point, they need to dive deeper into their proposed business models and focus on how they plan to get their product to the customer. The fellows should have a strong understanding of the business models of devices currently on the market, as well as those of their competition, and they should determine what makes sense for their product. Often, a business model can help set a product apart from the rest and make it more attractive than its competition.

More details surrounding the cost of goods, the price of the product, and the sales and distribution plan should be determined during this step. The fellows should work with local manufacturers to attain quotes for the cost to produce their product so that they can build that into their pricing strategy. They should also speak with sales and pricing experts to help them determine a suitable price range for their product, taking into account value-based pricing. Lastly, the fellows should work with hospital procurement specialists and value analysis committee members to determine whether or not their price reflects the value of their product.

Unless the team has a medical device sales experts as a member, the pricing and sales strategy will most likely be very preliminary at this point. These strategies are expected to change once the fellowship is over and the fellows continue to commercialize their device. As the design moves closer and closer to a design freeze, the cost of goods sold (COGS) will become more finalized, and as they move closer to launch-stage fundraising rounds, they will begin to bring on experts to help with building out a sales team or identifying and managing the relationship with a suitable distributor. As the product moves closer to launch, the business model will become more solidified.

2.3.1.7: The Go-To-Market Strategy

The key questions that should be answered in this section are as follows: What is the product's path to market; what is its regulatory pathway; how will the product be reimbursed; what is the initial target market; and what hurdles stand in the way of launch? The go-to-market (GTM) strategy should consist of everything necessary to bring the product to market, including information regarding regulatory classification and pathway, reimbursement strategies, and launch activities. It can also include information regarding sales and distribution of the product, but often times that is discussed during the business model section.

2.3.1.7.1: Regulatory

The fellows should already possess a strong understanding of their regulatory pathway and a comprehensive list of potential predicate devices from the research performed during concept selection. During this stage, fellows should engage with a regulatory consultant to review the research they have conducted and predicate devices they have identified in order to see if the consultant agrees with the fellows' assessment of their regulatory pathway. The fellows should also discuss a plan for meeting with the FDA and whether or not a pre-submission meeting would be beneficial for them. A pre-submission meeting is a meeting with the FDA wherein the company requests feedback on questions surrounding specific actions necessary to guide product development or preparation for their FDA submission. Pre-submission meetings are generally beneficial if the company is unsure about their classification, use of predicates, or testing strategy. It is usually advised that a company have a pre-submission with the FDA once they are close to a design freeze, so that the FDA can evaluate the design the company plans to submit for clearance, rather than early-stage versions that will most likely see many changes before submission.

It is often advantageous for a company to have a memo written and signed by a regulatory consultant detailing the company's classification, pathway, and strategy to show to investors during due diligence.

2.3.1.7.2: Reimbursement

The fellows should already have a very strong understanding of their reimbursement strategy due to earlier research. At this early stage, it is not expected for a company to have already begun the process of talking with payers to begin the process of acquiring a new code or being added to an existing code. What is important is that investors feel that the company possesses a strong understanding of the reimbursement landscape; a sound strategy for gaining reimbursement, if necessary for the business plan; and that there is a willingness to pay for the solution. The fellows might consider working with a reimbursement specialist to draft a memo similar to that of one drafted by a regulatory consultant to either help determine a reimbursement strategy or approve the strategy the team has already developed. It is also advantageous for the fellows to research similar devices and see what their reimbursement pathway looked like and how much those devices are reimbursed for. Having all of this included in a memo for future investors will be extremely beneficial during due diligence, and it will make the company look very prepared for investment.

2.3.1.7.3: Launch Market

The last part of the GTM strategy is choosing a market segment in which to launch the product. When launching a new product on the market, the narrower the target market is, the better. When a startup has a product that could be used in a variety of ways, it is often tempting to try to design and market the product for all potential users. However, this can be detrimental for a number of reasons. First, startups usually have a limited product development and promotional budget, so concentrating that money on a very clearly defined target group of users will produce much better results than attempting to spread it across multiple different groups. Second, it is nearly impossible to design one thing that satisfies the direct needs of all stakeholders. Companies that try to do this typically end up with a very general and mediocre solution that contains a lot of features, but fails to comprehensively solve any stakeholders' problems. The fellows should focus on developing and promoting a product that addresses one or two of their market segments.

They should also realize that once they are on the market and gaining traction in the initial market(s), they can expand into other markets.

The fellows should begin by looking at the different market segments they identified during their market research and evaluate how likely they are to adopt the product early on. The fellows should already possess a good understanding of what user types are more engaged with the product and which are more hesitant from the market research, stakeholder analysis, and value-proposition activities. However, users are not the only thing that needs to be considered when choosing a target launch market. The fellows should also consider which settings possess the lowest barrier to entry for testing, piloting, or getting it into the hands of their users.

It is important to remember that the largest market segment may not be the best segment to launch in. Although the fellows might encounter some push back from future investors if they choose to launch in one of their smaller market segments, as long as they have sound reasoning to back up their decision, it is okay.

2.3.1.8: The Financial Model

The important questions that need to be answered in this section are as follows: How much money is required to get to the next significant milestone, or the next three significant milestones; what partnerships need to be established to get to those milestones (product development firms, manufacturing firms, etc.); and how many products will be sold in three or five years? Creating a financial model is the last activity that needs to be performed before pitching in front of investors or applying to accelerators or business plan competitions. This can be an extremely challenging step, because it is hard to estimate how much money an early-stage company will need in order to meet important milestones. This section requires significant planning for all aspects of the business (R&D, testing, regulatory, legal, business, marketing, etc.). The fellows should start off by evaluating their timeline and the key milestones they will need to hit before launching their product. They should then determine which milestones they think they can meet within a reasonable amount of time that would significantly de-risk their product and raise their valuation. For example, for an early-stage medical device company, a common milestone that falls under

an initial seed round is completing proof-of-concept testing on animal models. There are a number of other milestones the company would hit along the way, but that might be the milestone they think will de-risk their product and increase their valuation enough to raise another round. So, the company would then look at their timeline and determine what exactly it would take for them to reach that milestone, as well as the other milestones along the way. They would determine how many more employees they would need to hire or if they would need to partner with a product development firm to help them get there. They would also look at what type of consultants they might need and how much prototyping and bench testing the product might cost. They would talk with advisors, mentors, and other startup companies to create estimates for each of the activities that would need to be done in order to meet those milestones. This is how the fellows should begin to approach creating a financial model.

After the fellows have worked with their mentors to plan out the activities and personnel required to reach certain milestones, they should begin working on creating financial projections for their product. Investors commonly want to know what the company's revenue will look like at least three and five years out. Adoption rates and growth rates can be very challenging to estimate, so it is advised that the fellows identify similar products, or products that have similar business models and are sold in similar settings. By researching similar products, the fellows should be able to acquire more realistic estimates for adoption rates, which will allow them to more accurately project early-stage revenues.

It is important to remember that adoption is much harder than it seems. A company could have significant physician enthusiasm surrounding their product, but when it comes time to sell it to the hospitals, the process all of a sudden becomes much more complex and can take more time than estimated. It is always better to be conservative rather than over-confident in estimates related to adoption rates. The fellows should continuously run their financial predictions by mentors and advisors, and may consider hiring an expert to help them develop their financial model and financial predictions at this early stage.

2.3.2: Investors, Accelerators, and Competitions

Creating a pitch deck is very different from an academic presentation. There should be very few words on each slide, and it should be very visually appealing. At this point, the fellows will have an abundance of information and will want to present it all to investors in order to demonstrate their knowledge. However, it is important to keep the pitch concise. The point of a pitch deck is to portray the most important information about a product and business opportunity to the audience, not all of the details associated with a business. It is important to craft a deck that resonates with the audience, so it is typical for startups to have multiple decks to present to different types of audiences (clinicians, investors, competition judges, etc.). They should work to pull the most important information gathered in each of the sections in Stage 3: Commercialize and determine the best way to visually represent the information. They should show the pitch deck to a variety of advisors to gain feedback before presenting to investors or submitting to competitions and accelerators.

The fellows should submit their deck to at least one local angel group, two startup accelerators, and any business plan competitions in the near future that they can find. They should research different types of startup accelerators and determine how their company might benefit from them in order to choose ones that could truly accelerate their company. Identifying and applying to accelerators and business plan competitions can be extremely time consuming. However, most applications ask the same type of questions, so it is suggested that the fellows create a master list of questions and formalize answers for each question. This way, each time they apply to an accelerator or business plan competition, they will already have the majority of questions answered, and simply need to modify them for that specific application.

The fellows will learn a great deal by presenting to investors and applying to competitions and accelerators. They should document all questions asked during any presentation and craft answers for them. It is common for the same questions to be asked after each presentation. If the same questions are being asked after each presentation, they might consider creating backup slides that have more information relating to the questions being asked. For example, if questions surrounding the current reimbursement landscape

often come up during presentations, they might want to consider creating a slide that contains the current codes used today and how they think their device would fit in under those codes, or how they plan to acquire a new code and what reimbursement would look like for their device.

The more pitches the fellows perform, the better they will become with them and the more they will understand about their product and what their audience cares about learning. It is a great experience and they should be encouraged to participate in any opportunities to present their business in front of an audience of stakeholders or investors.

CHAPTER 3: RESULTS

3.1: Stage 1: Identify

3.1.1: Needs Identification

Before beginning the fellowship, we were notified that our two clinical focus areas would be emergency medicine and cardiac surgery. Upon arrival to Houston, rotations were set up with one emergency medicine physician and one cardiothoracic surgeon. After initial rotations with them, it was our responsibility to set up follow-up rotations with them and any colleagues they were willing to introduce us to. We spent the majority of our time during the needs identification stage in clinical rotations shadowing a variety of healthcare providers in a range of settings. We spent a combined total of 245.5 hours in clinical rotations, approximately 120 hours conducting research on disease state fundamentals and market trends, and approximately 75 hours attending industry conferences. Throughout the needs identification process, we identified a total of 373 unmet clinical needs, 104 of which I identified. The percentage of needs identified for each need-finding activity can be seen in Figure 25.

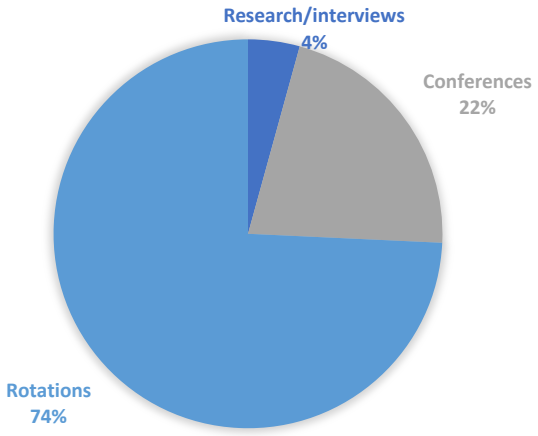


Figure 25: Percentage of needs identified from each need-finding activity.

3.1.1.1: Observation

As Figure 25 demonstrates, the majority of our needs were identified during clinical rotations (75%). This is most likely because the majority of our time was spent in clinical rotations during the need-finding stage. Additionally, I believe that observation is the most efficient method for identifying clinical needs. During the observation stage, we participated in both cardiac and emergency medicine rotations (Figure 26). The cardiac rotations were performed at the Texas Heart Institute (THI), and the emergency medicine rotations were performed in a local community hospital (part of Harris Health System) and with Harris County EMTs.

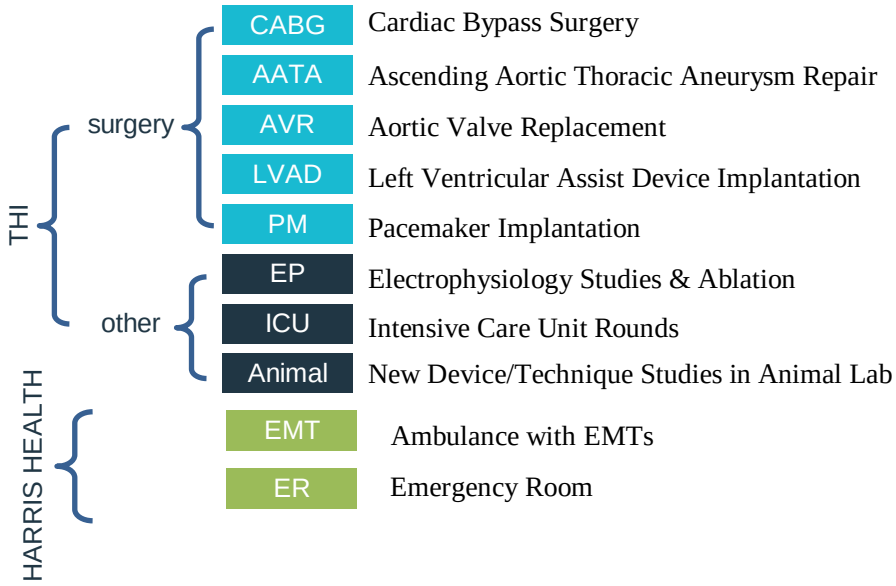


Figure 26: Types of rotations completed and procedures observed.

For each rotation, we documented the date of the procedure, the type of the procedure, the physician(s) we were rotating with, which fellows were observing (and where), and the number of hours spent in observation. The complete breakdown of our observations and the hours spent in each observation can be found in Appendix A. I performed 97.5 hours

of clinical rotations and observations, including the cardiac operating room (CVOR), where I observed multiple cardiac bypass procedures, a pacemaker implantation, ascending aortic thoracic aneurysm repairs, left ventricular assist device implantations, and an aortic valve replacement. In addition to my rotations in the CVOR, I rotated in the cardiac catheterization lab, the cardiac ICU, the community ER, and with EMTs. I was able to identify 98 needs from the 97.5 hours of clinical rotations I performed.

As a team, we spent over 245 hours in the various clinical rotations, the breakdown of which can be seen in Figure 27.

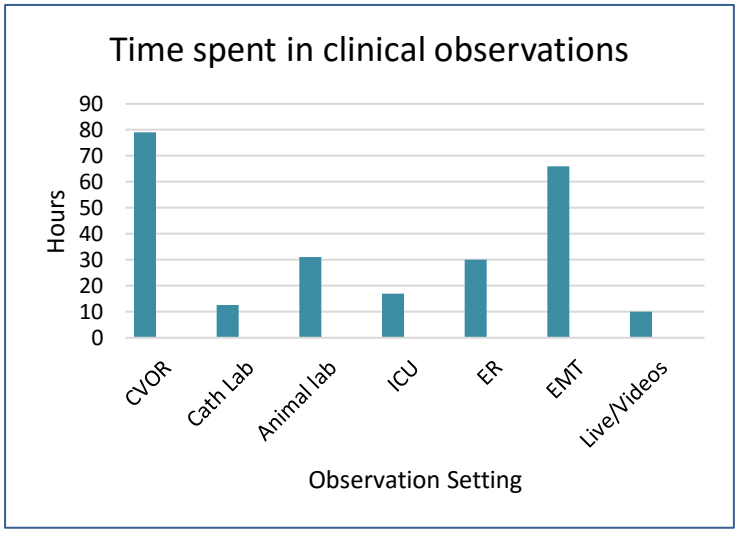


Figure 27: Hours spent in each observation setting.

The 245 hours of clinical rotations performed as a team resulted in the identification of 277 needs. The breakdown of the number of needs identified for each clinical observation setting can be seen in Figure 28.

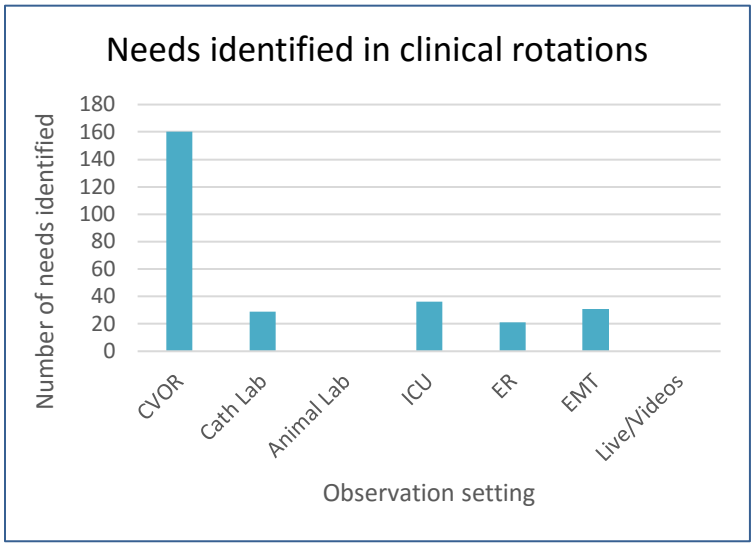


Figure 28: Number of needs identified in each clinical observation.

By comparing Figure 27 to Figure 28, it is not evident that there is a clear correlation between the amount of time spent in a rotation and the number of needs identified, but that is simply due to the nature of some rotations. For example, we spent 66 hours in EMT rotations but only identified 31 needs. This was because we shadowed EMTs for approximately half of their shift (roughly 10 hours), but there was a lot of downtime during those shifts, as EMTs are not constantly being called out to an emergency. The animal lab(s) was also not the best place to identify needs, as these involved devices in development that were already addressing a need. However, it was very beneficial to observe an animal lab in order to better understand what goes into designing and conducting an animal study.

For rotations in the emergency department, the number of good needs identified depended heavily on luck and the type of procedures that were occurring the day of observation. Due to the inconsistent nature of ER shifts, a lot of the needs identified in that setting were related to administration, communication, or patient throughput.

I found that, for surgical rotations, the more rotations I completed in one setting, the better I understood the procedures being performed or the processes implemented, and therefore, the more easily I could identify needs. I also felt that surgical rotations tended to result in more needs being identified because of the highly technical nature of the

procedures, in addition to the fact that there are a lot of people involved and a lot of things going on at one time.

Sometimes we had access to video streams of live surgeries, either from a conference or from online, so we would watch those whenever we had the chance. A total of 10 hours were spent watching live surgeries, which, while not resulting in any new needs, helped us to better understand some of the needs that had already been identified.

1. **Preparing for observation:** Before each procedure, we researched the procedure and strove to understand what happens before, during, and after the surgery. If multiple members of the team would be rotating at once, we would tradeoff which member would perform the initial research and present a quick overview of the procedure to the rest of the fellows. For rotations in the ER or with EMTs, it was much more difficult to prepare, as we did not know what to expect. Often, we would do research into the procedures we saw after our rotations and then go back to the ER and ask the physicians any questions we had about anything that happened during the previous shift.
2. **Observation techniques:** Each of us purchased a small notebook that could fit into the pocket of our scrubs that we took into every observation (with the exception of one animal lab where we were asked not to take notes due to the proprietary nature of the study). We tried to observe surgeries in pairs, because we found that it was difficult for one person to focus on the entire procedure, and we achieved more clarity and needs from having two fellows observing at once. If two of us were observing the same procedure, we either had one on the OR floor and one in the observation dome, or, if there was no dome, we divided up what we would be focusing on. For example, sometimes I would be standing by the anesthesiologist watching the surgeon perform the steps of the procedure while one of the other fellows would specifically be watching the surgical team and techs and how they interacted with each other. In this way, we were able to observe the procedure from multiple viewpoints and fully focus on different aspects of the procedure without worrying about having to document the entire procedure.

We timed each step of the procedure and looked for any inefficiencies or repetitive steps. Any step of the process that did not make sense to us or seemed unnecessary, we highlighted or starred in our notebooks so that we could ask about them after the surgery. After each surgery, we spoke with the attending, residents, and/or surgical team for approximately 15–20 mins to go over any observations we made and ask any questions we had during the procedure. If the doctors were performing something that was too complicated to explain with words, I quickly sketched out what was happening. Figures 29 and 30 are excerpts from my observation notebook, and they show my time-stamped notes, as well as a sketch I made to demonstrate how a physician tied off a chest tube.

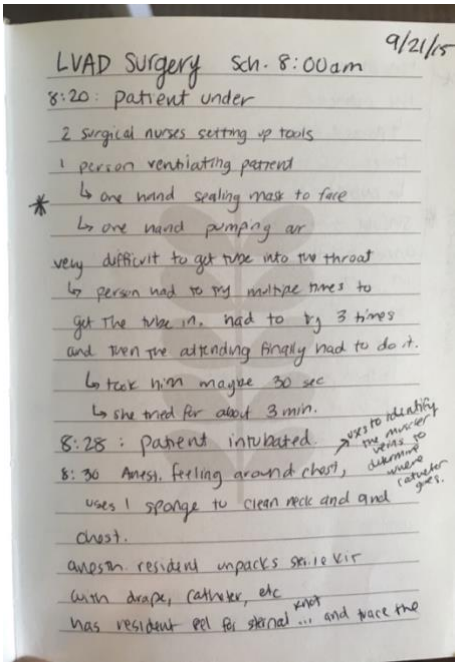


Figure 29: Example of time-stamping a procedure.

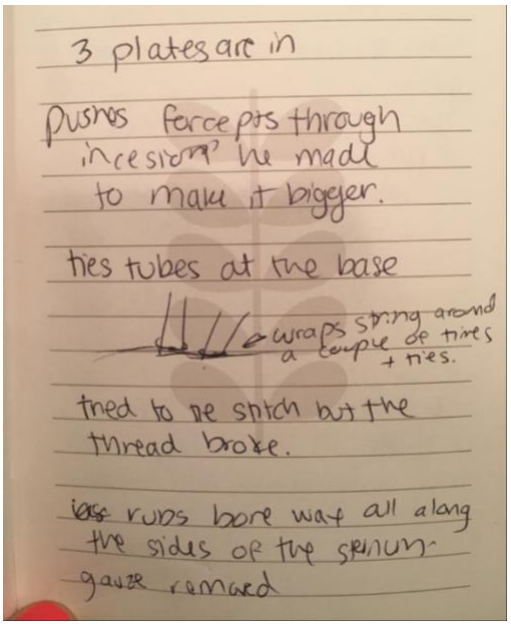


Figure 30: Example of a quick sketch that was used to explain what was happening in a procedure.

We created a shared Excel spreadsheet to document our needs and observations. After every rotation, we individually reviewed the notes and documented the needs

identified during the rotation, along with any questions or observations we made related to each need. At the end of every week, we debriefed as a team, discussed the observations we made, and went over the needs we identified during our rotations.

3.1.1.2: Industry Conferences

We attended three different conferences during the year, but only two of them occurred during the needs identification stage. Two of the fellows attended the Transcatheter Cardiovascular Therapeutics (TCT) conference where 80 needs were identified, and one attended the American Heart Association conference, where no new needs were identified, but a number of physicians that could help with needs validation were identified and connected with. The conference I attended was called The BIOMEDevice Conference, and this occurred during the concept generation stage. We decided that I would go to this conference during the concept generation stage because it was about design thinking, product development, and manufacturing. We believed that during the concept generation stage, it would be beneficial to attend a conference such as BIOMEDevice in order to gain a better understanding of the design and manufacturing process and identify potential product development partners or manufacturing partners.

3.1.1.3: Clinician Interviews and Market Research

In addition to clinical rotations, we interviewed physicians about problems they see often or needs that they would like to be addressed. For example, one of our needs, *"A way to restore elasticity to lung tissue affected by bullous emphysema or COPD that improves treatment,"* came out of an interview I conducted with a thoracic surgeon concerning common issues he sees in his patients. He explained that when a patient has late stage COPD, their lung tissue beings to lose its elasticity, and the equilibrium between the chest wall and the lung is affected. This leads to air being trapped in the lungs, causing patients to have short and fast breathing. He said there was some research being conducted concerning new techniques and devices that could help restore elasticity. However, the standard treatment was either a lung volume reduction surgery or a lung transplant, both of

which are extremely risky procedures and have very mixed results. By conducting interviews with clinicians, such as the one I conducted with the thoracic surgeon, we were able to identify eight new needs.

In addition to clinical interviews, we performed market research to identify some of the costliest and most common diseases and complications in our clinical focus areas. We each researched different segments of our focus areas and began performing research surrounding the needs that industry and clinicians were concerned with. I chose to research cardiac catheterization and minimally invasive cardiac procedures. Through market research, I realized that aortic valve replacements were common yet dangerous procedures, and they were often performed as an open-heart procedure. However, a minimally invasive procedure, called a transcatheter aortic valve replacement (TAVR), had been invented, and there was a big push for physicians to perform the replacements using the minimally invasive TAVR technique. With further research into TAVR procedures, I realized that there are still a lot of fatal issues with the TAVR, one main issue being that it is common for the valve to leak once inserted, a problem that is unique to the transcatheter approach. This research led me to identify the need for *"an improved method for interventional cardiologists to implant the aortic valve during a TAVR to reduce the incidence of paravalvular leaks (PVL)."* In total, eight new needs were identified during market research.

3.1.1.4: Need Statements

After we had completed the majority of our needs identification activities and had documented the observations and needs identified, we began translating the observations into official need statements. In our shared observation spreadsheet, we deconstructed each observation into the problem we identified, the stakeholder affected, and the desired outcome. This helped us to prepare for translating the observation into a need statement. Figure 31 is an excerpt from our Excel spreadsheet once we had taken the observations and broken them down into the problem, stakeholder, and desired outcome.

Problem	Stakeholder	Desired Outcome
Sternum retractors exert significant force on chest wall, leading to increased recovery time.	Patient	Accelerated patient recovery
Current methods for maneuvering and supporting the heart during open heart surgery are forceful, leading to extended recovery time.	Patient	Accelerated patient recovery
Unreliable methods of determining levels of sedation and paralysis in patients during heart surgery make it possible for patients to become conscious and begin autonomous processes during the procedure.	Patient	Increased patient safety
During heart surgery the wrong tools are often handed to the surgeon, leading to reduced productivity.	Surgical Team	Improved physician productivity
There is a disconnect between members of the surgical team in the cardiac OR; this poor communication leads to reduced productivity.	Surgical Team	Improved physician productivity
Current methods for closing off branches on harvested veins in CABG are not resistant to leaks.	Patient	Increased patient safety
Current methods for surgeons to identify viable grafts in CABG are inefficient.	Surgical Team	Increased physician ease-of-use
There is no widely accepted method of securing tools during heart surgery, which poses a risk to the patient.	Patient	Increased patient safety
During heart surgery, surgeons do not have a reliable method of localizing underlyin structures, and therefore must estimate when making incisions.	Surgical Team	Improved physician ease-of-use
Current methods of suturing in heart surgery require reinforcement (e.g. by pledgets), which introduces foreign bodies into the patient, thereby increasing the risk of infection.	Patient	Increased patient safety
During pacemaker implantation, it is difficult for the surgeon to know whether a lead has been properly secured.	Surgical Team	Improved physician ease-of-use

Figure 31:Excerpt from observation spreadsheet with observations broken down into the problem, the stakeholder, and the desired outcome in order to prepare for turning them into need statements.

We then went through and crafted initial need statements for each observation using the format described in stage one of the Methods section (Need Statements). After crafting need statements for each observation, we separated the needs by the procedure or observation activity in which they were identified, and then we further grouped the needs by type. For example, the needs identified during clinical observations were organized by the procedure they were associated with and further grouped by whether the problem related to a tool, communication, controls, the environment, or the procedure. The needs identified at a conference or through research were grouped based on the disease, setting, or procedure (heart failure, neuro-intervention, global health, TAVR, LVAD, etc.). If needs

were identified at a conference that were also identified through observation, we kept both needs in their respective groups rather than combining them so that we could track where each need was identified and who we should speak with to validate the need. Eventually, during the scoping process, we combined the needs that related to each other.

After grouping the needs, we gave each need a unique identifier to help us know where it was identified and the type of need it was. For example, a need identified during an aortic valve replacement surgery that related to a tool or device would be given the identifier AVRt1 (AVRt1 if it was the first need in that category, AVRt2 if it was the second one in the category, and so on).

After giving each need a unique identifier, we created a mind-map for each procedure, setting, and conference, as well as a miscellaneous map for the needs identified through other activities, such as clinical interviews or market research. We added each need statement, along with the problem and the desired outcome, to the mind-map. Figure 32 is an excerpt from our ER mind-map and demonstrates our naming system.

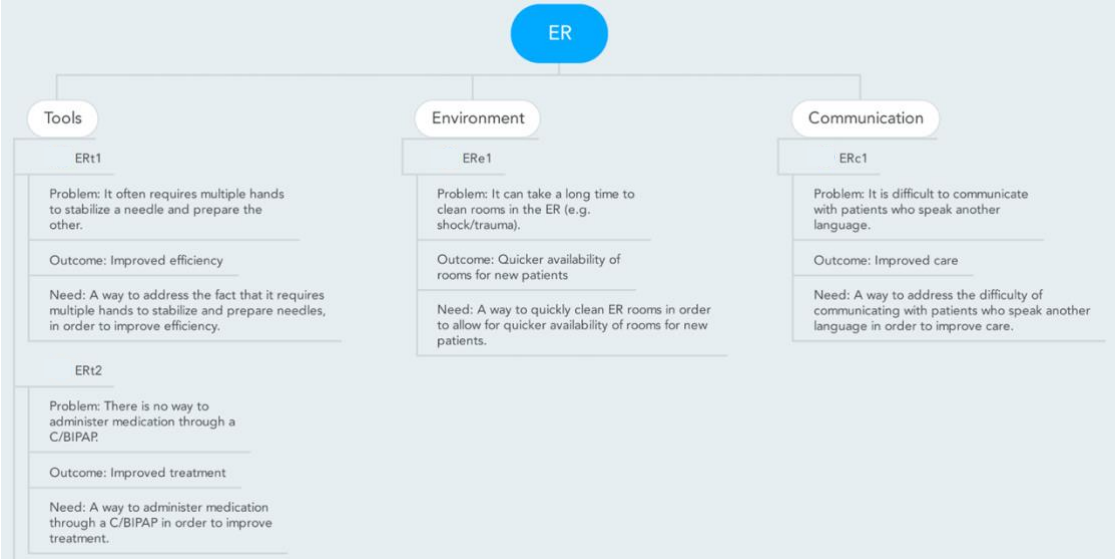


Figure 32: Excerpt from ER mind-map demonstrating how the needs were organized.

As evident in Figure 32, some of our needs were not properly scoped and did not include all of the necessary information (problem, stakeholder, and desired outcome) upon initial creation. Once all of the needs had been captured in a mind-map, we began scoping and refining the need statements. First, we looked for needs that were similar to each other in order to determine if we could combine them into one succinct need statement. For example, in an LVAD procedure, I noticed that closing the sternum was a time-consuming process and that it caused a great deal of trauma to the tissue, resulting in a long recovery. In a CABG procedure (and a follow-up interview with the physician after the procedure), I learned that closing the sternum with sternal wires was not only inefficient, but it also often caused infection at the site. These were three different needs, with three different outcomes, and two different stakeholders, so I combined them into one need with the most important outcomes: *"A less traumatic way to close the sternum after open-heart surgery that reduces the risk for separation and infection and allows for accelerated patient recovery."* Table 5 demonstrates how I combined each of the related needs into one comprehensive need focusing on the most important outcomes.

Table 5: Example of need statement scoping.

Need ID	Need	Desired Outcome
CABGt19	A less traumatic way for cardiothoracic surgeons to close the sternum after open-heart surgery that reduces the risk for separation and infection.	Reduce separation and infection
LVADt22	A way for cardiothoracic surgeons to close the sternum that causes less trauma to the tissue, reducing patient recovery.	Reduce patient recovery time
LVADt29	A way for cardiothoracic surgeons to quickly close the sternum after open-heart surgery that minimizes time in the OR.	Minimize time in OR
CABGt19 + LVADt22 + LVADt29	A less traumatic way to close the sternum after open-heart surgery that reduces the risk for separation and infection and allows for accelerated patient recovery.	Minimize time in OR

As evident in the combined need, I focused more on the outcomes associated with patient safety. I was able to make that choice based on conversations I had with cardiothoracic surgeons who validated the more important outcomes, in addition to looking into costs associated with the complications and recovery time versus costs associated with OR time.

We found need statement scoping to be an ongoing process, and one that continued throughout need screening, as we learned more information about each of the needs and better understood the problem. However, once we had created need statements for all of our observations and had taken a few passes at scoping each of them, we moved into initial needs screening so that we could begin diving into the necessary research to better understand and scope each need.

3.1.1.5: Initial Needs Screening

With over 370 unmet clinical needs identified, defined by need statements, and categorized, we performed an initial round of screening so that we could eliminate less important or incremental needs and begin diving deeper into researching the needs that could have significant impact. For an initial screen, each of us went through each mind-map and ranked each need with either a 1, 3, or 5, individually. This was essentially a gut check, but we used the information gathered from our clinical interviews and the observations we made to rank them based on perceived clinical impact and our personal enthusiasm. A ranking of 1 meant that we felt it had minimal clinical impact and/or there was minimal personal interest, a 3 meant it had medium clinical impact and/or there was medium personal interest, and a 5 meant it had high clinical impact and/or there was high personal interest. After each of us had a chance to rank the needs, we went through the mind-maps as a team and discussed our ranking for each need. There was a consensus on the ranking for the majority of the needs, but any needs that were not ranked the same by each fellow were discussed as a team and assigned a final ranking. Any need that we ranked as a 1 was immediately eliminated. Through this initial need screening, we eliminated 181 needs, leaving us with 192.

3.1.2: Needs Screening

With just under 200 needs remaining after the initial screen, we began researching the remaining needs and developing a more structured way to filter them. At this point, there was still a large number of needs, so research was very broad. In preparation for the first official screening, we each chose approximately 50 needs to research. After the first round of screening, we were able to narrow the list down to 50 needs, so each of us continued research into 11–14 needs to prepare for the second round of screening. After the second round of screening, we had narrowed the list of needs down to 16. At this point, we each performed deeper research into approximately four needs for the purpose of creating a need specification document, which we would present to stakeholders in order to receive feedback. We then used the information gathered during the clinical feedback panel to aid us in choosing our top three needs. The research we conducted throughout the need screening process, as well as the different rounds of needs screening, are described in more detail in the following sections.

3.1.2.1: Disease State Fundamentals

For each need, we researched the disease state fundamentals in order to try and understand the cause of the problem and the anatomy associated with it. When conducting my disease state fundamentals research, I specifically looked at the patients affected by the problem, what causes the problem, and how the problem is addressed or diagnosed. For example, for the need of *"an efficient way to restore elasticity to lung tissue affected by bullous emphysema or COPD that improves treatment,"* I broke my research down into what causes inelasticity (hyperinflation of the lung), the types of hyperinflation of the lung, at what stage hyperinflation occurs, the type of patients who get hyperinflation, and the current method of diagnosing the problem. I then looked further into the physics and biology of the problem. For example, I found that two types of hyperinflation occur with later stage COPD: static hyperinflation and dynamic hyperinflation.

As this need continued to make it through each screening round, I continued to perform deeper analyses into the disease state fundamentals. A more detailed analysis of

the disease state fundamentals for this need can be found in the need specification document created for this need in Appendix C.

3.1.2.2: Existing Solutions

In order to assess how well a need is already being met, or the potential competitive landscape for a solution, we had to look into the existing treatment options. For the needs I was researching, I created a table to document and organize the current treatment options. Table 6 is an example of an analysis I performed for the existing and emerging solutions for the need *"a way for physicians to perform lumbar punctures (LPs) that saves time and reduces the incidence of complications."*

Table 6: An example of a treatment analysis performed for a need relating to the inefficiency of LPs.

EXISTING TREATMENTS		
Treatment Option	**Benefits**	**Risks**
Blind technique (physician uses palpation to identify landmarks and estimates where to place needle; uses commoditized kit)	• Cheap/cost effective solution • No additional setup/prep (compared to US/Fluoro) • Can be performed in the ER/clinic (no additional resources necessary)	• Not placing needle properly on first try (causing harm to patient) • Causing post-LP headache • Causing "bloody-tap" (they cannot use the sample and will have to repeat the LP) • Having to send patient to radiology because they cannot properly place the needle
Ultrasound-guided LPs	• Provides visualization of midline • Provides some visualization of vertebrae and gap • Reduces first attempt failure rate	• Increases cost of procedure • Image output difficult to interpret, resulting in inaccurate needle placement • Potential to increase time of procedure
Fluoroscopy-guided LPs	• High precision for needle placement • Increases efficiency of needle placement process • Less pain to patient	• Significantly increases cost of procedure • Exposes patient to radiation • Could cause delays or throughput issues when patient has to wait for radiology suite to open up
EMERGING TECHNOLOGY		
Technology	**Benefits**	**Risks**

TABLE 6 CONTINUED:

Specialty ultrasound devices for vertebral gap identification	• Improved visualization of gap and vertebrae • Designed specifically for spinal needle placement	• Increases cost of procedure • Used prior to prepping patient, so still room for error when inserting needle • Potential to increase prep/setup time
Non-invasive intracranial pressure monitoring systems	• Non-invasive • Accurately measures intracranial pressure without harming patient	• No collection of CSF, so cannot diagnose meningitis • Limited to measuring intracranial pressure and diagnosing issues related to that

Similarly to the other research performed during this stage, the treatment options and existing solutions analysis continued to become more and more detailed as the needs progressed through each screening round. A more detailed example of a current treatment options analysis can be seen in the need specification document for the need "*a way to restore pulmonary function in lungs affected by COPD that improves clinical outcomes and patients' quality of life"* in Appendix C.

3.1.2.3: Stakeholder Analysis

We began the stakeholder analysis by first identifying all of the potential stakeholders involved with each need. We then reached out to those stakeholders and inquired about other potential stakeholders we might have overlooked. Once we felt that we had a comprehensive list of stakeholders, we began plotting each stakeholder on a chart according to their decision-making power and their level of interest. An example of an initial stakeholder analysis chart can be seen in Figure 33. This helped us to determine which stakeholders were primary stakeholders and which were secondary. It also helped us identify which stakeholders we needed to learn more information about to see if a potential solution could help us move them from one box to another. For example, it would be beneficial for us to be able to move stakeholders that are currently in the top left box (high power and influence, but low interest and commitment) to the right, into the high interest, high influence power box, and in order to know if that was possible, we needed to

find out more information about them and understand how a potential solution could affect them.

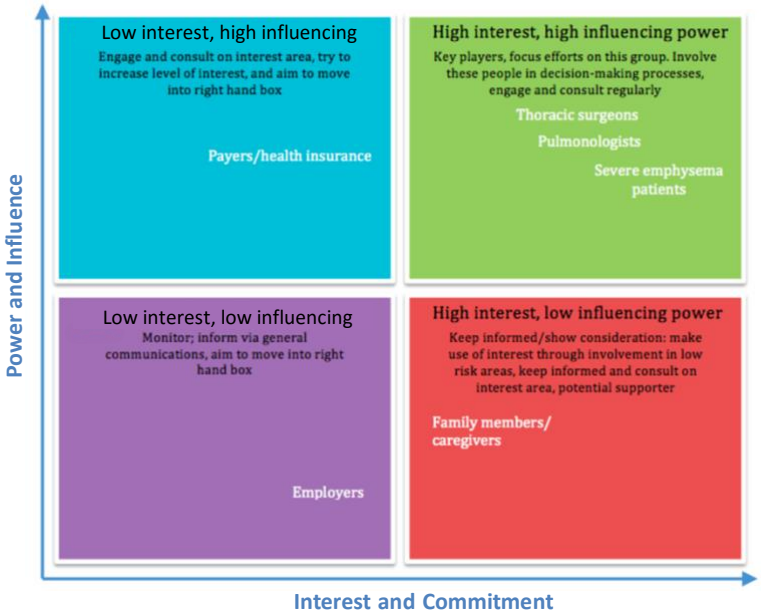


Figure 33: Example of initial stakeholder analysis created for the need: A way to restore pulmonary function to lungs affected by COPD that improves clinical outcomes and patients' quality of life.

After creating a stakeholder analysis chart, we began creating user profiles for each of the stakeholders with a significant focus on primary stakeholders and stakeholders that we believed could become primary stakeholders. At first, we categorized them by general type (i.e., physician, payer, patient, hospital administrator, etc.). However, as we learned more and more about the different stakeholders, we further categorized them into sub-users (i.e., ER resident, ER attending, physician's assistant, nurse, private insurer, public insurer, etc.) and created more detailed profiles on each new sub-user. We validated each assumption we made with a number of stakeholders in order to ensure that we were as accurate as possible in our characterization of each user.

These profiles were living documents and continuously changed as we learned more about each stakeholder and moved further along in this process. An example of a user profile that I created for a teaching hospital ER resident can be found in Appendix B.

3.1.2.4: Market Analysis

One of the criteria we used during each screening round was market size, and so we had to develop an understanding of the market(s) associated with each of our needs. We began by researching the number of procedures performed each year in the US or the number of people affected by the disease associated with the need, and we began narrowing our research from there. For example, with the need relating to COPD, I began by researching the number of people affected by COPD, after which I researched the different stages of COPD and the approximate number of people affected in each stage.

I also researched the cost associated with each need. Continuing with the COPD example, I looked at the cost of the different treatment options and the cost of the complications associated with each option. I also looked at factors such as the number of days of work missed each year due to COPD and the costs associated with those missed days. All of this information helped me develop an understanding of the size of the market, with respect to both the size of the population and the cost associated with the need.

1. **Market mapping and segmentation:** For many of the needs, it was beneficial to create a basic map of the market. An example of a basic market map I created for a need relating to COPD, segmented largely by stage of COPD, can be seen in Figure 34.

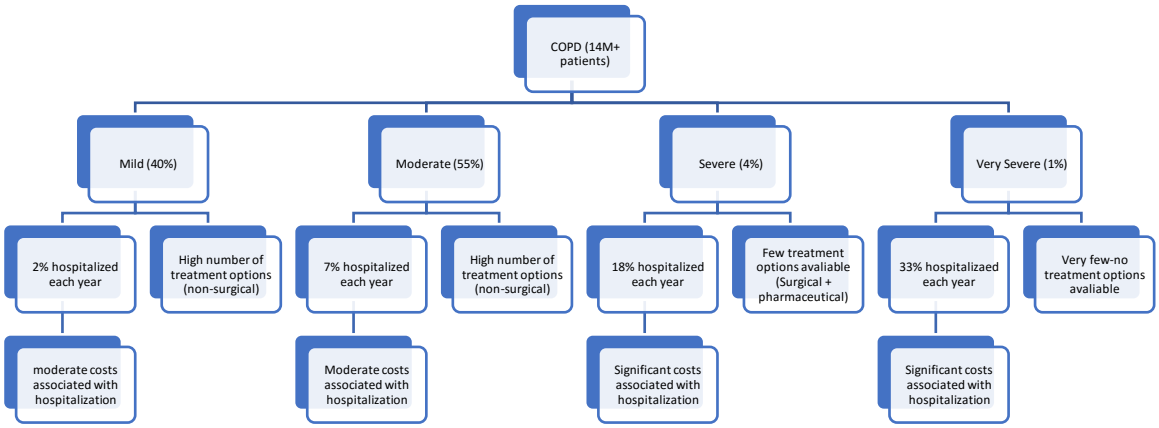


Figure 34: Example of a simple market map for a need relating to COPD.

Although this map is very simple and is segmented in a very basic manner, I was able to understand how the stage of the disease affected the market based on both population and cost. From the map, it is clear that even though the majority of COPD patients are categorized as mild/moderate, the hospitalizations for severe and very severe patients are much costlier. This helped me to better understand how different solutions would work in different market segments. For example, a solution focused on helping the severe/very severe COPD population might not have a large market size in terms of the number of patients affected, but it could have significant value if it was able to keep those patients out of the hospital. Conversely, a solution that addressed mild/moderate stage COPD would be able to affect a large number of people, but it might not be as valuable in terms of lowering costs to the healthcare system due to hospitalizations. Creating maps like this not only helped me in understanding the different segments of the market, but also what a solution would have to address in order to be valuable.

I also segmented markets based on factors other than stage of disease, such as the type of physician performing the procedure, the reason for the procedure, procedure setting, population demographics (low-income vs high-income), and so on. Different types of segmentation made sense for different needs, and thus I created different market maps. An example of a market map I created for a need

relating to LPs, which I segmented by the reason for performing the procedure and the setting in which it is performed, can be seen in Figure 35.

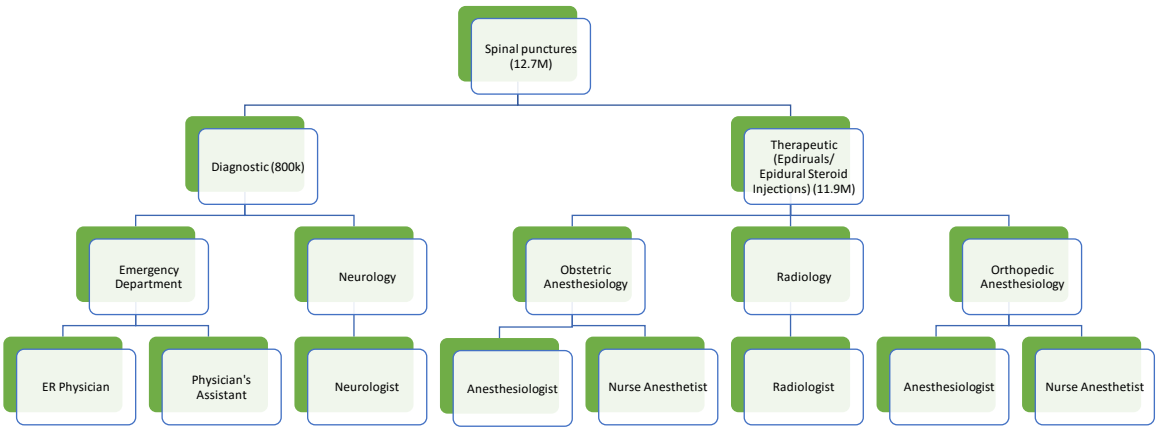


Figure 35: Example of a market map segmented by the procedure and the setting the procedure is performed in.

Originally, the need associated with the market map in Figure 35 was specific to only LPs, a diagnostic procedure. However, when we began market research and segmentation, we were able to uncover a number of other markets that a solution addressing the inefficiency of LPs could also address. Epidurals and epidural steroid injections are very similar to LPs in terms of anatomy, the methods used, and the materials used, so we were able to include those procedures as part of our market as well. If the only potential opportunity had been with LPs, we would not have been able to move forward with that need because the market size would have been too small to make a solution commercially viable.

2. **Target market:** After we understood more about the market and the different ways to segment it, we picked the market we thought would be the most advantageous for us to focus on (our target market). This initial choice was based on information gathered during this stage of the process. However, in Stage 3: Commercialize, we conducted a much deeper market analysis on the top need and

solution, and thus were able to make a much better informed decision as to what market we should target first.

Choosing a target market was necessary in order to scope the need and evaluate it against others during the need screening process. We chose the target market based on multiple factors, including market size (population and financial size), market dynamics, existing solutions/solution gaps in certain market segments, and stakeholder enthusiasm.

3.1.2.5: Needs Screening & Selection

We performed two official rounds of needs screening to reach the 16 top needs that we presented to a panel of clinical experts for the final screening round. For each round of screening, we determined the criteria that we would use to rank the needs against. Each fellow individually ranked the needs based on the determined criteria, after which we compiled all of the rankings and determined which needs made it into the next round. Before eliminating any needs, we went through the list as a team and highlighted any needs that any of us felt should not be eliminated and discussed them as a group. A detailed explanation for each round of needs screening is described below.

3.1.2.5.1: Round 1

During this round, we conducted broad research focused on the clinical impact and market size. We each chose approximately 50 needs to research. After we conducted broad research into each of our needs, we summarized the initial findings and presented them to the team before screening. The needs were ranked by each individual on a scale of 1–4 so as to avoid any neutrality (i.e., the rank of 3 if it was on a 1–5 scale). We assessed each need using the four weighted criteria, which can be seen in Figure 36. Explanations for the criteria and their weight are described in more detail below.

Factor	Criteria	Weight
Opportunity	Market Size	0.2
Team	Personal Enthusiasm	0.25
	Feasibility	0.15
Impact	Clinical Impact	0.4

Figure 36: Criteria for the first round of need screening.

1. **Clinical impact (weight: 0.4):** This was deemed the most important criteria because we did not want to create an incremental solution. We wanted to solve a need that could have significant impact.
2. **Personal enthusiasm/interest (weight: 0.25):** This was the second highest-weighted criteria because we agreed that it was important for all of us to be interested and passionate about the problem so that we would be dedicated and see it through development.
3. **Market size (weight: 0.2):** This was the next criteria because we felt that without a large market, it would be very difficult to raise capital and create a sustainable business model.
4. **Feasibility (weight: 0.15):** This was defined by the team's experience, the basic understanding required to create a solution to address this problem, and the expected timeline for a solution. This was weighted the lowest because at this point, it was difficult to know what types of solutions could address the problem. However, we still wanted to include this in order to eliminate any needs that seemed more like research projects, or needs that would lead to solutions requiring significant experts in a certain field just to reach a proof-of-concept prototype.

After defining the criteria and assigning them a weight, each of us took one day to individually rank each need based on the four criteria. We then inserted all of our rankings into a shared spreadsheet and calculated the average ranking for each need for each person, as well as the overall average ranking for each need based on all of our rankings. Needs were then organized by ranking and color-coded to determine which needs should be eliminated and which should move on to the second round. Any need with an average score

of 2.85 or lower was colored red. We chose 2.85 as a cutoff value because that allowed us to cut the list down to approximately 50 needs Any need ranked higher than 2.85 was left white. We spent the following two days going through all of the needs and flagging any we thought were unfairly ranked (i.e., should be eliminated but were not, or were eliminated but should not have been). These needs were highlighted yellow. We also flagged any needs that we thought were similar to others and could either be eliminated or combined and scoped to be turned into one need statement. These needs were highlighted purple. We then discussed every need that was highlighted and decided whether or not to eliminate it. After discussing each flagged need, we finalized a list of our top 49 needs for further research. An excerpt from our need ranking spreadsheet can be seen below in Figure 37.

	Rank as 1, 2, 3, or 4 (4 being the highest; only integers)	Enthusiasm (E), Compatibility (C), Impact (I), Market Size (S).																	
ID	Need	Previous	Yashar					Xavier					Jessica					Nicole					Avg
			E	C	I	S		E	C	I	S		E	C	I	S		E	C	I	S		
ERt1	A way to address the fact that it requires multiple hands to stabilize and prepare needles in order to improve efficiency.	3	1	3	2	2	1.9	4	2	2	4	2.9	2	4	2	4	2.7	1	4	1	2	1.65	2.29
ERt2	A way to administer medication through a C/BIPAP in order to improve treatment.	3	3	3	4	4	3.6	1	2	2	3	1.95	2	3	3	1	2.35	2	3	3	3	2.75	2.66
ERt4	A method for PAs to tie off sutures that increases efficiency.	3	1	2	2	3	1.95	1	2	2	3	1.95	1	4	1	4	2.05	1	4	1	2	1.65	1.90
ERt5	A method of suturing more quickly without a high risk of infection, in order to increase efficiency.	3	2	3	3	3	2.75	2	3	2	3	2.35	3	4	2	4	2.95	1	4	3	2	2.45	2.63
PMp5	A method of reliably pacing a patient's heart after PM implantation.	3	1	1	2	2	1.6	1	2	3	3	2.35	1	2	2	3	1.95	1	2	3	3	2.35	2.06
TCTpah1	A way to address inadequate treatment of PAH.	3	2	1	4	2	2.65	3	2	3	2	2.65	4	2	3	3	3.1	1	2	3	4	2.55	2.74
TCTlv1	A less invasive way to restore heart wall motion and compliance/recoil in infarcted heart tissue that improves treatment.	3	4	3	3	3	3.25	3	3	3	3	3	4	3	3	2	3.05	2	2	3	3	2.6	2.98
TCTang1	A way to improve blood flow to endocardium in patients with angina refractory to medical therapy that improves outcomes.	3	1	1	3	3	2.2	3	3	3	3	3	2	4	3	2	2.7	2	2	3	3	2.6	2.63
TCTttvr2	A way to address high risk of damage to adjacent structures during tricuspid repair/replacement that reduces complications.	3	3	3	4	2	3.2	2	3	3	2	2.55	3	3	3	3	3	2	2	3	3	2.6	2.84
TCThocm1	A way to identify and place catheter in angiographically occult septal perforator vessels during ASA procedures.	3	4	4	4	3	3.8	3	3	2	2	2.4	4	3	3	2	3.05	1	2	3	3	2.35	2.90
TCThocm2	An accurate method of predicting cardiac ablation areas that increases ICs' confidence.	3	3	3	4	3	3.4	3	2	3	2	2.65	4	3	2	3	2.85	3	3	1	2	2	2.73
TCThocm3	An automated, repeatable, and precise EtOH infusion rate that results in intended myocardial ablation with fewer complications.	3	2	3	4	3	3.15	3	3	2	2	2.4	3	3	3	3	3	2	1	3	3	2.45	2.75
TCTcva1	A method to make doctors comfortable doing neurointervention so as to give more patients access to acute interventional stroke care.	3	3	2	4	3	3.25	3	2	4	3	3.25	4	3	3	3	3.25	3	2	3	4	3.05	3.20
TCTcva2	A method that allows catheter access to smaller branched vessels in the brain to allow for more successful thrombus retrieval in more distal branches.	3	4	4	4	3	3.8	4	3	3	4	3.45	4	3	3	3	3.25	3	4	3	2	2.95	3.36
TCTni2	A way to treat ICAS that allows for improved patient outcomes.	3	2	3	4	3	3.15	3	3	3	2	2.8	3	2	3	3	2.85	2	2	3	4	2.8	2.90

Figure 37: Excerpt from the needs screening ranking spreadsheet for the first round of screening.

3.1.2.5.2: Round 2

With only 49 needs left, we began extensively researching each need. We split up the needs amongst the fellows, so each of us chose between 11 and 14 needs. We tried to split up the needs by who observed them and had been doing research on them, but this wasn't possible for every need, because some fellows had many of their needs make it through to the next round, while other fellows only had a few of their needs make it. In the event that we were assigned a need that we had not been researching, the person who had any preliminary research on the matter shared the research with whomever was assigned the need. I was given 13 needs to research, the majority of which I had already been researching.

We created a shared document on our Google drive with sections for the need, a summary of the disease state fundamentals, the competitive landscape, the important stakeholders and their requirements for a solution, the market size, and other key facts about the need. As we performed research into these needs, we summarized the information we found and added it to the document on the shared drive. After approximately three weeks of in-depth research into each of our needs, we each presented our findings to the group and discussed each of the needs in great detail.

After each of us had presented our findings for the needs, we performed another round of screening. We identified and weighted seven different criteria for ranking the needs for this round. The criteria and weights can be seen in Figure 38. In this round, we determined the weight by having everyone individually weight each criterion and then averaging the weights from each individual. The sum of the weights for each criterion added up to one. We included market size, team enthusiasm, and feasibility from round one, and then we expanded on "clinical impact" to include patient impact, provider impact, and facility impact. We did this because at this point, we had much more detail surrounding the type of impact a solution could have, and we wanted to weight different impacts differently. We felt that patient impact was the most important, followed by provider impact and then facility impact. We also added a criterion that was not included in round one, namely, competitive landscape, because after our in-depth research into treatment landscapes during this round, we had enough information to rank needs based on how adequately current solutions were meeting them.

Factor	Criteria	Weight
Opportunity	Market size	0.11875
	Competitve landscape	0.145
Team	Feasibility	0.165
	Enthusiasm	0.2025
Impact	Patient impact	0.1825
	Provider impact	0.14125
	Facility impact	0.045

Figure 38: Criteria for the second round of needs screening.

We each took a few days to review all of the research conducted on each need and individually rank the needs, similarly to what we did for the first round of screening. I then aggregated everyone's rankings and calculated the average ranking for each need, sorted the needs by average ranking, and determined the top 15 needs based on average rankings. I also went through everyone's individual rankings and flagged any needs that were in someone's top 5 that did not end up making the overall top 15, or that were in at least two team members' top 15 that did not make the list. For example, the need *"an efficient method of simultaneously sealing tissue and skin layers after an open-heart procedure that reduces time in the OR"* was ranked 18th once everyone's rankings were averaged, but it was included in the top 15 needs for both myself and Nicole, so it was flagged for discussion. Once all necessary needs were flagged, we discussed them as a team and determined that we had 16 strong needs that we wanted to move forward with and develop need specification documents for. Figure 39 shows the top needs taken from the ranking spreadsheet for this round of screening. As evident in Figure 39, we decided to keep need 19 after discussing it as a team, and it became our 16th need. It is also evident that we added another color to the spreadsheet for flagging, namely, blue. This color was used to mark needs that we had specific questions about that came up during the needs screening process and that needed to be answered during the next stage of research.

Row	Area	Old	Updated	ID	Need	Notes	Yashar Avg	Xavier Avg	Nicole Avg	Jessica Avg	Avg Tot	Upd Std	Top 15
11	Misc	47	1	ERt8	A way for physicians to perform LPs that saves time and reduces the incidence of complications		3.185	2.7463	3.24125	3.42625	3.1	0.5	4
25	Misc	27	2	MISCdiag4	A way to detect silent myocardial infarction (MI, also: heart attack) in diabetic patients at risk for heart disease.		3.625	2.6438	3.2975	3.1175	3.2	0.5	3
18	CABG	14	3	CABGp10	A less invasive way to perform CABG that reduces risk to patients.		3.2775	2.8725	3.2275	2.81875	3	0	3
43	Surgery	17	4	ICUt26	A way to address the high rate of infection and coagulation with implantable devices to improve patient outcomes.	Redefine as lines; not implantables	3.6938	2.8538	3.10625	2.635	3.1	0.6	3
36	Interv	32	5	CLt8	A way to address the difficulty of vessel identification in an angiogram in order to improve clinical efficiency.		2.97	2.9488	3.0525	2.89375	3	0.6	2
21	Surgery	20	6	AVRt4	A way to identify bleeding sites in chests prior to closing that decreases the incidence of post-operative hemorrhaging.	Validate this—may be hard to do market analysis?	3.435	2.835	3.105	2.75125	3	0.6	3
40	Interv	4	7	TCTni9	A better way to remove intracranial clots that improves treatment.		3.2075	2.7638	2.645	3.11125	2.9	0.6	3
33	Surgery	24	8	AATAp1 PMp4	A method by which underlying structures can be localized in surgery to reduce the need for estimation when making incisions and increase physician ease-of-use.	Competition? Feasibility? (Can we do this well enough to succeed?)	3.645	3.07	2.80625	2.62	3	0.6	2
14	HF	2	9	TCThf1	A method of diagnosing HFpEF.	Strangle? Talk to more and validate?	2.8638	2.6438	3.36375	2.89625	2.9	0.5	2
17	HF	12	10	TCThf7	A way to address the fact that new fluid monitoring platforms for HF patietns reduce hospitalizations but don't allow patient control over their diuretic intake, in order to improve their quality of life.		2.4488	2.7138	3.5525	2.875	2.9	0.6	2
2	Misc	6	11	AVRt5	An efficient way to restore elasticity to lung tissue affected by bullous emphysema or COPD that improves treatment.	We convinced Nicole	2.7188	3.1025	2.07	3.4825	2.8	0.8	2
16	Interv	11	12	TCTcva1	A method that makes doctors more comfortable performing neurointervention to increase patient access to acute stroke care.		2.3825	2.8088	2.935	3.31375	2.9	0.6	2
15	CABG	8	13	TCTcomp5	A method of ensuring long-lasting revascularization in patients undergoing CABG.	Nicole convinced us	3.6488	2.5488	3.3925	2.53625	3	0	2
29	Interv	3	14	CLt12	A way to address tortuous vessels in CAD patients that cannot be treated with conventional stents in order to improve treatment.	Is the market big enough? Is there any freedom to operate in stents?	2.5125	3.03	2.405	3.01875	2.7	0.5	2
1	Surgery	1	15	CABGt19 LVADt22	A less traumatic way to close the sternum after open heart surgery that reduces the risk for separation and infection and allows for accelerated patient recovery.	Why are current solutions not being adopted? Need to really differentiate our solution.	2.9088	2.3538	3.01875	3.325	2.9	0.6	2
22	Misc	25	16	ERt11a	A way to sense and treat allergic reactions in order to improve patient care.	Gone	3.2113	2.4638	3.185	2.615	2.9	0.6	2
8	Surgery	41	17	LVADt25 AMBt17	A smooth way to transfer patients from one bed to another that increases physician ease-of-use.	Gone	3.0363	2.6888	3.1975	2.34125	2.8	0.6	1
41	Interv	9	18	TCTus1	A way to address diffuse atherosclerosis that allows for improved flow.	Nicole wants to continue researching	3.05	2.3125	2.99875	2.90875	2.8	1	2
26	Surgery	28	19	LVADt24	An efficient method of simultaneously sealing tissue and skin layers that increases physician ease-of-use.	It's alive! We all agreed to keep it and continue research	2.335	2.5813	3.01875	3.1775	2.8	0.6	2

Figure 39: Excerpt from needs screening spreadsheet for round two.

3.1.2.6: Need Specification Document

With only 16 needs remaining, we conducted more in-depth research so that we could create a need specification document. During this stage, we looked for any gaps in our research and sought to fill them. We elaborated on the research already compiled for the disease state fundamentals, competitive landscape, stakeholder analysis, and market analysis. We summarized all of the research we conducted for each need into a need specification document. We chose to format them into PowerPoint presentation so that they could easily be presented to stakeholders for validation and our clinical panel for final

needs selection. An example of a need specification document I created can be seen in Appendix C.

3.1.2.7: Final Selection

Once we created a need specification document for all of our top needs, we presented them to a group of mentors of varying clinical and entrepreneurial backgrounds for feedback and validation. We presented each need to the panel, opened the floor for questions, and had detailed discussions about each need. After the feedback session was over, the mentors summarized their thoughts on each need, and ranked the needs based on their opinion and the topics discussed in the session. By the end of the session the top 5 needs were very clear, so we had to decide on two to eliminate. We reviewed the top 5 needs as a team, took into account the mentors feedback and all of the research we had conducted, and decided on our top 3 needs. The top 3 needs we decided to move forward with into Stage 2: Create can be seen in Figure 40.

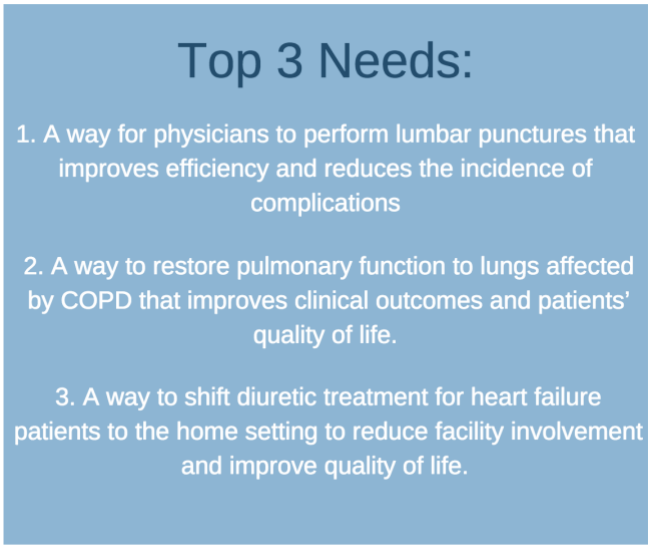


Figure 40: Our top three needs.

3.2: Stage 2: Create

3.2.1: Concept Generation

Once we finalized our top three needs, we began the brainstorming and concept generation phase. We used a variety of the brainstorming techniques listed in the Methods section (Methods, Stage 2: Create, Concept Generation) to account for every team member's individual style, and we closely followed the methods recommended for concept generation.

1. **Establish Rules:** We created a list of rules similar to those used at IDEO, but we added and changed some to suit our specific needs (Table 7). We posted the rules during every brainstorming session to ensure we remembered them and held ourselves and others accountable.

Table 7: Team rules for brainstorming sessions.

Rule	Description
Rule 1: Capture *every* idea	Use the space around you to document your ideas, either on post-its, white boards, notepads, etc. Capture all of the ideas at the end of the session.
Rule 2: Encourage wild ideas	Think outside the box—wild ideas get people thinking and they lighten the mood to allow the mind to flow.
Rule 3: No devil's advocates	Do not dismiss any ideas during the session.
Rule 4: One conversation at a time	Allow everyone to get their entire thought out before you begin another. Do not interrupt anyone.
Rule 5: Stay focused on the problem at hand	Try to stay on the topic of the brainstorming and don't allow for tangents.
Rule 6: Build on the ideas of others	Collaborate as much as possible during these sessions and allow others' ideas to spark your own.
Rule 7: Quantity over quality	At this stage, the goal is to come up with as many ideas as possible in the allotted time. No idea is stupid or unrealistic during this stage.

2. **Break needs down into smaller problems, causes, or functions:** We completed 2–3 general brainstorming sessions for each need before deciding to break the needs down into sub-problems for brainstorming. We found that brainstorming on an entire need or problem was good for initial brainstorming sessions and for preparing

us for the concept generation stage. However, it also quickly became overwhelming and resulted in scattered, partially thought-out concepts. Additionally, we noticed that during brainstorming sessions on broad needs, there was not much building off of others' concepts. To help ourselves focus and be more collaborative in the sessions, we broke down the overall problems or functions required for a solution into sub-problems or sub-functions. Figures 41 and 42 below are examples of how we broke down two of the problems associated with a need into sub-problems.

Need: A way to restore pulmonary function to lungs affected by COPD that improves clinical outcomes and patients' quality of life.

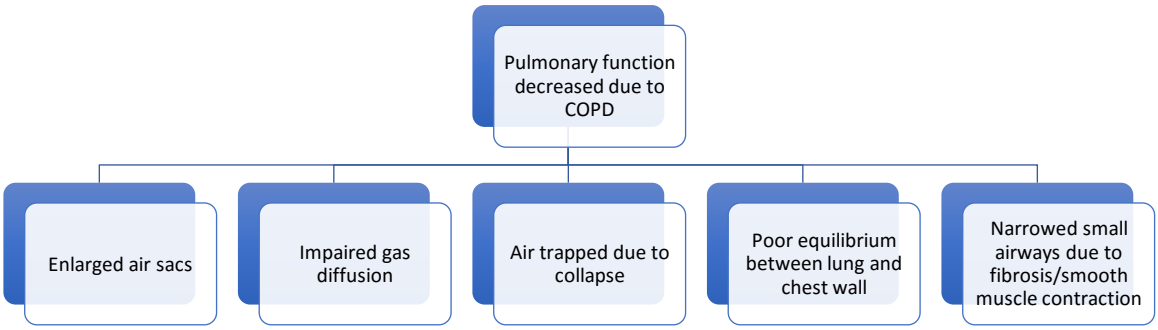


Figure 41: Example of problem/sub-problem breakdown for our COPD need.

Need: A way for physicians to perform LPs that improves efficiency and reduces the incidence of complications

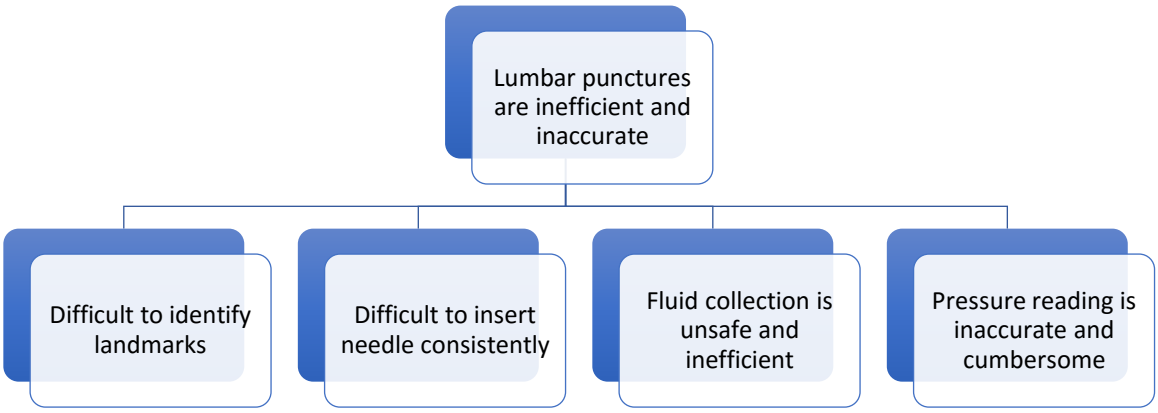


Figure 42: Example of problem/sub-problem breakdown for our LP need.

3. **Implement different brainstorming techniques:** We implemented a variety of brainstorming techniques throughout the concept generation process and found that it was beneficial to use a combination of different techniques for each need and sub-need so that every person on the team could be productive in a session. The techniques we used most are described below
    a. **Timed brainstorming:** The goal was to come up with as many ideas as possible as a team in a specified amount of time (usually 30–60 mins). This was great for the extroverts in the team and helped to prepare our minds for concept generation. It was easy for certain people to dominate in this type of brainstorming session, though, so it was important to have a moderator to keep everyone on track and following the rules.
    b. **Individual brainstorming:** We set aside a few hours over a couple of days (we did a couple of hours over three days on average) to focus on the problem individually and to brainstorm ideas, after which we came back together as a team and presented our ideas. This was productive because it allowed each team member to think about concepts generally throughout the day and document them as they came into their minds.

Usually, these concepts/ideas were more thought out and detailed compared to the ideas generated in the timed brainstorming sessions. An example of a concept that was generated during an individual brainstorming session on fluid collection for the need relating to LPs can be seen below in Figure 43.

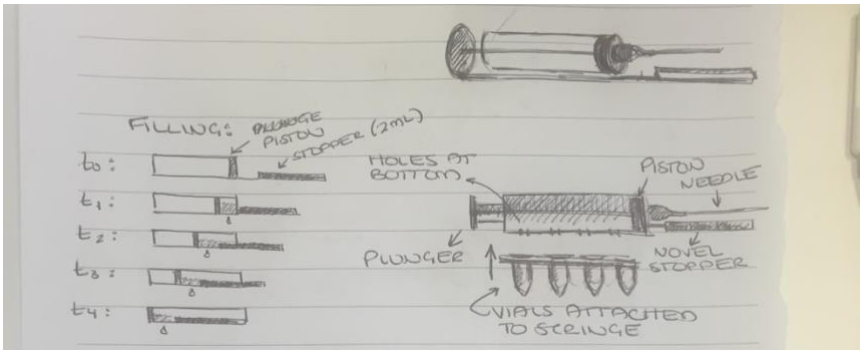


Figure 43: Example of a concept that was generated during individual brainstorming on fluid collection.

c. **Silent team brainstorming:** We spent between 3–5 minutes coming up with as many ideas as possible individually for the specific need being addressed, and then we presented and discussed our ideas as a team once the time ran out. This worked well for the introverts in the group because they were able to gather their thoughts without the constant talking that occurred during the group timed brainstorming sessions. After everyone presented their ideas, we brainstormed on the ideas that were presented and tried to build off of the ideas of others.
d. **Cross-pollination sessions and research:** We conducted research on technologies and devices in other practices that were solving similar problems to help in our brainstorming. For example, when researching ways to solve the need *"a way for physicians to perform LPs that improves efficiency and reduces the incidence of complications,"* we looked at other devices that were eliminating blind insertion techniques,

as well as devices or technology that helped visualize underlying structures in the body. Not only did we look across different areas in medicine, but we also looked at solutions in completely different industries. One of our sub-problems was *"identifying landmarks for LP placement."* During cross-pollination sessions and research, we looked at many different industries, including medicine, oil and gas, defense/military, and home improvement. Some examples of the technologies that we identified in various industries can be seen in Table 8.

Table 8: Findings from cross-pollination research session.

Medicine (How do you image for other procedures?)	**Oil & Gas (How do you know where to drill?)**	**Defense/Military (How do you find landmines and objects hidden underground?)**	**Home Improvement (How do you find objects hidden in walls?)**
• Ultrasound • X-Ray/Fluoroscopy • Tactile • IR • UWB • MRI • Echo	• Thermography	• Radar • SONAR	• Radar • Capacitive sensing

After the cross-pollination sessions, we added all of the technologies we identified into a mind-map and organized them by type of technology used (i.e., acoustic, electrical, EM waves, etc.). An excerpt from the mind-map created for *"identifying landmarks for LP placement,"* with a focus on identifying the gap between vertebrae, can be seen in Figure 44 (next page).

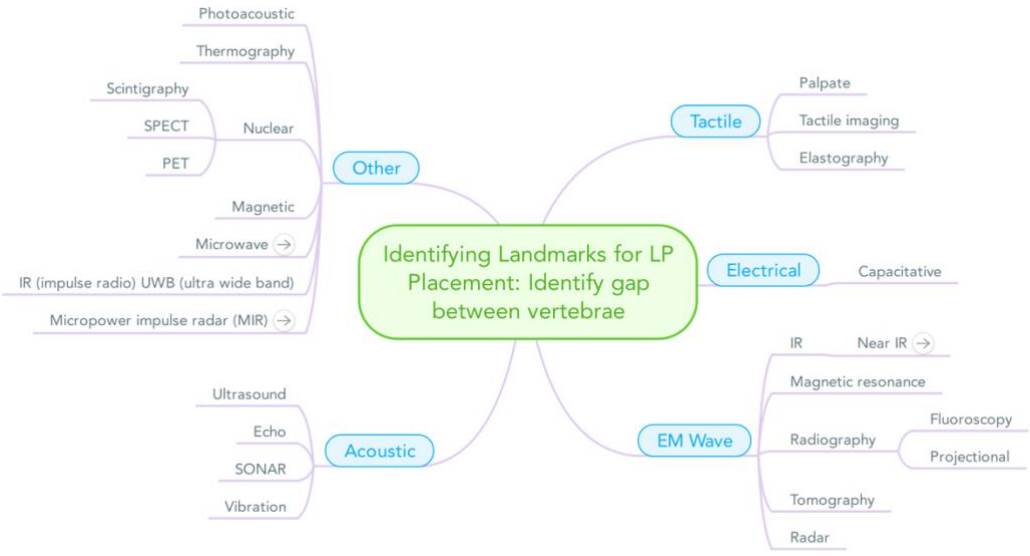


Figure 44: Excerpt of mind-map for "identifying landmarks for LP placement: Identify gap between vertebrae," with findings from a cross-pollination and research sessions.

e. **Brainstorming sessions with external people/experts:** After multiple brainstorming sessions, it was common for us to feel stuck and have the opinion that we had exhausted our ability to come up with new solutions. When this happened, we often brought outside people into our brainstorming sessions, and we found that this helped generate new ideas. These people were either mentors or physicians who were familiar with the problem or people who knew nothing about the problem at all. We found that bringing in someone who had not been a part of past sessions could help spark new ideas and generate types of solutions that nobody in our group had ever thought of. However, we realized that this can also be tricky and cause some issues surrounding IP, so we always discussed this potential issue before a session and had an agreement in place before starting regarding any Intellectual Property (IP) that was generated during the session.

4. **Capture and organize the results:** During sessions, we documented ideas on paper, post-its, and white boards, and we sometimes explained concepts using low-fidelity prototypes. After each session, we named each idea, photographed sketches or prototypes if necessary, and then documented them in mind-maps. We created a mind-map for each of our top three needs and found that it was easiest to group ideas based on function and sub-function. These functions/sub-functions were defined by the problems/sub-problems that were previously defined for brainstorming. For example, for the need *"a way for physicians to perform LPs that improves efficiency and reduces the incidence of complications,"* the concepts were organized by their sub-functions: localize underlying landmarks, consistently insert needle, measure spinal pressure, and collect CSF.
5. **Initial concept screening:** In order to perform the initial concept screen, we re-engaged with the physicians that led the rotations where the need that the solution addressed was identified. We gathered their feedback to determine whether the solution was meeting the needs defined in the need specification document. In addition to talking to physicians and other important stakeholders, we developed some general criteria to use to help us screen some of the concepts and perform "gut checks" on the solutions. Our team focused primarily on perceived feasibility, time required to develop a proof-of-concept, team enthusiasm, and whether or not the skillsets necessary to develop an early-stage prototype were represented on the team. For example, we knew that some concepts would require more technical expertise than the team possessed in order to develop a proof-of-concept prototype, so we had to eliminate those concepts; other concepts relied on technology that did not exist yet and would require significant R&D to develop, and were therefore also eliminated. During this initial screening process, we were able to eliminate the wild ideas or concepts that were generated during brainstorming sessions that were really intended to help spur creativity and lighten the mood of the session. This made moving into concept screening more manageable because we had a smaller number of concepts that needed to be evaluated.

3.2.2: Concept Screening and Selection

After eliminating a number of concepts in the initial concept screening stage, and understanding which concepts needed a great deal more information in order to assess, we began the concept screening stage.

3.2.2.1: IP Basics and FTO

In order to determine the IP landscape, and whether or not we would have FTO with the concepts we were assessing, we began searching existing patents using the websites of USPTO (http://patft.uspto.gov), Google Patents (https://patents.google.com), Lens (www.lens.org), and Free Patents Online (www.freepatentsonline.com). We began by identifying key search terms for each of our top needs and the concepts that addressed them. An example of some of the search terms used for the concepts associated with the need *"a way for physicians to perform LPs that improves efficiency and reduces incidence of complications"* is listed in Table 9.

Table 9: Examples of search words used for concepts for our LP need.

Concept	Function	Search words (also searched combination of these words)
General	Help physicians place needle for epidural and spinal taps	Epidural, epidurals, spinal tap, spinal taps, spinal anesthesia, combined spinal anesthesia, combined spinal epidural, combined spinal epidurals, spinous process, spinous processes, lumbar spine, meningitis, meningitis diagnosis, dural puncture, dural punctures.
Tactile sensing	Identify landmarks	Tactile sensing, tactile imaging, FSR, FSRs, force sensing resistor, force sensing resistors. (**in combination with search terms defined in "General").*
Fluid collection system (multiple concepts surrounding this)	Fluid collection	Spinal fluid collection, fluid collection, CSF collection. (**in combination with search terms defined in "General").*
Needle guide (multiple concepts surrounding this)	Needle guidance	Needle guide, needle guidance, needle stand, needle injection, automatic needle injection, needle insertion, automatic needle insertion (**in combination with search terms defined in "General").*
Radar	Identify landmarks	Uwb, uwb radar, ultra wideband radar, ultra-wideband radar, ultrawide-band radar, radar **in combination with search terms defined in "General"*

Some of the websites we used to search the patents had "Similar Documents" or "Related Patents" listed at the bottom of the patent, so when we found patents that were similar or related to a concept we were researching, we often researched and documented those as well. We documented every relevant patent in an Excel spreadsheet, along with the patent number, the website used to find it (with a link to the patent), the title, the function of the concept to which it was related, the publication date, the filing date, the expiration date, the abstract, and the key claims. After we felt we had gathered a comprehensive list of existing patents related to the concepts, we ranked each patent on its claims and their relevance to our concepts. A rank of 1 meant the claims were very relevant to our concept and had to be researched further to understand if we could still have FTO, a rank of 2 meant there was some relevant claims, but there was room to work around them, or we could still have FTO with the current design of our concept, and a rank of 3 meant the claims had no relevance to our concept at all.

During this processes, we were forced to eliminate some concepts that we knew would not have FTO. The majority of our concepts relating to the need *"a way to restore pulmonary function to lungs affected by COPD that improves clinical outcomes and patients' quality of life"* were eliminated during this stage because the IP landscape was very competitive and a lot of our concepts would not have FTO. At this point, we decided to move forward with concepts from our other two top needs.

3.2.2.2: Regulatory

We found that one of the best ways to determine the FDA pathway for our concepts was to research proxy devices and then look up their required regulatory pathway and studies for clearance. We documented any similar devices we came across for each concept we were researching and determined whether or not we believed they could be used as a predicate device for an FDA submission. To find proxy/predicate devices, we used a variety of sources, including the FDA 510(k) website, physician and entrepreneur advisors who knew of similar devices, and regulatory advisors who worked in acquiring similar devices through the FDA. We also conducted our own individual research into similar devices and emerging technologies related to our concepts.

For example, one of our concepts utilized tactile sensing as the means of identifying underlying landmarks, so we researched devices in the medical industry that utilize tactile imaging and came across the SureTouch device. According to their website, the SureTouch device (Figure 45) utilizes tactile sensing for pain-free and radiation-free imaging to identify breast lesions. They were considered a class II device and went through the FDA 510(k) process for approval.

Figure 46: SureTouch Breast Exam device. Retrieved from www.suretouch.us.

Figure 45: Mirador Compass (now owned by Centurion). Retrieved from http://compass.centurionmp.com/?compartment.

Another one of our concepts related to real-time fluid pressure measurement and the measurement of intracranial pressure. During a search for predicate devices, we discovered the Mirador Compass (Figure 46). Their indications for use related to measuring and monitoring intracranial pressure, which was very similar to what we would expect the indications for use to be for one of our concepts. The FDA classified the Mirador Compass as a class II device, and it went through the FDA 510(k) process without the need for clinical testing. They were only required to provide data from pre-clinical tests, including *in vivo* studies (bench studies) and *in vitro* (animal studies) studies to prove efficacy, along with the necessary biocompatibility, packaging, sterility, software validation, and electrical/EMC studies. With the help of one of our regulatory advisors, we determined that this would be a very suitable predicate device if we decided to move forward with a concept involving intracranial pressure measurement, meaning that the concept could most likely also be classified as a class II device and be submitted through the 501(k) process with the Mirador Compass as a reasonable predicate device.

At the beginning of the fellowship, we decided as a team that an important criterion for our device would be that it would have a relatively quick time to market, and therefore, we were not interested in pursuing any devices that would require PMA approval from the FDA. As a result, we eliminated multiple concepts based on their required regulatory pathway. We also wanted to avoid solutions in consumer health, but we did not eliminate

concepts based solely on whether they would be a class I device or would not be regulated by the FDA (like many consumer health devices). However, we made note of the class and required pathway of each concept and used that information during final concept selection as a way to eliminated some of the concepts.

3.2.2.3: Reimbursement

We looked into reimbursement strategies in parallel to potential business models because we felt that, for our concepts, these subjects were closely related. At this time, we did not yet have access to any reimbursement specialists, so we performed all of the research surrounding reimbursement as a team. We began by researching reimbursement codes that related to the procedures our concepts would be used in. We documented all of the relevant codes, broke down what parts of the procedures were actually reimbursed and for how much, and gathered information to determine whether we thought our concept would be able to fit under an existing reimbursement code or if we would need to apply for a new code. We researched devices that had similar value propositions and business models to the ones we were considering to see how they were able to gain reimbursement (i.e., fall under an existing code or require a new code). If they required a new code, we looked into the steps that would need to be taken in order to prove their value and be granted the code. We mapped out the procedure and reimbursement process for our concepts in order to better understand how the codes were used and how the facility and physicians were reimbursed based on different aspects of the procedure. An example of a map of the reimbursement process I created for a concept addressing the need *"a way for physicians to perform LPs that improves efficiency and reduces the incidence of complications"* can be seen in Figure 47.

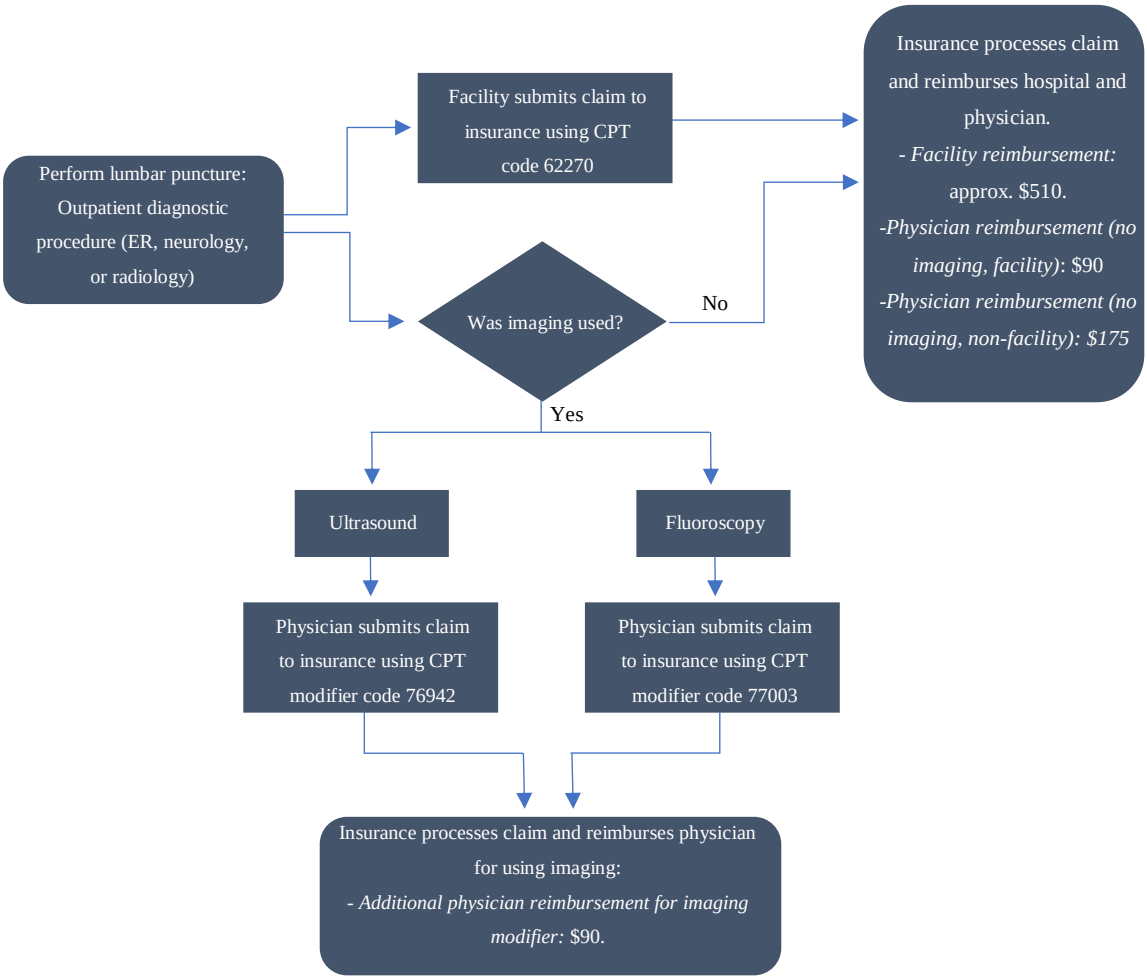


Figure 47: Flow chart of reimbursement and coding for performing a diagnostic lumbar puncture

We did not eliminate any concepts based solely on reimbursement at this stage. However, the information gathered from researching potential reimbursement pathways for the concepts was used during final concept selection.

3.2.2.4: Business Models

determine the best business model for the concepts we were assessing, we filled out multiple business model canvases. One of the more detailed business model canvases that we created for a concept for our LP need can be seen in Figure 48.

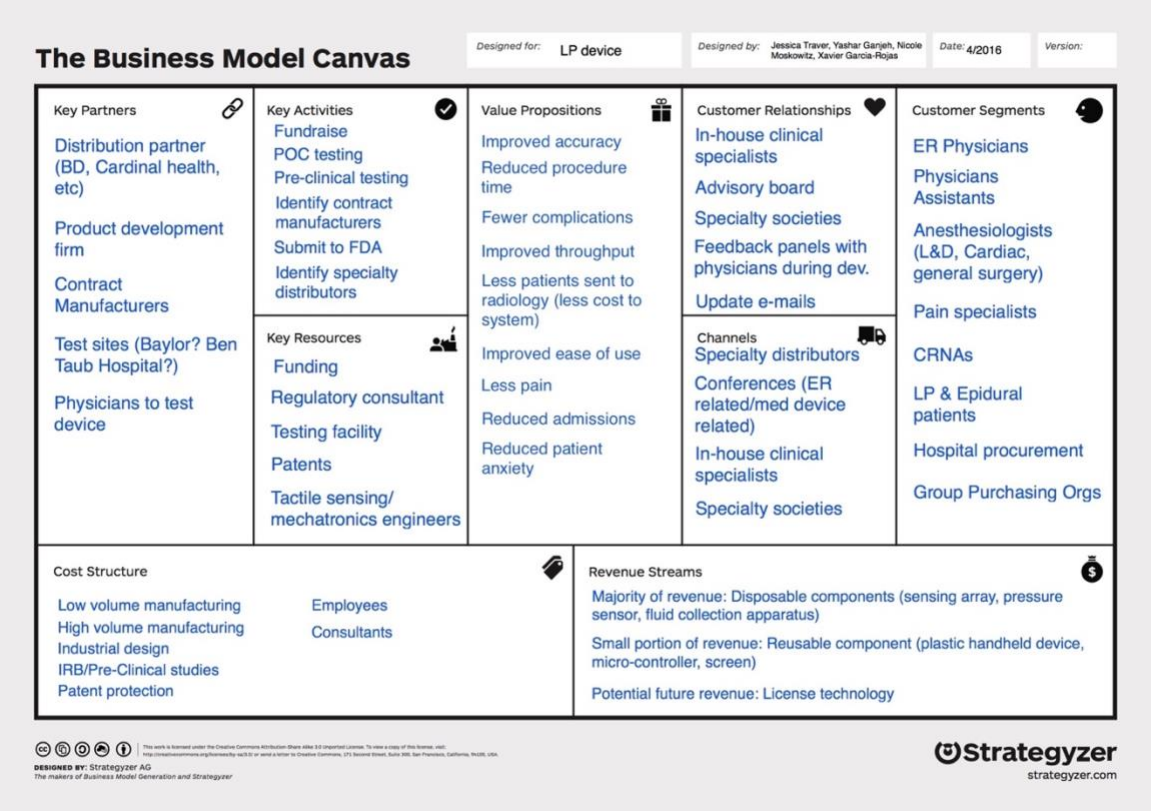


Figure 48: Example of a business model canvas created for the LP need.

The concept that was used in this example had an imaging component to aid in identifying landmarks, a needle guide for improved insertion accuracy, a digital pressure sensor for measuring intracranial pressure, and a fluid collection component for easy collection of CSF. The device would follow a razor/razorblade model in which the commoditized products (fluid collection system, collection tubes, needles, fluid pressure sensor, etc.), as

well as the tactile imaging sensor array, would be single-use and the handheld component with the micro-controller and screen would be reusable.

1. **Customer segments:** In this section, we listed all of our important customers and stakeholders. The people we were creating value for included ER physicians, physician's assistants, anesthesiologists, pain specialists, CRNAs (nurse anesthetists), patients, hospital procurement staff, and group purchasing organizations.
2. **Value propositions:** The concept would offer a variety of value propositions to the different customer segments we identified, with each customer segment valuing different propositions more than others. The physicians, physician's assistants, and CRNAs would value the improved accuracy provided by the device, improved ease of use, and reduction in procedure time the most. The hospital procurement and group purchasing organizations would value the reduced complications, improved throughput, reduced costs associated with keeping patients out of radiology, and reduced re-admissions the most. Lastly, the value propositions most important to the patients would be related to decreased pain, improved accuracy, fewer complications, reduced time, and reduced patient anxiety.
3. **Channels:** For the business model created in this canvas, we would partner with specialty distributors and in-house clinical specialist to sell our device. We would use a specialty distributor because of the reusable components in this design. A specialty distributor would be able to help us sell our device to multiple hospitals very quickly, similarly to a mass distributor. However, unlike a mass distributor, they can commit more attention to the devices they sell, and they possess more technical knowledge about their products. Because this concept would require some technical knowledge, a specialty distributor would work well. We would also hire in-house clinical specialists to work with the specialty distributors and help drive adoption sales of the device. They would also help train physicians on how to use the device. We would also attend industry conferences and reach out to leaders of specialty societies for ER physicians and anesthesiologists to help get the word out about our device and educate them on its benefits.

4. **Customer relationships:** We identified a variety of ways to create and uphold relationships with our key customer segments. The in-house clinical specialists that we would hire for sales and distribution would be the contact person for the physicians when they had issues, questions, or comments regarding the product. We would also add a number of physicians to our advisory board who could help with outreach and act as champions for our product. Additionally, we would hold frequent feedback sessions or panels with physicians during development, which would serve two purposes. First, it would be extremely helpful to continually receive user feedback on the concept during development, and second, it would engage physicians early in the process and allow us to establish relationships with key customers before entering the market, so when ready to enter the market, we would have physicians that were excited and willing to use the device. Lastly, we would develop customer relationships at industry conferences and specialty society meetings focused on ER and anesthesiology.
5. **Revenue streams:** In this example, the majority of our revenue would be generated from our disposable components, which we would sell as part of a LP or epidural kit. This is how the tools currently used in one of these procedures are sold. Unlike the kits currently on the market, however, our kit would contain the technology necessary to image the vertebrae (tactile sensing array) and read the opening pressure more accurately (fluid pressure sensor in place of the currently used manometer). These technological improvements would allow us to price our kit significantly higher than the kits that are used currently. In addition to the disposable component, we would sell a reusable component. This would be the handheld device and would contain the micro-controller, the battery, and the LCD display.

   Another potential revenue stream we see with this device would be licensing the technology to other companies. If we attained a patent on the tactile imaging array, we could license the technology out to other companies who might want to develop similar devices for different uses.

6. **Key resources:** Some of the key resources we identified in order to develop the product included funding, regulatory consultants, patents, engineers, and testing facilities. We would require funding to hire the necessary employees for sales and distribution, as well as to cover costs associated with product development, manufacturing, and testing. A regulatory consultant would help us determine both the best path through the FDA and the necessary tests to perform for clearance. Patents would protect our technology and keep others from commercializing a similar device. Tactile sensing and mechatronics engineers would help us with development and optimization of the technology, and having access to a testing facility would allow us to test the device and iterate on our design before submitting to the FDA.
7. **Key activities**: The key activities required to launch this product with this business model would be identifying a contract manufacturer and a specialty distributor to work with closer to launch, performing proof-of-concept testing and pre-clinical testing to gather data for submission to the FDA, submitting to the FDA, and raising funds.
8. **Key partnerships**: Some of the most important partnerships we would need to develop for this concept are highlighted in this section. It would be crucial for us to partner with medical institutions for testing the device, as well as physicians for both testing the device and championing the product post-launch. It would also be very beneficial for us to partner with a product development firm and a contract manufacturer in order to help us design the product for manufacturing and usability, optimize the technology, and manufacture the device. Lastly, it would be beneficial to find a distribution partner—either a large one like Becton Dickinson or Cardinal Health, who already has distribution channels in place for kits similar to the one we are proposing, or smaller distributors like the specialty distributors discussed in earlier sections.
9. **Cost structure**: The costs required to operate this business model include manufacturing (low volume initially, then high volume), salaries for employees, consultant costs, and patent protection costs. Additionally, to get the product to

market, we would need to conduct pre-clinical testing and industrial design and engineering activities. Pre-launch, the R&D and testing would be the most expensive activities. After launch, manufacturing and general operating costs would be the most expensive activities.

After creating multiple business model canvases, we were able to determine what business models would work best for each of our top concepts. We had to eliminate some concepts based on the lack of a viable business model. For example, one concept would require us to charge the customers an extremely high price to justify development of the device and cover the cost of the sales force necessary to sell the device. The price required to cover development costs was much higher than industry averages, and the value propositions were not strong enough to support the increase in price; therefore, the concept had to be eliminated.

3.2.2.5: Prototyping and Feasibility Testing

Due to the time constraints of the fellowship, it was important to us that we chose a concept that we could demonstrate proof-of-concept with fairly quickly. The fellowship covered our expenses for one year, and it would be important for fundraising to have a prototype and initial data. This constraint forced us to eliminate concepts we were enthusiastic about. For example, we were very enthusiastic about our need regarding heart failure; however, after reviewing the concepts that came out of concept generation for this need, it became clear that we did not have the skillsets or expertise necessary to develop proof-of-concept prototypes for the top concepts. We could not develop a proof-of-concept prototype without adding team members with additional skillsets, and we would not be able to do that without raising money, so we were forced to eliminate many of the concepts for that need. As a result, the majority of the concepts that we prototyped and tested addressed the need *"a way for physicians to perform LPs that improves efficiency and reduces incidence of complications."*

1. **Define the core questions that need to be answered for each concept to mitigate risk:** Because we brainstormed on sub-functions of a potential concept, a lot of our

initial concepts were grouped by function (i.e., fluid collection, needle guidance, identification of landmarks, etc.) and were already broken down into sub-concepts (concepts focused on addressing a sub-function). This meant that we did not yet have any comprehensive concepts that could be used to answer core questions. Rather, during the initial stages of prototyping, the majority of questions we had concerned the feasibility of the sub-concept. For example, for the sub-function "*identifying underlying landmarks,"* the top concepts we were evaluating used ultrasound, tactile sensing, and radar. The main question we had for each of those modalities was *"can we use this technology to image bone through multiple layers of soft tissue?"* This question would require us to build multiple low/mid-fidelity prototypes to test functionality. These prototypes will be explained further later in this section.

During later stages of prototyping, once we had proved functionality of different sub-concepts and eliminated sub-concepts that didn't work, we began mixing and matching sub-concepts to create different comprehensive concepts. During this stage, there were still multiple questions concerning functionality, but they were specific to how the sub-functions would interact with each other. Additionally, there was a larger focus on answering questions about how physicians would interact with the device. For example, for a concept involving tactile sensing, an important question we needed to answer was *"how will the physician apply force to the device?"* This was both a question concerning technical feasibility (*which force application method results in the highest resolution and most accurate image*) and usability/human factors (*which method of applying force was most comfortable to the physician? Which method allowed them to hold the device comfortably while also performing other steps of the procedure?*). These questions required a number of different prototypes to be constructed and tested to determine the answers. More information on the types of prototypes that were built to answer these questions is provided in later parts of this section.

2. **Break concepts down into smaller, essential sub-concepts to test**: As discussed in the previous section, due to the way we brainstormed, our concepts were initially

sub-concepts. So, we began prototyping and testing the individual sub-concept components relating to *"identifying underlying landmarks, collecting CSF, consistently inserting the needle, and measuring opening pressure"* before putting them together to create a cohesive solution. This allowed us to quickly eliminate sub-concepts that would not work without needing to spend time determining how to build them into a comprehensive concept. We created multiple lo-fidelity prototypes initially (Figures 49 and 50) using pre-existing medical equipment, clay, pipe-cleaners, paper, Legos, and so on to help us determine the feasibility of sub-concepts.

Figure 49: Low-fidelity prototype of fluid collection system using K'NEX tongue depressor, plastic tubes, and clay.

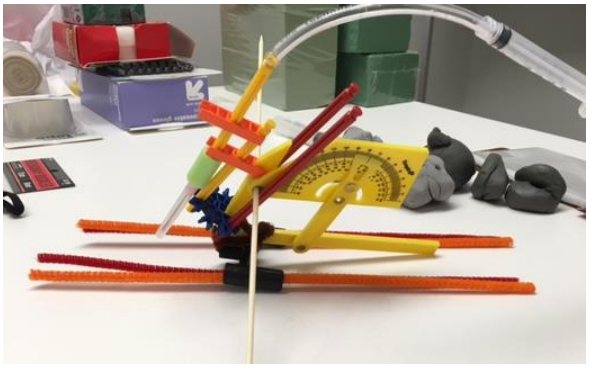


Figure 50: Low-fidelity prototype of a concept where the needle slides along a track and has a variable needle guide angle.

3. **Determine the best type of prototype to answer the questions surrounding the concept:** During the initial stages of prototyping, the majority of our questions concerned feasibility. Therefore, we built multiple low- and mid-fidelity prototypes to see if our concepts could be feasible. Continuing with the example from part one

of this section, in order to answer the question *"can this technology be used to image bone through multiple layers of soft tissue,"* we not only had to build a "works-like" prototype, but we also had to build a suitable testing platform. For example, in order to evaluate our tactile sensing concepts, we used a lumbar spine block (Figure 52) that is used to teach medical students how to perform LPs and epidurals to test our prototype. We began building a tactile imaging platform by using commercially available, single-point, 5.1mm active-diameter, model-400 FSRs (Figure 51). These are two-wire, robust polymer thick film (PTF) sensors that decrease in resistance in response to an increase in force.

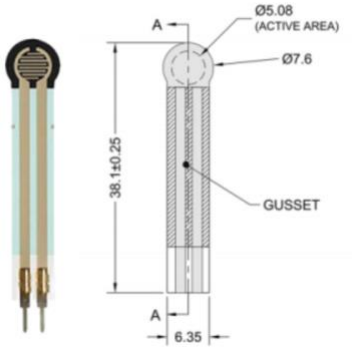


Figure 52: Image and mechanical representation of model 400 FSR.

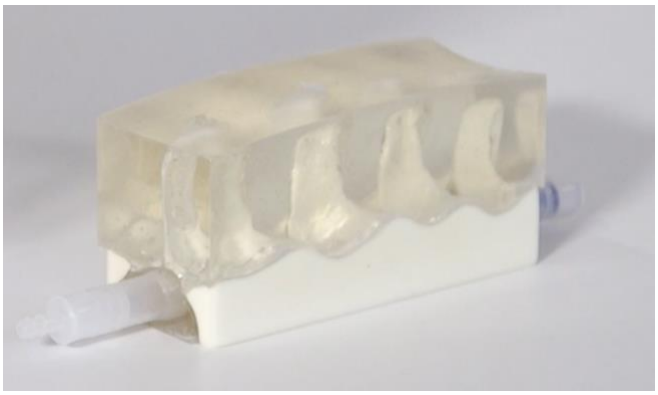


Figure 51: Lumbar spine block used to perform bench testing.

Our initial proof-of-concept testing was performed using a single sensor with a voltage-divider and output to an oscilloscope. By visualizing the outputted voltage as the sensor was advanced along the spinal model, we were able to verify its sensitivity to underlying bone versus interspinous ligament and fat. These findings proved that tactile sensing could be a viable technology for this application, and so we continued to develop more robust prototypes involving tactile sensing.

In order to answer questions related to usability and gather physician feedback on the form factors of a concept or sub-concept, we built some low-

fidelity feels-like prototypes to show to physicians. These prototypes were just form factors and had no technology integrated into them. They were used to gather feedback on the way the device would be held, how the physician would have to apply pressure to the device, and the position of the screen.

During later stages of the fellowship, we developed a looks-like prototype for investor pitches and startup competitions (Figure 53). This looks-like prototype was created using a CAD drawing of a concept that was then rendered to resemble a final product. We expect multiple changes to be made to this prototype as we continue to test different versions of the device and learn from those tests. As the design changes, the looks-like prototype will change as well. A final, constructed looks-like prototype will be developed closer to a design-freeze once more usability testing has been conducted and when we need to gather feedback on aesthetics, packaging, and so on.

Figure 53: Example of a looks-like prototype developed for the LP need.

1. **Refine design requirements and design more detailed prototypes:** We built many low-fidelity prototypes, performed initial testing on the sub-concepts, and eliminated multiple sub-concepts based on feasibility and team skillsets. For

example, although our initial simulations proved that radar could be used for identifying bone through soft tissue, we determined that we did not have the skillsets necessary to develop a solution using that technology, and we would need to bring on a radar specialist and spend a great deal of time and resources in R&D before the technology could be ready for commercialization.

For the concepts that passed the initial phases of prototyping and testing, we continued to iterate on their design. The example that has been used throughout this section concerning testing tactile sensing will continue to be used to explain the iterative process we used to develop a more robust prototype. After the initial proof-of-concept test, we developed signal acquisition, processing, and visualization schemes in Arduino and Python to allow us to more robustly observe the sensors' characteristics. In our initial studies, we recorded the voltage distribution for a single sensor moved in 1 cm increments along the lumbar spine model and observed its change with applied force. It was clear that voltage increases could be seen when the sensors were over bone with an applied force as low as 20g, so we decided to develop an even more robust prototype. To allow for more comprehensive visualization of the lumbar spine, we designed and constructed a 12-sensor array utilizing multiplexer circuitry (Figure 54). The array consisted of two 6-sensor columns with 1 cm spacing between neighboring sensors (along both axes). First, we set out to validate sensor uniformity and sensitivity. We recorded voltages across each sensor for six trials with the column advanced along the spinal model in 1 cm increments (Figure 55). Again, voltage increases were reliably observed when sensors were above spinous processes ("bone"). Additional studies observing sensors' resolution with changes in force-application method and BMI were also performed to optimize the design and construction of our electronics.

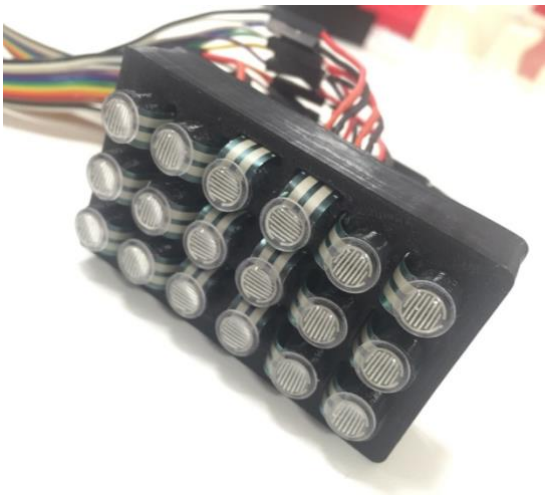


Figure 54: Prototype of tactile sensing array.

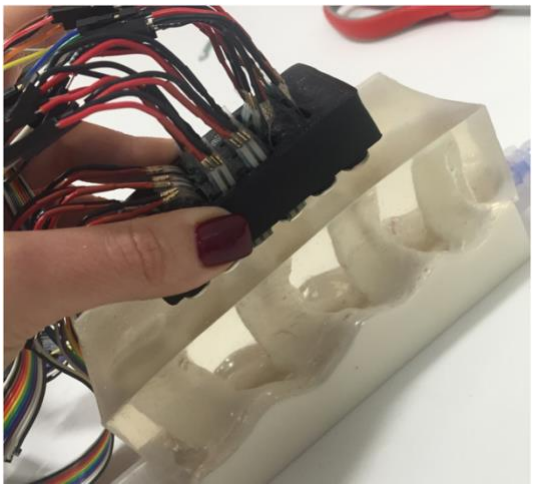


Figure 55: Bench test of tactile sensing array.

In parallel to continuing development on the tactile sensing platform and other sub-concepts, we used a morphological matrix to mix and match promising sub-concepts to create complete concepts that we would show to stakeholders to determine which features they found most important. Our morphological matrix can be seen in Table 10.

Table 10: Morphological matrix for concepts surrounding the LP need.

Localization	UI/Feedback	Needle Positioning	Pressure Sensing	Fluid Collection
Tactile sensing	LEDs	Grid	Digital	Spoke
Ultrasound	LCD screen	Frame	Pressure gauge (analog)	Iris diagram
Radar	Lasers (project entry spot)	Transducer	Manometer (status quo)	Faucet
Blind (status quo)	Haptics	Concentric housing	--	4 compartment plunger
--	Overlay with structural image	Handheld guide + display	--	Rail with cartridges
--	Voice over/walk through	2 part grid	--	Standard drip (status quo)
--	Sound/beep	Split array/vertical needle adjustment	--	--
--	None	Sticky display/multiple holes	--	--
--	--	Skin marking (status quo)	--	--

We wanted to create prototypes that exaggerated the different benefits our sub-concepts could create if combined so that it would be easy to tell what features were important to the key stakeholders. Using the morphological matrix above, we mixed and matched sub-concepts to create a very low-cost/low-tech integrated prototype, a high-cost/high-tech integrated prototype, a low-cost/high-tech integrated prototype, a high-cost/low-tech integrated prototype, and a prototype that we thought embodied the perfect solution. We then developed the five integrated prototypes to show to physicians and gather their feedback. After speaking with multiple physicians, iterating on the prototypes, and going back to the physicians for more feedback, we were able to finalize the five sub-concepts that physicians were most interested in. The concept that

made the most sense for adding value while keeping costs low included tactile sensing, an LCD display, a needle guide, a digital pressure sensor, and a rail with cartridges for fluid collection.

We created CAD models for a variety of form concepts and 3D printed them in order to receive feedback from physicians concerning their usability and ability to meet the physicians' needs (Figures 56 and 57). With each prototype and each physician feedback session, we gathered valuable insights into the design and usability of our prototype, and we were able to adjust the need specification documents accordingly.

Figure 57: Example of a form factor prototype.

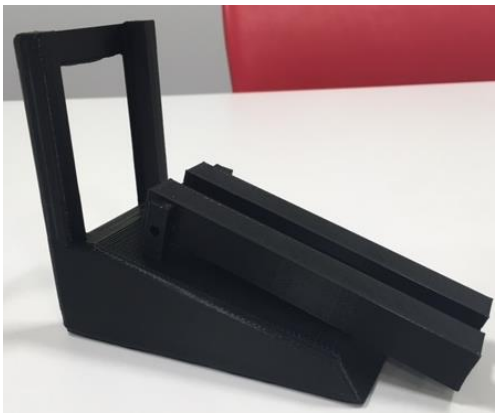


Figure 56: Second example of a form factor prototype.

By prototyping and testing the form-factors and integrated concepts, and by showing them to physicians and gathering feedback, we were able to decide on a general embodiment that incorporated all of the essential elements necessary to meet the user needs.

3.2.2.6: Define Ranking Criteria and Perform Final Concept Screen

Following all of the research performed during the different concept selection phases, we were able to identify our top concept without having to define ranking criteria and go through a final selection process, as discussed in the previous section (Prototyping and feasibility testing). We continued to iterate on that design, as well on the design of the

tactile sensing array for improved imaging. After multiple design iterations and bench tests, we were able to build a works-like/feels-like model that we could use to demonstrate the device's capabilities at conferences, competitions, and investor pitches. We expect that this design will change multiple times throughout development after the fellowship, but the final prototype developed during the fellowship can be seen in Figure 58, with the image output shown in Figure 59.

Figure 58: Integrated prototype of lumbar puncture assist device.

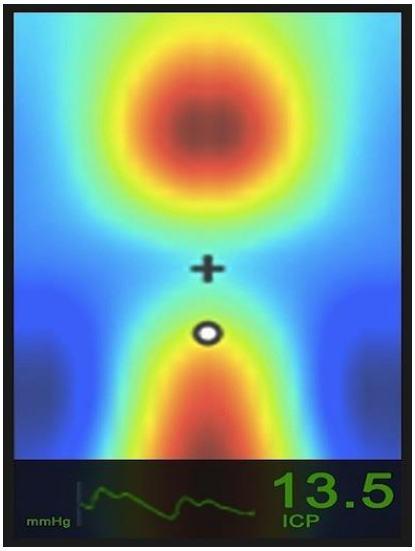


Figure 59: Real-time image generated on computer when device is pressed against the patient's back.

3.3: Stage 3: Commercialize

3.3.1: Strategy and Pitch Deck Development

Once we built and tested the proof-of-concept prototype, we began the final phase: Commercialization. During this stage, we built upon all of the research we performed in previous stages concerning the need and the concept for the purpose of developing a sound strategy for commercializing our device. We summarized all of the research into memos and a final pitch deck that we would use at the end of the fellowship to apply to accelerators, pitch in business plan competitions, and present to angel investors for funding. I was in charge of creating the pitch deck. I designed the slides, wrote the script, and presented to investors and at business plan competitions.

For some research areas, we split the work up amongst the team members and worked individually, while for others, we worked on the research together. I lead the research for the problem, the competition, and many aspects of the GTM strategy. I also took the lead on developing the financial model and determining how much money we would need to raise in our seed round.

3.3.1.1: The Problem

I began this section by listing every issue we had identified with the current procedure and available devices, and I attempted to rank the ones that were the most important based on research we had performed during needs finding and the stakeholder analyses we had previously performed. Table 11 categorizes all of the issues I identified with the procedure based on the stakeholder they affect.

Table 11: Summary of issues related to the LP need.

Hospital/System	*Physician*	*Patient*
• LP patients occupy ER beds for a long time • Complications= return for treatment (additional cost, potential loss of reimbursement) • ER throughput suffers due to multiple attempts • Throughput suffers due to failed attempts—sent to radiology • Multiple attempts lead to low patient satisfaction scores—reflects poorly on hospital and affects reimbursement	• Identifying landmarks via palpation is unreliable and inconsistent • Difficult procedure, especially for non-experts • Technology available is unreliable or unintuitive (ultrasound) • Multiple attempts required, which leads to frustration • Multiple attempts increase likelihood of "bloody tap," which requires a repeat LP • Multiple attempts lead to low patient satisfaction scores—reflects poorly on physician and can affect compensation • Manometers used for determining opening pressure are cumbersome • Manometers are outdated and inaccurate • Using manometers to determine opening pressure adds time to procedure • Collecting fluid is cumbersome and time consuming • Collecting fluid exposes physicians to potentially harmful CSF • Procedure requires three hands (always need assistant) • Radiologists are unhappy when failed LPs are sent to them—disrupts their schedule and causes bottleneck • (Epidural) not knowing depth can cause physician to accidently puncture the dura, potentially causing CSF leak or improperly administered anesthetic	• Multiple attempts are painful • Increased time in ER due to multiple attempts, leads to frustration and anger • Increased time in ER due to failed procedure—sent to radiology, leads to frustration and anger • Unnecessary exposure to radiology in the event of failed LP (unsafe) • Multiple attempts increase likelihood of post-LP headache; affects QOL and potential need for additional treatment • Inaccuracy of procedure can cause "bloody tap," resulting in misdiagnosis or extended stay • Inaccuracy of procedure can cause "bloody tap," requiring additional LP • Inability to accurately place epidural can result in patient not receiving epidural for labor

Originally, I struggled with which problems to include in the deck and which to exclude. I felt that all of the problems were important and helped to support the argument for a new device. At first, I tried to include as many of the issues as possible, but after presenting the slide to some of our advisors, I realized that I was spending too much time explaining the problem, when in reality people just wanted a short summary of the most important issues

associated with the current procedure. I then went back through the needs identification and validation research, as well as the stakeholder analyses we created, to identify which problems were the most important. It was clear that the main issue was that the current method for performing LPs and epidurals is inefficient and inaccurate. That became the main focus of the slide and determined how I needed to structure our value slide.

After I was able to clearly and concisely state the overall problem, it was clear that every other issue was a result of that problem. After breaking down all of the problems associated with the need, it was clear that most of them could be covered by highlighting four categories: physician frustration, patient satisfaction, procedure length, and ER throughput. These became the four points I highlighted in my pitch deck regarding the problem.

I then had to conduct more research into the problems I was highlighting on the slides so that I could present supporting data. I researched failure rates of epidurals and LPs, the average duration of the procedure, and the costs associated with complications. There was literature to support the claims I made about first-attempt failure rates, but there was not much data surrounding the average duration of the procedures, which was necessary to convince people that the procedure length was in fact a problem. To determine a range for this, I had to review our notes from observation and see how long the LPs we observed were, in addition to interviewing physicians to determine an estimate for how long they believed the procedures took. I also returned to the hospital to observe and time more LPs. I used this information to create supporting sentences for each of the four issues I was highlighting on the problem slide. Figure 60 shows an example of the problem slide I created for our pitch. The slide was animated to display different statistics and information on the bottom section of the slide based on the different problems. Figure 60 is a screenshot of the presentation when highlighting the issues associated with patient satisfaction. The entire pitch deck can be found in Appendix D.

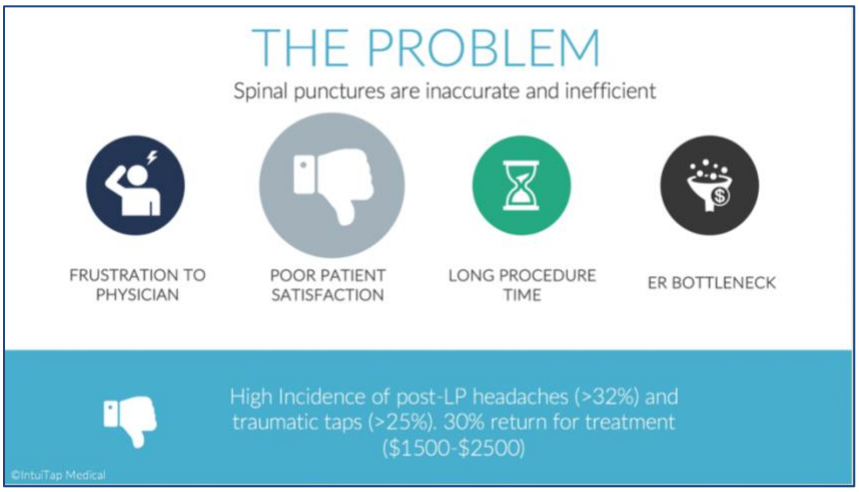


Figure 60: Example of one of the "problem" slides I created for the pitch deck.

I also created a simple background slide to help the audience understand why the procedure is performed, the steps of the current procedure, and what cases are considered difficult (Appendix D, Slide #2).

3.3.2.2: The Market Size

The market research conducted throughout the fellowship helped us to identify a number of procedures that required a spinal needle to be inserted into the lumbar region. In order to calculate the total addressable market, I had to determine the number of procedures performed in each setting and then add those numbers up to calculate the overall market size based on procedures. There are four main spinal puncture procedures performed: diagnostic LPs (performed in ER and neurology), epidurals for anesthesia in surgery (performed in orthopedics), epidurals for anesthesia in labor and delivery (performed in obstetrics), and epidural steroid injections for back pain (performed in pain management). I found that approximately 800k diagnostic LPs are performed each year in the US, 500k epidurals are performed in orthopedic surgeries, 2.4M epidurals are performed in labor and delivery, and 9M epidural steroid injections are performed annually in the US for pain management, resulting in a total annual number of 12.7M spinal puncture procedures performed in the US.

The next task involved determining the average cost of the procedure. Because there are no devices on the market that really address the need like our proposed solution, it was challenging to determine the Total Addressable Market (TAM) the way in which it is normally calculated. There were no comparable devices on the market that we could use as a cost estimate to size the market in terms of economics, so we decided to look to reimbursement data for the different procedures to estimate the cost of the procedure, which would also help us in pricing our device. I will discuss this in more detail in the GTM strategy section, but to summarize, we determined the average cost of the procedure across the different settings based on reimbursement to be approximately $500. This led me to determine that the total addressable market would be $6.4B. The slide I created on the market opportunity can be found in Appendix D.

3.3.2.3: The Competition

3.3.2.3.1: Understanding the Pros and Cons of Existing Products or Emerging Products

I took the lead on researching the competition and performing an analysis on the competitive products on the market. I began by identifying what products could be considered competition. During our research in the concept selection stage, we came across our only technologically relevant competitor, the Accuro by Rivanna. It is a handheld ultrasound unit designed specifically to help physicians identify the epidural space. I also researched the standard LP and epidural procedure kits/trays, because they currently capture the majority of the market share and were considered the standard of care, in addition to standard ultrasound machines, which are often used in the event that a physician cannot accurately identify the vertebral gap. Additionally, I researched products that addressed certain aspects of our need, including the Mirador Compass, previously discussed in the concept selection section, and Loss of Resistance Syringes, which are commoditized tools used to help anesthesiologists know when they reached the epidural space based on a pressure drop that occurs when entering that space. I included Loss of Resistance Syringes because people often asked if any innovations had been made in this area in the last couple of years and were often interested in adoption rates, business models, and so on of those products. Loss of Resistance Syringes are really the only product on the

market that is somewhat related to helping physicians place spinal needles for epidurals, so I included them in my analysis, even though they only solve a very small part of the problem.

To start the analysis, I had to determine the most important criteria to evaluate the competition against. To help with this analysis, as well as our value analysis and adoption rate predictions, I created a survey to send out to ER physicians and anesthesiologists. The questions on the survey focused on features and their perceived importance. It also contained questions concerning the need, such as the number of attempts they think it takes them to place an LP/epidural on average, the number of LPs/epidurals they perform a week, and the most difficult steps of the procedure. I sent this out to a number of physician contacts, who forwarded it on to their colleagues. We received a total of 79 responses, which were used to help us to better develop our competitive strategy and value analysis and to predict adoption rates. I will discuss these results and how they related to specific strategies in the respective sections. Based on feedback from the survey, in addition to the research conducted during the previous two phases, I was able to identify five criteria on which to evaluate the competition, namely, their ability to reduce the procedure time, reduce the number of attempts required, improve the pressure measurement process, improve the fluid collection process, and whether or not they incorporated needle guidance. I created a competition table to visually represent how the IntuiTap device compared to its competition. This table can be seen in Figure 61.

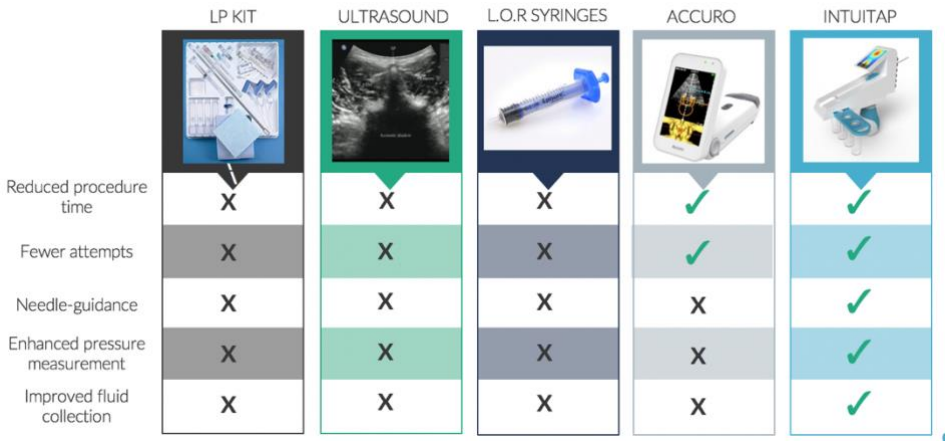


Figure 61: Competition table for IntuiTap device.

3.3.2.3.2: Protecting Against Competition

The second part of the competition strategy is determining how to defend against new or existing competition. As part of the fellowship, the law firm Wilson Sonsini Goodrich & Rosati (WSGR) agreed to write a provisional patent for us pro-bono. Technically, a couple of drawings and a description would suffice as a provisional patent, however, they drafted a provisional patent as if they were creating a utility patent application so that it would reduce the time and costs associated with filing for a utility in a year, so it was very beneficial. They were extremely helpful in determining what types of claims we should include and in conducting a more official prior art search than the one we conducted previously. They also conducted a preliminary FTO search to see if any patents stood out right away as ones that could pose a problem down the line, but they suggested that we hold off on having them perform an official FTO search until we had raised money and were closer to converting to a utility, because they can cost anywhere between $10–$20k.

We worked with them to develop a preliminary patent strategy. Sometimes, it is advised to only include technology that has already been developed, as well as any obvious changes or improvements, in a first patent so that patent protection can be extended by filing separate patents at a later date on other ideas, inventions, or improvements. However, due to the terms of the fellowship, the program would cover half of the costs associated with the filing of our first patent, so we decided to include as much information as possible into our first patent. In this way, we could reduce costs related to patents in our first year as a company by not having to pay for additional patents relating to different aspects of the device. Any IP generated during the fellowship was owned by the TMC, but it was exclusively licensed back to our company, so it made sense to include all of the IP that had been generated in the fellowship in the first provisional patent. We knew that new IP would be generated after the fellowship was over, so we could try to grow our patent portfolio with the new IP that was generated once the fellowship was over.

WSGR worked with us to brainstorm all of the different ways our device could be described and generated over 100 claims for us to include in our provisional patent. The provisional included information about all of the top concepts we generated, not only the

final form factor we selected to move forward with. We submitted the provisional patent in April 2016 so that we could begin publically presenting our solution.

3.3.2.4: The Solution

Determining a strategy around our solution largely consisted of creating an R&D timeline and testing strategy, since the desired features were identified and conceptualized during the concept generation and selection stages. The first slide that I created concerning our solution was a simple slide that included a rendering of our device and a brief summary of the features, as shown below in Figure 62.

Figure 62: The solution slide created for IntuiTap pitch deck.

The majority of our time and effort developing a strategy around our solution was spent creating a plan for R&D. As a team, we went through each feature of our product and determined what we needed to do to develop and test it. We knew that it would be extremely important to have data to show to investors when raising seed money, so we worked with researchers at Baylor College of Medicine and professors at Rice University to develop a protocol for a low-risk study involving healthy human subjects to prove the accuracy of our core technology. The goal of this study was to compare our device's ability to image the vertebrae and identify an accurate insertion location against the palpation

technique and an ultrasound. We conducted the study through a Rice University IRB. An overview of the study and its results can be found in Appendix E.

We learned a great deal from the IRB study and had very promising results. However, we felt that we had exhausted our team's knowledge of tactile sensors and that we would need to either build a team of experts or hire an engineering firm to help us take our core technology to the next level. We decided that it would be more efficient and cost-effective to partner with an engineering firm, and so we began researching firms and startup accelerators that focused on helping companies with devices with electronics and sensors. We also realized that we had hit our limit for brainstorming new form factors and decided we needed an outsider's opinion on how to improve the device for usability and human factors. We looked into hiring a human factors expert, but it seemed that working with a firm, or trying to work on that during an accelerator, would be more cost effective, so we added human factors and usability as criteria for a firm we wanted to work with. We came across a couple of engineering firms that seemed suitable, and we reached out to them for more information regarding costs and timelines. Two of the companies we identified often worked with startups and had their versions of accelerators where they would work with the startup companies at cost in exchange for equity in the company. This was extremely attractive to us, as we did not have any money, and even after a seed raise, money would be tight. We applied to this company's accelerators in hopes of working with them to optimize our imaging platform and re-design our device for usability.

For the fluid pressure sensor that would be used to determine the opening pressure of the spinal column, we found that there were multiple off-the-shelf options and that it would be cheaper to purchase those rather than attempt to build our own to incorporate into our device. Because the pressure sensor was primarily beneficial for the ER case and was not critical for improving the accuracy and efficiency of the procedure, we decided to delay testing of the fluid pressure sensor until the spring of the following year so that we could focus most of our R&D efforts into optimizing the sensor array for improved vertebral gap detection.

We created a Gantt chart to organize our R&D milestones, and we aligned them with the fundraising round we expected them to be associated with. The exact numbers

associated with each range will be explained in more details in Section 3: Financial Model & Predictions. The high-level Gantt chart can be seen in Figure 63. The green boxes are for testing milestones, light blue are prototyping milestones, navy are operational (fundraising, hiring, etc.) milestones, and grey are IP and regulatory milestones.

Figure 63: Gantt chart for development of the IntuiTap device.

I then took the information from the Gantt chart and summarized it to put on a slide for the pitch deck. The timeline I created for the pitch deck can be seen in slide 15 in Appendix D.

3.3.2.5: The Value

I began our value analysis by focusing on our three stakeholders' (hospitals, physicians, and patients) pain points and how our device could add value to each of them. We knew from our research concerning the need that the overall issue with the current procedure, for all stakeholders, is that it is inaccurate and inefficient. As such, our biggest value driver is that our device makes the process more accurate and more efficient. I created a value tree (Figure 64) to break down in more detail the different value propositions related to the

overall goal of improving accuracy and efficiency. Our product primarily addresses the need by reducing the number of required attempts to place a needle. By reducing the number of required attempts, our device can reduce complication rates, reduce the need for patients to be sent to radiology, and decrease procedure times. These were the most compelling value propositions that addressed each of the stakeholders needs, and we defined them in such a way that they matched up with needs explained in "the problem." However, after testing our value proposition statements with a variety of stakeholders, it became clear that simply stating that we add value in these three ways was not sufficient. Instead, we needed to further explain our value adding in terms of the endpoints they care most about, which is typically cost.

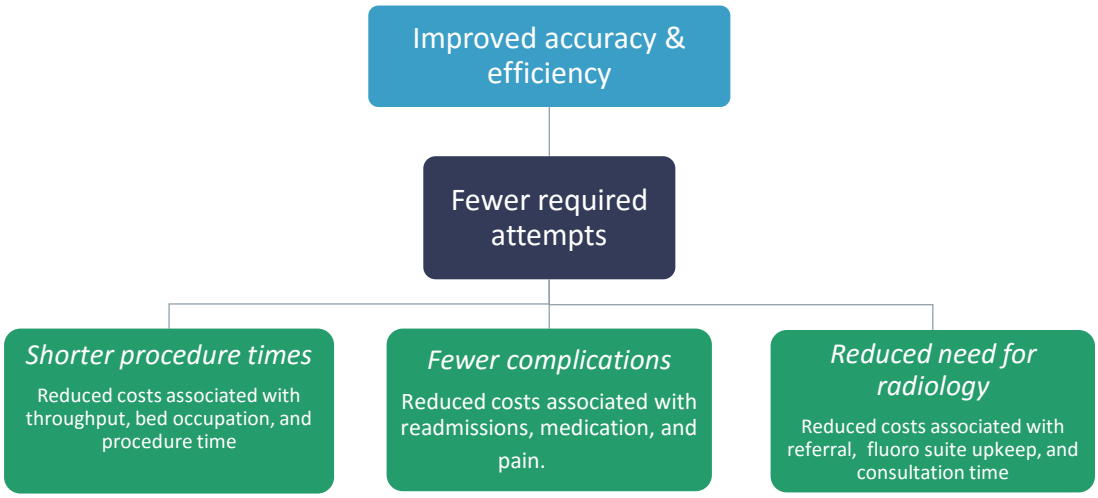


Figure 64: Value tree for IntuiTap device.

I hypothesized that the three main cost drivers associated with the need were procedure time, complication rates, and radiology referrals. However, I needed to put numbers to each assumption in order to determine whether my hypothesis was correct. We began researching the different value propositions, assumed cost drivers as a team, and attempted to determine accurate values for cost-savings associated with each value proposition.

1. **Shorter procedure times:** It is commonly known that throughput is extremely important in the ER, in addition to the fact that ER beds are valuable and efficiency is essential, so this is the value proposition we focused on first. We began by breaking down LP cases into three categories: easy, difficult, and failed (sent to radiology). We defined an easy LP as one that required 30 mins or less and had a maximum of two attempts. A difficult LP was one that required more than two attempts and help from a colleague, and on average took an hour. A failed LP was one that required multiple attempts in the ER with no success and was sent to radiology; we predicted that failed LPs took on average an hour and a half. Based on the survey we conducted with physicians, and on some studies about failed epidural and LP rates, we estimated that approximately 45% of cases fell into the "easy" category, 40% fell into the "difficult" category, and 15% fell into the "radiology" category.

   In order to calculate cost savings associated with simply reducing the procedure time, we had to determine the hourly cost of an ER bed during a procedure. One study determined that the hourly cost of an ER bed is $99.50 [26], so we used that amount to determine costs associated with procedure time for each procedure. Figure 65 shows the cost comparison of the palpation technique and the IntuiTap device for case.

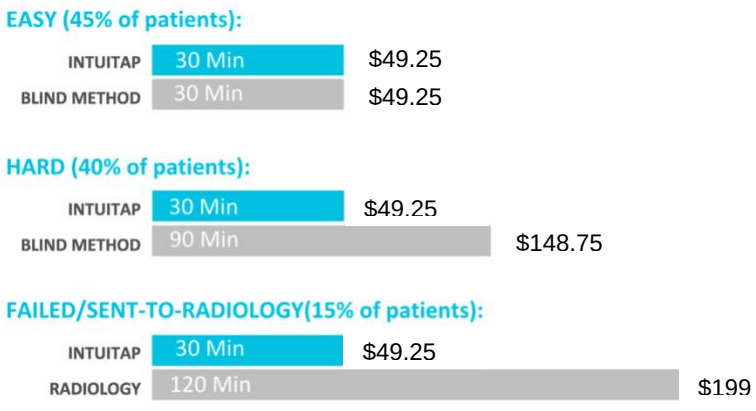


Figure 65: ER bed costs comparison by case types.

We felt that if we could reduce the number of required attempts, we could not only reduce the overall procedure time, but also reduce bed time associated with having to wait for an attending to assist in the procedure, or physicians delaying the procedure because of inconvenience or reluctance. We attempted to quantify this using costs associated with ER boarding time. We assumed, based on a number of cost estimates surrounding boarding time and revenue loss due to diversion, that the average hourly cost of boarding in the ER is approximately $1,100 [26-30]. This number is applicable for situations in which a patient is waiting for treatment, or to be transferred to radiology, in addition to the costs associated with taking up an ER bed that could be used for other patients. Based on our observations, research, and survey responses, we estimated that for easy cases, the average boarding time would be approximately 30 mins, for difficult cases 75 mins, and for failed cases 120 mins. This would result in costs due to boarding to be $543.00, $1,357.50, and $2,172.00 for each case respectively.

After we calculated the costs associated with procedure time and boarding time for each type of LP case, we calculated the potential cost savings of using our device compared to the standard procedure (Figure 66). We estimated that our device could save approximately $570/patient in boarding time reduction, and $43/patient in procedure time reduction, resulting in a total cost savings to the hospital of over $600/patient.

Figure 66: Cost savings of the IntuiTap device by type of case and type of cost.

We decided to omit this figure from the pitch deck due to amount of space and the information we wanted to provide. However, we often included it as a backup slide in case there were questions concerning how we calculated our average cost savings of $600/patient. The final design of our value slide can be found in Appendix D.

2. **Fewer complications:** The medical community has hypothesized that the need for multiple attempts leads to an increased chance of causing a variety of lasting patient complications; however, no studies have been conducted to prove this. Until we conduct a study using our device and track the rate of complications that occur when our device is used compared to when the traditional technique is used, we can only assume that our device will have some sort of cost savings due to reduction in complications, but we cannot assign a number to that value. So, we focused on researching costs associated with current complications and noting that we hope our device can reduce such costs. The most common complications are post-dural puncture headaches (PDPHs), which occur in approximately 40% of cases, with incidences cited between <1% and 88% depending on the setting and needle type [31-34]. PDPHs account for 15% of anesthesiology malpractice claims (40% of which result in successful lawsuits), and treatments alone cost the healthcare system $10.4M per year, with per-patient costs of over $500 in epidural cases where dural puncture is specifically unintended [35–40]. Other complications are related to local trauma, including nerve-root irritation and low-back pain in 13% and 35% of cases, respectively, in addition to bleeding, including traumatic taps and needle-induced blood in the CSF—a diagnostics concern—in 14% and 72% of cases, respectively [41–43]. However, we do not yet have cost estimates for these types of complications. Due to the fact that we do not have estimates concerning cost-savings, we often do not include numbers referring to complications in our pitch deck. Usually, we have back-up slides that contain some of the statistics listed above in case investors ask for more details, or we send them this information in a follow-up e-mail if they are interested.

3. **Fewer referrals to radiology:** We struggled to quantify the costs associated with sending a patient to radiology, and we are still working with hospitals, pain physicians, and radiologists to better quantify this cost. In the meantime, we focused on identifying the potential cost drivers of sending patients to radiology based on interviews with hospital staff and radiologists. We determined that the major issues and cost drivers concern having to reschedule already scheduled procedures due to unforeseen procedures, such as failed LPs; the fact that LPs are relatively poorly reimbursed procedures compared to many of the other procedures done in fluoroscopy suites, so doctors do not get reimbursed for their time as well; and lastly, the costs associated with having to compile a team to perform an LP in the fluoroscopy suite (not just a doctor and a nurse or two like in the ER). We are still working with stakeholders to determine a better idea of the actual costs associated with each of these issues, but we will most likely have to hire a consultant to help us pull the necessary data.

At this point in the fellowship, this was all we could do to estimate the monetary value our device could add. In the future, we plan to conduct studies to determine how effective our device is at reducing complication rates, in addition to working with consultants to determine potential cost-savings associated with keeping patients out of radiology. After we acquire a better understanding of the numbers associated with those value propositions, we will be able to better craft our value propositions and more accurately factor that into our pricing strategy.

3.3.2.6: The Business Model

We already possessed a strong understanding of the type of business model that would best suit our product based on the research and business model generation activities we performed during concept generation and concept screening. For our device, we knew that a hybrid business model including both reusable and consumable parts would make the most sense and allow us to generate reasonable profits. However, nobody on our team possessed any experience with hybrid business models, so I reached out to multiple

industry contacts to better understand what the sales and distribution process might look like for a hybrid device and determine how to price our products.

3.3.2.6.1: Sales & Distribution

I met with mentors and advisors to better understand what typical relationships with distributors look like, how much market penetration can be expected with a hybrid model such as ours, and the costs associated with working with distributors versus hiring in-house sales people, as well as how adoption rates could be affected by that choice.

I researched products that possessed similar business models and came across the EZ-IO device. The EZ-IO is an intraosseous bone drill used in almost every ER and ambulance in the country to place IVs on difficult patients or patients with collapsed veins. The device is made up of a reusable handheld component (a drill) and a specialty needle kit that has to be used with the drill. Because the business model is so similar to ours and the market it was being used in was also very similar to our initial target market (ER), I felt that Dr. Larry Miller, the inventor of the device and CEO of the company that commercialized it, would be an extremely valuable mentor. I reached out to him and asked if he would be willing to meet with the team and I to discuss our business plan, and he was more than happy to help. He quickly became one of our best resources for developing our sales and distribution strategy, and for building out our financial model. He gave us detailed information about his sales and distribution strategy and how many hospitals he was able to get his device into in the first one, two, three, and five years of sales. We based our sales and distribution strategy very closely after his because of the similarities of our business model and the success he had with his product. From the discussions with Dr. Miller, as well as our other mentors, we decided that it made the most sense to move forward with the hybrid business model consisting of a reusable handheld component that included the LCD screen, microcontroller, battery, and wiring, and a disposable kit that included the array of sensors, fluid pressure sensor, collection tube and holder, and other commoditized components that came in the current kits. For our sales plan, we decided on a hybrid model where we would work with specialty distributors to sell our product, but also include a

number of in-house clinical specialists (i.e., ex-nurses) that would work with the distributors to help train physicians on how to use the device and help drive adoption.

3.3.2.6.2:Pricing

The last aspect of the business model we needed a better understanding of for the pitch was pricing. Again, nobody on the team had any experience with pricing products, so I reached out to multiple medical device sales and pricing experts to help us determine a plan for pricing our product. The general response from every person I spoke with was that pricing is extremely complicated and there is no standard way of determining it, and that further down the line, closer to a product launch, it would be beneficial to work with a consultant or bring someone on in house that could help us really refine our pricing strategy. However, they also said that, for the early stage we are in, it is acceptable to estimate a selling price based on similar products and value-based pricing.

We decided to take a blended approach and base the cost on both the cost to make the products, the value created by the product (i.e., value-based pricing), and how much the product could be reimbursed for. We needed to determine the cost of goods sold (COGS) for the financial model in order to determine an estimate for revenue, as well as to determine the type of profit margin we would need to survive. By speaking with many of our advisors, we determined that most medical device companies using a consumable business model aim for ~70% profit margins, so we needed to determine how much the disposable products would take to make in order to determine the minimum price we would need to sell them for in order to achieve a 70% profit margin. We met with local manufacturers to get quotes on how much it would cost to develop our device at different volumes (low-volume, high-volume), and we developed an estimate of the COGS for each of the different components for our device. We determined that the disposable components would cost approximately $35 to make at high-volume and that the reusable components would cost approximately $45 to make at high-volume. We determined in our value-analysis that our device could save on average approximately $600/patient, making that the ceiling for value-based pricing, meaning we should sell the product for less than that so we can still claim they are saving money by using our device. Additionally, based on the goal

of ~70% profit margins on the disposable, the floor price we could sell our kit for would be approximately $150. However, it is not advantageous for a company to simply use COGS-based pricing and not include any value-based pricing in the pricing strategy, so we determined that our kit should be priced somewhere between $200 and $500.

We then used information gathered from our reimbursement strategy research (explained in more detail in the GTM strategy section) to further help us narrow the pricing range. We determined that the average reimbursement rate for an LP or epidural is approximately $500. From talking with our advisors and mentors, we learned that we should price the product somewhat lower than the reimbursable rate so as to incentivize hospitals to buy the product. We decided that we would price our product at $300. This way, even though the hospitals would be paying approximately $280 more on our kit (typical epidural/LP kits cost between $10 and $30), hospitals would still receive approximately $200 in profits from reimbursement (after removing the cost of the kit), and they could save up to $600/patient due to the improved accuracy and efficiency our product brings to the procedure, allowing them to save up to $800/case, which is $320 more than if they were using the standard kit (Table 12).

Table 12: Summary of cost savings with IntuiTap device.

	Kit cost	*Reimbursement*	*Cost-savings due to increased efficiency*	*Total savings/profit*
Standard Kit	*$20*	*$500*	*$0*	***$480***
IntuiTap Kit	*$300*	*$500*	*$600*	***$800****
		**Up to $320 additional savings with IntuiTap*		

At this early stage, it is challenging to determine a cost based on value, as we have not yet been able to prove any of the claims made, so these numbers are still very rough approximations of what we will sell our device for. Once we are closer to a product launch and have some studies conducted demonstrating our value, we plan to work with hospital procurement specialists and pricing specialists to better refine our pricing strategy. As discussed in the value section, we also plan to perform large studies to back up the claims

we make concerning value, including our device's ability to reduce the number of complications and reduce ER bed time.

3.3.2.7: The Go-To-Market Strategy

to finalize the majority of our GTM strategy. She led the research into predicate devices for regulatory, but I identified a regulatory consultant with whom I then worked to finalize a memo to send to potential investors outlining our regulatory strategy. For reimbursement strategies, Nicole and I both researched potential procedure codes that our device could potentially be categorized under and how much each code is reimbursed. Lastly, I led the majority of activities concerning determining a suitable launch market and growth activities after launch.

3.3.2.7.1: Regulatory

Through our own research conducted in earlier stages of the fellowship, we believed we would be a class II device and would have to go through the standard 510(k) process. However, after speaking initially with a couple of regulatory experts, some believed there might be a chance we would have to submit to the DeNovo pathway due to new rules concerning split predicates. We decided to engage with a regulatory consultant who was a former FDA reviewer to review our research and perform some initial research of her own to determine, in her expert opinion, if we were in fact a class II device and which pathway we should expect to submit through (typical 510k or DeNovo). We had our consultant write and sign off on a memo of her findings so that we could have an official document to present to investors as part of due diligence. Her research stated that she was confident that, with the predicates we had identified, we would be a class II device and would be able to submit our device to the FDA through the traditional 510(k) pathway. She included the predicates and reasoning for her opinions in the memo as well.

3.3.2.7.2: Reimbursement

I began this research by identifying potential CPT codes that could be used for our device. We had already identified some during our initial research stages, but I continued to

research the reimbursement codes currently used for different spinal puncture procedures in order to determine if we missed any codes. After gathering a preliminary list of potential CPT codes that could be applied to our device**,** Nicole Moskowitz (fellow) then took the lead on developing this strategy and worked closely with CPT coders to conduct more detailed research concerning a strategy for reimbursement. There are two different payment types we looked into for this strategy, namely, facility fees and provider fees, and findings for both are described below.

1. **Facility fees:** The CY 2017 hospital outpatient prospective payment system (OPPS) was used to determine facility reimbursement rates for LP, epidural, and epidural steroid injection (ESI) procedures. For the facility case, it is important to distinguish between reimbursement for surgical punctures (i.e., LPs and ESI) and administration of perioperative anesthesia.

   In the case of diagnostic and therapeutic taps or injections, we determined that facilities are reimbursed at a rate of $507 (this value is slightly higher in the case of continuous ESIs; however, considering their comparably small share of the market, these were ignored for simplification). It is important to note that this rate remains the same for procedures performed with or without imaging—that is to say, that imaging is bundled at the facility level. The perioperative anesthesia case (e.g., for orthopedics and obstetrics) is slightly more complex, since, at the facility level, these punctures are fully bundled into their respective procedures. We are still working with reimbursement experts to determine with greater accuracy the reimbursement landscape for those procedures. Since we are initially targeting the ER setting, we therefore considered procedure costs as the $507 rate.
2. **Physician fees:** It is of interest to note that while imaging is bundled into these codes at the facility level, physicians do get reimbursed for add-on imaging codes. For the LP and ESI codes, 2017 fee schedules suggest the following average non-facility and facility payment rates: $175 or $90, respectively, without image guidance; and $265 or $145, respectively, with image guidance. The imaging component, specifically, is reimbursed at a rate of ~$90 and varies depending on

whether it is claimed as an add-on code (i.e., for LPs) or as a specialized imaging code (i.e., for ESIs).

Similar physician fees are observed in the case of perioperative anesthesia administration. As an aside, there are is no flat rate for these codes; instead, reimbursement for anesthesia services is based on the multiple of a pre-assigned base fee with case-specific factors, including anesthesia time and a provider identity. Physician's fees are of interest because, if we can get our device to be included under the image-guidance code, it will incentivize physicians to use our device, as they will receive higher reimbursement.

Reimbursement is very complicated, and because there are few devices like ours on the market, it is unclear exactly what our pathway for reimbursement will look like, or whether our device will be allowed to be classified under current reimbursement codes. We decided that, after the fellowship, we would work more closely with the CPT coders to better understand how bundling affects our product and better understand the epidural reimbursement landscape. We made this a main goal moving forward with accelerators.

3.3.2.7.3: Launch Market

We had three main markets to choose from as a potential launch market (diagnostic LPs, epidurals in L&D, and ESIs in pain management). I worked to put together a list of pros and cons for each of the target markets and present them to our team. In validating our solution across potential stakeholders, we identified ER physicians as the earliest technology adopters, primarily due to the fact that their work requires a high degree of flexibility. Thus, we decided to focus the first iteration of our device on the most emergent application of spinal-needle placements, LPs, resulting in a beachhead market of ~$350M. We planned to start out at the Texas Medical Center through our close network of ER physicians at Ben Taub hospitals' acute-care and level-I trauma facilities. Once we gain traction in the ER, we plan to expand to spinal anesthesia and epidural markets, whose physicians are generally more conservative and require larger amounts of data when it

comes to adopting new technology. Along the way, we also plan to target other LP settings (e.g., neurology) with help from our clinical network.

The prospective investors we spoke with, as well as some of our advisors, brought up the pain management market and why we were not targeting that as a launch market, simply because of the size of the market. We decided that, because we identified that market later in the fellowship and had not completed much analysis on the market and the stakeholders, we did not possess a thorough enough understanding of the market to make it a launch market. It was also not a great launch market, as the majority of pain procedures are performed with higher levels of technology than our device (fluoroscopy) compared to the ER setting, where they use no technology (palpation technique). Through initial physician interviews, we felt that it would be challenging to convince pain specialists to switch to our device without a great deal of supporting data proving its accuracy. We decided that, moving forward, we would conduct market research into the pain management market and consider a co-launch in that market if, after gathering more research, we thought it might be beneficial, while still keeping ER as the initial target market.

3.3.2.8: Financial Model & Predictions

We created a detailed model in Excel to help us determine the amount of money we would need to raise in our seed round and future rounds in order to reach a point of profitability. We attended workshops held at the local startup accelerator, TMCx, taught by Silicone Valley VCs to help us develop our first version of the financial model.

1. **Determining necessary personnel and costs associated with developmental milestones:** We created spreadsheets for costs associated with the employees/consultants we would need to hire over the next three years, the expenses we expect to incur throughout development and preparing for launch, and lastly, the fixed assets we would have. On each sheet, we broke down the costs by business department (i.e., engineering, operations, sales, marketing, consultants, etc.). I then went through our timeline and expected milestones and attempted to identify how many employees we would need at each stage and when we would

need to bring them on, or engage with them if they were consultants. I also went through our expected milestones to determine what type of activities it would take to meet each milestone so that we could develop a cost estimate associated with each milestone. Once I came up with a list of types of employees/consultants I thought we would need and the activities necessary to meet our milestones, I presented them to the team and we discussed what I had come up with. We then went through the list as a team to determine when we would need to hire each person, how much we think the market salary would be for each position, which activities would be done in house and which we would hire consultants for, and how much we thought consultants would cost, and we added our estimates in to the financial model. We then met with advisors, consultants, manufacturers, and so on to develop a better understanding of what expenses to expect at each stage, and we continued to refine our estimates as we talked to more and more people and were able to get more accurate estimates for each type of activity we would complete or employee we would hire. Figure 67 is an excerpt from the "heads" sheet of our financial model, which shows estimates of the type of employees we think we need to hire, when we expect to hire them, and how much we expect to pay them.

Hiring Plan				Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9
Annual rate of Salary Increase		4%		Sep-16	Oct-16	Nov-16	Dec-16	Jan-17	Feb-17	Mar-17	Apr-17	May-17
Name	Title	Start Date	Salary									
Engineering												
To be hired	EE	1/1/17	$ 75,000	$ -	$ -	$ -	$ -	$ 6,250	$ 6,250	$ 6,250	$ 6,250	$ 6,250
To be hired	Industrial engineer	9/1/17	$ 70,000	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
To be hired	intern	1/1/17	$ 36,000	$ -	$ -	$ -	$ -	$ 3,000	$ 3,000	$ 3,000	$ 3,000	$ 3,000
total				$ -	$ -	$ -	$ -	$ 9,250	$ 9,250	$ 9,250	$ 9,250	$ 9,250
Operations												
To be hired	Production	6/1/17	$ 45,000	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
To be hired	Field Engineer	7/1/18	$ 75,000	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
To be hired	Intern											
Total				$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Sales												
To be hired	VP Sales	7/1/18	$ 130,000	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
To be hired	Head of Distribution	7/1/18	$ 90,000	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
To be hired	Customer Service Rep	7/1/18	$ 45,000	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
To be hired	Customer Service Rep	7/1/18	$ 45,000	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Total				$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Marketing												
To be hired	Business Dev Mgr	7/1/18	$ 85,000	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
To be hired	Product Manager	7/1/18		$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
To be hired	Marketing Admin	7/1/18		$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Total				$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -

Figure 67: Excerpt from "heads" sheet of financial model, estimating the cost of hiring new employees.

Figure 68 (below) is an excerpt from our expenses sheet on the financial model showing some of the estimates we made regarding engineering activities, consultants, and SG&A expenses.

EXPENSES	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
	Sep-16	Oct-16	Nov-16	Dec-16	Jan-17	Feb-17	Mar-17	Apr-17	May-17	Jun-17	Jul-17	Aug-17
Engineering												
Salaries	$ -	$ -	$ -	$ -	$ 9,250	$ 9,250	$ 9,250	$ 9,250	$ 9,250	$ 9,250	$ 9,250	$ 9,250
Fringe Benefits	$ -	$ -	$ -	$ -	$ 1,850	$ 1,850	$ 1,850	$ 1,850	$ 1,850	$ 1,850	$ 1,850	$ 1,850
Travel	$ -	$ -	$ -	$ -	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500
low volume manufacturing								$ 3,500				
Rush charges												
Other												
Reversal of Plan												
Actual												
Subtotal	$ -	$ -	$ -	$ -	$ 13,600	$ 13,600	$ 13,600	$ 17,100	$ 13,600	$ 13,600	$ 13,600	$ 13,600
Consultants												
Engineering (Design)	$ -	$ 11,000	$ 11,000	$ 11,000	$ 11,000	$ 11,000	$ 11,000	$ 11,000	$ 11,000	$ 11,000	$ 11,000	$ 11,000
Manufacturing	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 5,000	$ 5,000	$ 5,000
Regulatory	$ -	$ 5,000	$ 5,000	$ -	$ -	$ -	$ -	$ -	$ -	$ 3,000	$ 3,000	$ 3,000
Reimbursement	$ -	$ 4,000	$ 4,000	$ 4,000	$ 4,000	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Operations	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Marketing	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Other	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Subtotal	$ -	$ 20,000	$ 20,000	$ 15,000	$ 15,000	$ 11,000	$ 11,000	$ 11,000	$ 11,000	$ 19,000	$ 19,000	$ 19,000
SG&A												
Executive Team Salaries	$ -	$ 24,083	$ 24,083	$ 24,083	$ 24,083	$ 24,083	$ 24,083	$ 24,083	$ 24,083	$ 24,083	$ 24,083	$ 24,083
Fringe Benefits	$ -	$ 4,817	$ 4,817	$ 4,817	$ 4,817	$ 4,817	$ 4,817	$ 4,817	$ 4,817	$ 4,817	$ 4,817	$ 4,817
Travel	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500
legal fees	$ 25,000	$ 1,500	$ 1,500	$ 1,500	$ 1,500	$ 1,500	$ 30,000	$ 1,500	$ 1,500	$ 1,500	$ 8,000	$ 8,000
Accounting fees	$ 417	$ 417	$ 417	$ 417	$ 417	$ 417	$ 417	$ 417	$ 417	$ 417	$ 417	$ 417
Supplies	$ 100	$ 100	$ 100	$ 250	$ 250	$ 250	$ 250	$ 250	$ 250	$ 250	$ 250	$ 250
Rent	$ -	$ -	$ -	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500
Entertainment	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 500	$ 500	$ 500	$ 500

Figure 68: Excerpt from "expenses" sheet of financial model, showing estimates made for expenses related to engineering, consultants, and SG&A.

1. **Creating revenue predictions:** After refining our expected expenses and costs associated with our hiring plan, we began creating projections for yearly revenue. I worked closely with Dr. Xavier Garcia-Rojas, another medical device TMC Biodesign fellow, to gather information on similar device companies that we could use as economic proxies to help us predict potential revenues for our target launch market (ER). For example, we worked very closely with our advisor Dr. Larry Miller, who developed the EZ-IO, to learn more about how his device gained traction in the marketplace and what his revenue looked like by its third year of sales. The EZ-IO device reached approximately 1,000 hospitals by its third year of sales, capturing approximately 20% of the market. We used this data to help determine potential adoption rates for our device. However, we felt that the EZ-IO device was more successful than the average medical device in capturing market

share, so when estimating our potential adoption rates, we were more conservative. We conservatively estimated that our product could capture half of what the EZ-IO device captured by year three (10% market share, 500 hospitals) and decided to set that as our base projection for market penetration. We then created two more scenarios for market penetration: a high estimate and a low estimate. We estimated that our highest possible adoption rate by year three of sales would result in 15% market penetration, which is still more conservative than the actual adoption rate for the EZ-IO device, and that a lower than expected adoption rate would lead to 5% market penetration by year three.

We also worked with Dr. Miller and some hospital staff to help determine the number of units each hospital would need or use. We estimated that an ER would keep an average of two units on the floor, an OR would potentially have one, and inpatient floors would have an average of four units. This led us to determine that the average hospital, using the device for both diagnostic and therapeutic purposes, would purchase an average of seven units. However, we did not know at what point we would expand into markets outside of ER, so we did not incorporate information regarding adoption in those markets in our three-year revenue projection.

We then used information gathered by talking with Dr. Miller and hospital staff, as well as information gathered about the frequency of spinal puncture procedures, to estimate the number of kits an average ER would use each year. We estimated that the average ER would use approximately 220 kits/year. Therefore, with an assumed market penetration of 10% (base assumption), and only including our target market, we calculated that our revenue by year three of sales would be approximately $33M. See Figure 69 for a breakdown of the calculation for year three of sales revenue.

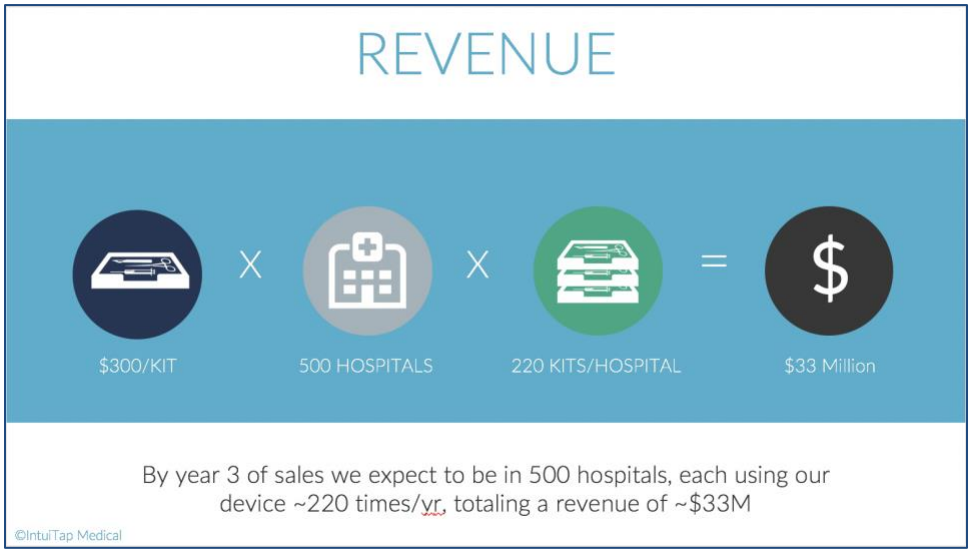
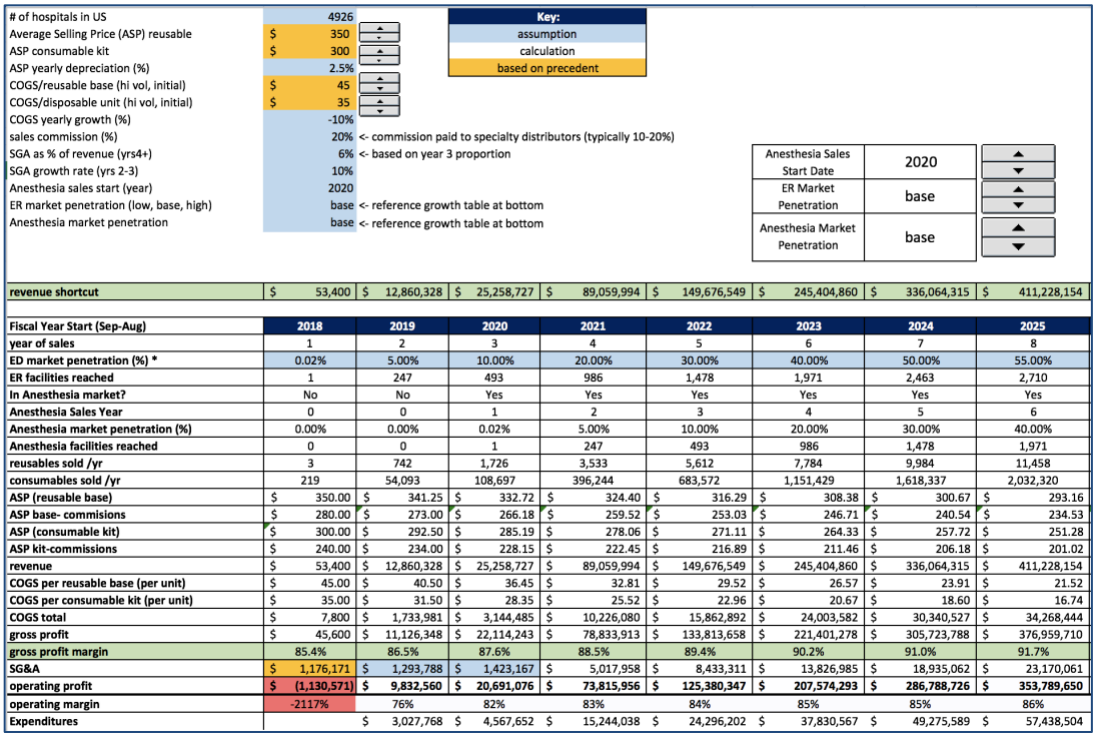


Figure 69: Revenue calculations for year three of sales for the IntuiTap device in ER market.

We also spoke with advisors and experts to determine how to model our revenue after year three of sales and how to estimate how our costs would grow as the company grew so that we would not have to build out a plan for 5–10 years of the company to the detail we did for the first two years of the company. We also built in costs associated with our business model, such as distribution cuts and costs to manufacture the product. Examples of the assumptions we made to generate future predictions for revenue can be seen in the excerpt from our "yearly revenue" sheet in Figure 70. It should be noted that the revenue in Figure 70 was calculated assuming a yearly depreciation in selling price (2.5%) of the reusable and consumable parts and after removing the commission taken by the distributor. Therefore, the revenue value is smaller than that calculated using the simple method explained in Figure 69 (above).



# of hospitals in US	4926	
Average Selling Price (ASP) reusable	$ 350	
ASP consumable kit	$ 300	
ASP yearly depreciation (%)	2.5%	
COGS/reusable base (hi vol, initial)	$ 45	
COGS/disposable unit (hi vol, initial)	$ 35	
COGS yearly growth (%)	-10%	
sales commission (%)	20%	<- commission paid to specialty distributors (typically 10-20%)
SGA as % of revenue (yrs4+)	6%	<- based on year 3 proportion
SGA growth rate (yrs 2-3)	10%	
Anesthesia sales start (year)	2020	
ER market penetration (low, base, high)	base	<- reference growth table at bottom
Anesthesia market penetration	base	<- reference growth table at bottom

Key:
assumption
calculation
based on precedent

Anesthesia Sales Start Date	2020
ER Market Penetration	base
Anesthesia Market Penetration	base

revenue shortcut	$ 53,400	$ 12,860,328	$ 25,258,727	$ 89,059,994	$ 149,676,549	$ 245,404,860	$ 336,064,315	$ 411,228,154

Fiscal Year Start (Sep-Aug)	2018	2019	2020	2021	2022	2023	2024	2025
year of sales	1	2	3	4	5	6	7	8
ED market penetration (%) *	0.02%	5.00%	10.00%	20.00%	30.00%	40.00%	50.00%	55.00%
ER facilities reached	1	247	493	986	1,478	1,971	2,463	2,710
In Anesthesia market?	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Anesthesia Sales Year	0	0	1	2	3	4	5	6
Anesthesia market penetration (%)	0.00%	0.00%	0.02%	5.00%	10.00%	20.00%	30.00%	40.00%
Anesthesia facilities reached	0	0	1	247	493	986	1,478	1,971
reusables sold /yr	3	742	1,726	3,533	5,612	7,784	9,984	11,458
consumables sold /yr	219	54,093	108,697	396,244	683,572	1,151,429	1,618,337	2,032,320
ASP (reusable base)	$ 350.00	$ 341.25	$ 332.72	$ 324.40	$ 316.29	$ 308.38	$ 300.67	$ 293.16
ASP base- commisions	$ 280.00	$ 273.00	$ 266.18	$ 259.52	$ 253.03	$ 246.71	$ 240.54	$ 234.53
ASP (consumable kit)	$ 300.00	$ 292.50	$ 285.19	$ 278.06	$ 271.11	$ 264.33	$ 257.72	$ 251.28
ASP kit-commissions	$ 240.00	$ 234.00	$ 228.15	$ 222.45	$ 216.89	$ 211.46	$ 206.18	$ 201.02
revenue	$ 53,400	$ 12,860,328	$ 25,258,727	$ 89,059,994	$ 149,676,549	$ 245,404,860	$ 336,064,315	$ 411,228,154
COGS per reusable base (per unit)	$ 45.00	$ 40.50	$ 36.45	$ 32.81	$ 29.52	$ 26.57	$ 23.91	$ 21.52
COGS per consumable kit (per unit)	$ 35.00	$ 31.50	$ 28.35	$ 25.52	$ 22.96	$ 20.67	$ 18.60	$ 16.74
COGS total	$ 7,800	$ 1,733,981	$ 3,144,485	$ 10,226,080	$ 15,862,892	$ 24,003,582	$ 30,340,527	$ 34,268,444
gross profit	$ 45,600	$ 11,126,348	$ 22,114,243	$ 78,833,913	$ 133,813,658	$ 221,401,278	$ 305,723,788	$ 376,959,710
gross profit margin	85.4%	86.5%	87.6%	88.5%	89.4%	90.2%	91.0%	91.7%
SG&A	$ 1,176,171	$ 1,293,788	$ 1,423,167	$ 5,017,958	$ 8,433,311	$ 13,826,985	$ 18,935,062	$ 23,170,061
operating profit	$ (1,130,571)	$ 9,832,560	$ 20,691,076	$ 73,815,956	$ 125,380,347	$ 207,574,293	$ 286,788,726	$ 353,789,650
operating margin	-2117%	76%	82%	83%	84%	85%	85%	86%
Expenditures		$ 3,027,768	$ 4,567,652	$ 15,244,038	$ 24,296,202	$ 37,830,567	$ 49,275,589	$ 57,438,504

Figure 70: Excerpt from "yearly revenue" sheet of the financial model.

1. **Determining how much to raise:** Once we had revenue projections and the costs associated with our hiring plan and potential expenses, we were able to determine how much money we should expect to raise in order to reach a point of profitability. We created a cash flow sheet that used the total expenses for each month and the revenue generated each month to determine how much money we would have left at the end of each month. We then used that to determine how much money we would need each year. In the early stages, before we were generating revenue, this was simply the sum of expenses. We used the cash flow sheet to determine how much money we would need each year. We decided that the milestones we sought to reach after our first round of fundraising (seed round) would be optimizing our imaging array, conducing human factors and usability testing, filing for a utility patent, and testing the device on cadavers and, potentially, animals. We decided that those milestones would be sufficient for us to raise our next round on a higher valuation without losing too much control of the company. Using our financial model, we determined that we would need to raise $1M in our seed round, that this

money would last us a little over one year, and that this would allow us to meet the previously mentioned milestones. We also used the model to estimate that we would need to raise a $4M Series A round to take us through the FDA and launch our product.

After creating a financial model and revenue projections, the pitch deck was ready for submission for business plan competitions and presentations to potential investors.

3.3.2: Investors, Accelerators, and Competitions

After creating a complete pitch deck and refining it with the help of our advisors and mentors, we were ready to submit to accelerators and business plan competitions, and to present it to potential angel investors. We applied to four startup accelerators, five business plan competitions, and two angel groups. We performed a comprehensive search of angel investment groups in the medical device space to determine which groups would potentially be interested in our device. Before the fellowship ended, we applied to the Houston Angel Network (HAN) and the Central Texas Angel Network (CTAN), and we were able to pitch to HAN (CTAN's initial pitch occurred after the fellowship ended). We applied to four accelerator programs: TMCx medical device startup accelerator, Medtech Innovator, Insight Accelerator Labs, and Highway1. We were accepted into every accelerator we applied to. Lastly, we applied to five business plan competitions: the Innovation Showcase, the SoGal ventures challenge, 43 North, the James Dyson design competition, and Tech.Co startup of the year. We noticed that having students on a team significantly increases the number of business plan competitions that a team can apply for, as many competitions are geared towards students. After the fellowship, we plan to continue applying for business plan competitions and applying for grants to supplement our fundraising efforts with non-dilutive funding.

CHAPTER 4: DISCUSSION

Considering the difficulty of true innovation and the complexity of the healthcare system, the medical industry could benefit greatly from a structured framework to guide the development and innovation process, such as the one presented in this thesis. Utilization of the methodology presented here could significantly reduce the amount of product failures in the medical industry and increase the ability to launch new and innovative products more quickly and effectively, and with greater success. It could also reduce costs associated with the development process and the time required to get a product to market. The framework presented in this thesis can significantly mitigate the numerous risks involved in innovation and product development in the medical industry, and it can also better prepare innovators to develop a successful company, as evidenced by the results presented.

The fellowship was successfully launched for the first time in September of 2015 with two teams of fellows, one medical device and one digital health. This thesis focuses on the framework and fellowship as it is applied to the medical device industry, in addition to the results of the first medical device team, of which I was a part. The fellowship is currently in its third year and has graduated two classes of fellows (the third class is currently in the fellowship). From this, two medical device companies have been successfully started (i.e., the fellowship has enabled a medical device team to successful create a product and company each year it has been running).

It was extremely beneficial to have been afforded the opportunity to participate in the fellowship after being a part of the team that developed the fellowship and framework. It offered a great deal of insight that could only be gained through participation within it. It was also helpful for the growth and development of the fellowship to have me participate during the inaugural year. Getting a program off the ground can be difficult, and it allowed for more open communication between the fellowship directors and the fellows about what was and was not working.

I learned a great deal about the comprehensiveness of the fellowship and what about it enabled success by participating in it and implementing the framework we developed.

Through this process, I was able to identify a number of key factors for enabling success in the program. The most important factors were identifying a real need, having access to a wide variety of mentors and stakeholders, having a truly cross-functional team, and lastly, having a team member or fellowship director that can ensure the fellows follow the framework.

4.1: Identifying the need

After participating in the fellowship, it is very clear that the most critical part of the program is the needs finding and validation stage. As discussed in the introduction, this step is often overlooked or rushed, and that significantly contributes to the failure of medical products. A great deal of our success in the fellowship can be attributed to the fact that we closely followed the guidelines for needs finding and validation and were able to identify a real need that stakeholders wanted to be solved. By spending a great deal of our time at the beginning of the fellowship in clinical immersion, we were able to truly understand the needs we identified, as well as how they affected the procedure or setting they were related to.

Needs identification and observation is a skill, and like any other skill, it gets easier the more frequently it is performed. Having three months set aside specifically for rotations significantly contributed to our success and allowed us to identify concrete needs. Only spending a week, or even a month, in clinical rotations results in feeling rushed and pressured to identify needs quickly, which often leads to identifying general or incremental needs. We experienced this feeling and saw these results in the needs we identified in our first few weeks of rotations. While there were a few early needs that made it through to later stages of screening, the majority of our top needs were identified after a significant amount of time was spent in clinical rotations. It was clear that the more time we spent in rotations, the better we became at understanding the needs, how they related to the procedures, the issues they caused, and whether or not they were being addressed or needed to be addressed.

4.2: Mentors and stakeholders

Another critical component for enabling success in the fellowship was our unprecedented access to mentors and a variety of stakeholders. This factor is very closely related to successfully implementing the needs identification stage. Without access to dedicated mentors and a number of different stakeholders, we would not have been able to gain the deep understanding of the problems we identified, which was necessary for developing a solution that successfully addressed the need. We also would not have been able to understand, especially with such depth, the complexities of each stakeholder involved with the need and how a solution affected each stakeholder differently. Having access to a variety of stakeholders throughout the fellowship was extremely beneficial from identifying an important need to developing a solution that successfully met the need and identifying the value that the solution could bring to each of the different stakeholders.

Additionally, without consistent interaction with clinical and business mentors, in addition to our deep understanding of the need, we would not have been able to efficiently generate concepts and iterate on our device. Our ability to frequently interact with key stakeholders during the different stages of the innovation process enabled us to gather feedback often and iterate quickly to develop a successful product more efficiently.

4.3: Program director

It is very important to have someone involved in the fellowship who is very familiar with the framework and can ensure that the fellows stick to the process. Because I helped develop the framework and possessed a clear understanding of the process and why it is important, I was able to act as this person on the team. However, we also had two fellowship directors who helped us stay on track. For other programs looking to implement this framework in their area, it is important to have a fellowship director or lead mentor. This person needs to understand the framework and be able to enforce the process during the fellowship. They are responsible for determining the milestones and timeline and keeping the fellows accountable for their deliverables. While they should engage with the fellows frequently, they also need to be able to guide the teams without actively working on the project. This person can be thought of as a high-level project manager.

This role is very important, because at times, it can be very challenging to follow the methods outlined in the framework. My team struggled often with the notion of constant feedback and failing fast. It is normal to be adverse towards failure and rejection or looking stupid, and therefore to want to think through an idea in more detail, or to develop a prettier or better prototype before presenting to a group of experts. Even though we all understood the importance of gathering feedback frequently at all stages of development, and in fact had seen the benefits of doing so, we were still often hesitant to gather feedback out of fear that someone would have negative things to say. It is tempting to ignore negative feedback, but in our experience, that feedback will typically come back over and over again, and it is better to address it early rather than push it off in the hopes that it will eventually go away or that other parts of the product will make up for it. Negative feedback or issues with the device do not simply go away, and by delaying the gathering of feedback or the addressing of the issue, this only results in the team having to deal with it in a later stage when it is a bigger deal. Having someone outside of the team, such as a program manager or director, to push the team to stick to the process, like gathering feedback consistently and often, for example, is crucial to enabling success in the fellowship.

One of the main reasons this framework works is because of the constant interaction and feedback being received by key stakeholders. Without that feedback, understanding, and interaction, this program would not be successful. So, it is important to make sure that the fellows are asking the tough questions and listening to the feedback, taking it seriously, and using it in their evaluation of needs and concepts.

4.4: Team composition

I also found that it is very important to have a truly cross-functional team. The goal of this fellowship, and the framework implemented within it, is to teach all of the stages of innovation, from idea to commercialization, in such a way that every type of person involved in the process (engineers, clinicians, business-minded people, etc.) possesses an understanding of what it takes to successfully innovate.

It may seem inefficient at times during the fellowship to have only one or two experts for each stage participating in the entire fellowship rather than segmenting each

stage and building teams of experts for each part of the process, but that is what enables this program to be so successful at teaching the innovation process and creating innovators that can successfully evaluate an idea. Having a truly cross-functional team participate in this fellowship enables the team to grow together, learn together, and gain a deep understanding of the process extremely quickly.

By having one person that knew enough about the process at each stage, our team was able to execute and move through the different stages extremely efficiently. The person familiar with the stage of development would lead the rest of the team through the activities. They had enough knowledge to develop a plan for the stage and answer general questions while still requiring the rest of the team to participate in the activities. For example, during the concept generation stage, I led brainstorming sessions and helped the non-engineers on the team to learn about different brainstorming activities, low-fidelity prototyping, and competitive analyses. In most settings, the engineers would do this stage by themselves and the clinicians and business people would rarely interact. The way the fellowship was structured required the fellows with non-engineering backgrounds to participate in this stage, giving them hands-on experience with design and allowing them to develop an understanding of the design process very efficiently.

By guiding the team through the stage, the experts were also able to gain valuable insights and a deeper understanding of the process for themselves. For example, although I had conducted a number of competitive analyses for projects in undergraduate and graduate school, having to apply those skills to a real-world application, on a product we were creating, to solve a need we had spent months validating and that we planned to actually commercialize, required significantly more detail, and a different perspective, than projects I had performed these analyses for in the past. This furthered my understanding and knowledge of the process and skills required.

By having different members of the team take on leadership positions and guide the team through the different stages of the process while also allowing all team members to participate in every stage of the process, the fellows were enabled to learn incredibly quickly and gain insights into each stage of the development process. This is what makes this fellowship and framework so incredible, and this is what allows it to be successful.

4.5: IntuiTap now

After the fellowship ended, the inaugural team went on to create a company, IntuiTap Medical. IntuiTap Medical has now gone on to win five business plan competitions and has been a finalist in numerous others. It has also raised $2.4M of angel investments and participated in seven startup accelerators. The company has hired two additional employees, conducted IRB-approved studies and cadaver studies, and has built multiple versions of their prototype, approaching a design freeze. IntuiTap has applied for one utility patent for the design of their device and has additional provisional patents filed. The device is on track to be FDA cleared by 2019.

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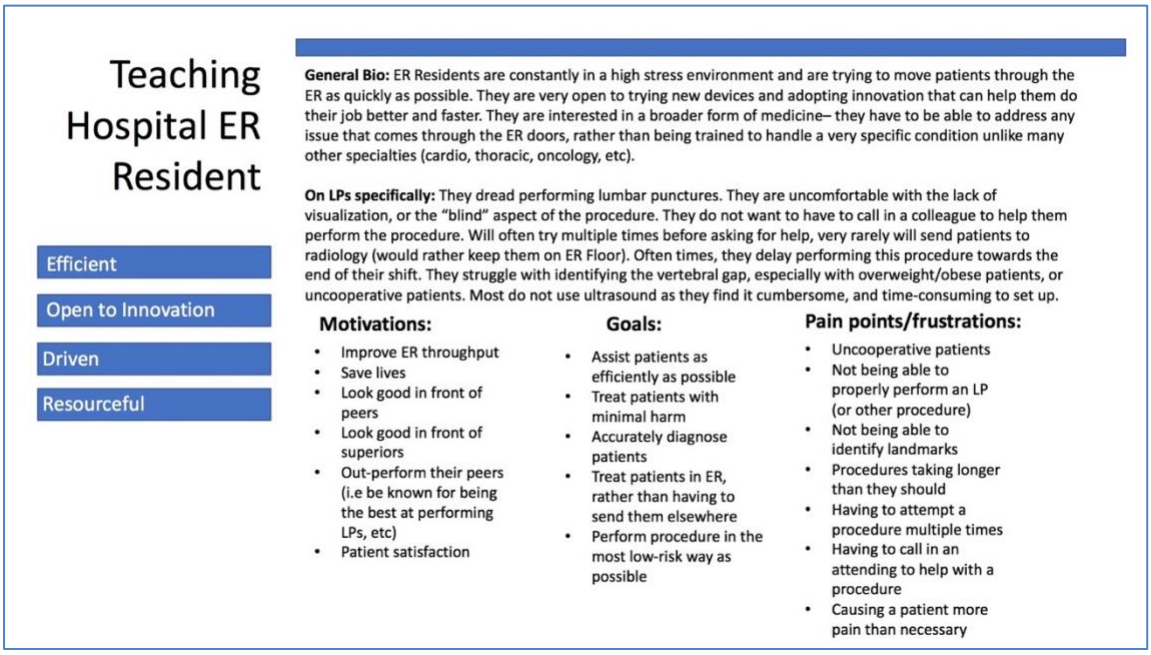
APPENDIX A: BREAKDOWN OF OBSERVATIONS PERFORMED

				Observer Location								Location Key	
Date	Procedure	Site	Attending	YG	XGR	NCM	JT	Hrs	#ppl			Not Present	-
9/11/2015	Quadruple Bypass (CABG)	THI	Dr. Billy Cohn					3	4	CVOR	12	Present	General
9/16/2015	Patient Flow Observation	THI	N/A					1	4	ICU	4		Observation Dome
9/17/2015	Aortic Aneurysm Repair (AATA)	THI	Dr. Joseph Coselli					1.5	4	CVOR	6		OR Floor
9/17/2015	Pacemaker Implantation	THI	Dr. Steve Singh					1.5	4	CVOR	6		
9/21/2015	LVAD	THI	Dr. Steve Singh					5	4	CVOR	20		
9/22/2015	LVAD (Cow Experiment)	THI	Dr. Billy Cohn					1.5	2	Animal	3		
10/2/2015	Core B / Critical Care	Ben Taub	Dr. Rohra					8	1	ER	8		
105/2015	ICU / Critical Care	SLEH	Dr. Pat Herlihy					3	2	ICU	6		
10/5/2015	Aortic Valve Replacement	THI	Dr. Billy Cohn/Dr. Jess Joymon					6	3	CVOR	18		
10/6/2015	CABG	THI	Dr. Billy Cohn					6	1	CVOR	6		
10/8/2015	CABG	THI	Dr. Steve Singh					2	4	CVOR	8		
10/8/2015	Ablation for Afib	THI- Cath	Dr. Mehdi Razavi					2.5	2	Cath lab	5		
10/8/2015	Ablation for PVC	THI- Cath	Dr. Mehdi Razavi					2.5	3	Cath lab	7.5		
10/10/2015	Ambulance Shadowing	M97	HCEC					8	1	Amb	8		
10/13/2015	Ambulance Shadowing	M91, M93	HCEC					8	2	Amb	16		
10/14/2015	Ambulance Shadowing	M95	HCEC					8	1	Amb	8		
10/14/2015	ER	Ben Taub	Farzad/Dark					6	1	ER	6		
10/15/2015	Ambulance Shadowing	M91	HCEC					10	1	Amb	10		
10/22/2015	Ambulance Shadowing	M91	HCEC					12	1	Amb	12		
11/9/2015	Ambulance Shadowing	M91	HCEC					12	1	Amb	12		
	ICU	THI	Dr. Pizlak					3.5	1	ICU	3.5		
	ICU	THI	Dr. Meyers/Pisklak					3.5	1	ICU	3.5		
10/26/2015	Animal Lab (Obesity)	THI	Dr. Cohn/Delgado					3	2	Animal	6		
	Animal Lab (HF)	THI	Dr. Cohn/Sunshine Heart					2	2	Animal	4		
	Animal Lab (plates)	THI	Dr. Cohn					6	3	Animal	18		
10/24/2015	ER	Ben Taub	Farzad					8	1	ER	8		
10/21/2015	Critical Care	Ben Taub	Anderson					8	1	ER	8		
11/7/2015	TAVR	P&P Conference/ Live Case	N/A					1.5	2	CVOR	3	Total:	
10/14/2015	Live Cases	TCT/Live case	N/A					10	1	Live	10	245.5	

APPENDIX B: EXAMPLE OF USER PROFLIE



APPENDIX C: EXAMPLE OF NEED SPECIFICATION DOCUMENT

The Need

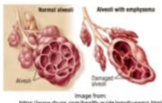
A way to restore pulmonary function to lungs affected by COPD that improves clinical outcomes and patients' quality of life.

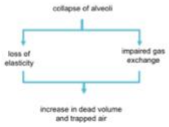
The Problem

- COPD affects over 14 million people in the United States and is the 3rd leading cause of death.
- The rate of COPD continues to increase worldwide due to worsening air pollution
- COPD is an important cause of hospitalization in our aging populations
- The symptoms of COPD cannot be eliminated with treatment and the condition worsens over time.

Disease State

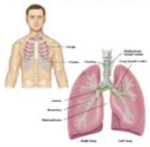
- COPD Risk Factors:
  - smoking, pollution fumes
  - Genetic (alpha-1 antitrypsin deficiency
- Exposure causes irreversible airway narrowing and alveolar collapse
  - loss of elasticity
  - poor gas exchange
- Air trapped in lung
  - breathlessness
  - inability to perform everyday functions

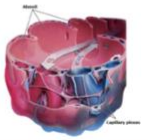




Disease State

- Emphysema, one form of COPD, causes air to become trapped inside of the lungs, causing them to over-inflate
- Patients with emphysema have difficulty expelling the air, causing shortness of breath
- This lung damage makes it harder for oxygen and carbon dioxide to pass across the walls of the air sacs
- Emphysema is chronic, and causes irreversible damage to lung tissue





Disease State

- COPD results in hyperinflation of the lungs
  - Static hyperinflation
    - Destruction of elastic tissue alters lung recoil so that at a given lung volume lesser recoil pressure is produced when compared to a healthy lung
    - Shift in lung recoil and its pressure volume alters the balance between the opposing recoil pressures of the chest wall and lung, requiring greater lung volume in order to balance the chest wall recoil.
  - Dynamic hyperinflation
    - Patients commence inhalation before exhalation has been achieved
    - Air is trapped within the lungs with each successive breath, causing a shift in the equilibrium point between the chest wall and lung recoil

Treatment

- There is no cure for COPD
- Current treatment options attempt to control symptoms and can sometimes slow the progression of the disease
- Treatment options span from daily medications to lung transplant surgery
- There is still a large need for a device that can successfully restore lung function to patients with COPD

Treatment

Treatment Category	Treatment Options	Benefits	Risks
Pharmacologic Therapy	Bronchodilators Long acting & Short acting	• Help keep airways open and possibly decrease secretions • Reduces frequency and severity of exacerbations • Improve exercise tolerance • Non-invasive • Improves hyperinflation • Improves airflow (FEV1) and symptoms during acute exacerbations (short term).	• Stop working overtime • Have to take daily (sometimes up to 3 different medications) • Increase risk of heart attack or stroke • Does not slow the progression of COPD • Some have high toxicity • Can be very costly (from $100-$300+/mo) • Does not effect mortality • Does not increase FEV1 long term
	Corticosteroids	• Reduces frequency of exacerbations (little impact) for patients with severe COPD • Decreases hospitalization rates • Non-invasive • Shorten recovery time, improve FEV1 and hypoxemia (systemic corticosteroids, not inhaled corticosteroids)	• Mainly used for short term treatment—long term can have adverse side effects • Does not slow progression of COPD • Costly ($200-$300/month) • Must be used in combination with other drugs • Reduced bone mineral density • Candidiasis and dysphonia • Increased risk of Pneumonia • Offers little advantage in terms of exacerbations • Does not improve mortality

Treatment

Treatment Category	Treatment Options	Benefits	Risks
Supplemental Therapy	Oxygen Therapy	• Improves survival in COPD patients with severe hypoxemia • May improve general alertness and psychological state in some patients • Only pharmacologic therapy that has been shown to improve mortality • Non-invasive	• Does not improve survival in patients with moderate hypoxemia or desaturation at night • Must be used for >15 hrs/day to be beneficial for patients with severe COPD • Quality of life
	Pulmonary Rehabilitation	• Can ease symptoms of breathlessness • Has been shown to improve a persons ability to exercise, enhance quality of life, and decrease frequency of exacerbations	• Must be done in addition to other therapies- not a standalone treatment
Surgery	Lung Transplant	• If successful it improves symptoms	• Has not yet been shown to prolong life • Only considered in cases of severe COPD • Extremely invasive surgery

Treatment

Treatment Category	Treatment Options	Benefits	Risks
Surgery	Lung Volume Reduction Surgery (LVRS)	• Reduces size mismatching between the hyperinflated lungs and the chest cavity, restoring the pull on the bronchioles (i.e increasing elastic recoil) and improving expiratory airflow • Greater ability for the lungs to inflate and deflate properly, improving breathing • Reduced need to rely on portable oxygen tanks • Provides room for the diaphragm and chest wall to return closer to their normal positions • Improvement in quality of life	• Complications such as pneumonia, infection and air leaks within the chest cavity • Air leaks from the lung tissue coming from the suture line into the chest cavity (40% have air leaks and require a chest tube to manage this) • Very expensive • Requires highly qualified/experienced surgeons • No guarantee surgery will work • Causes substantial morbidity • Irreversible procedure • Requires removing lung tissue • Strict requirements on what patients are candidates • Invasive procedure (sternotomy or thoraoscopy)

Emerging Technology

Technology	Description	Benefits	Risks
VALR System	• Uses biocompatible elastomeric silicone sleeve that is mechanically expanded and placed onto the lung surface to produce radial compression of the targeted lung tissue	• Potential reduction or elimination of air leak and reversibility after the initial application of the elastomer device • Could be relatively straightforward to apply, rapid and incremental administration might be possible.	• Potential for chronic tissue reactions, infarction, or infection in the areas of compressed lung tissue • Stability of the site, long term effects and delayed air leaks • Compression may not be adequate to prevent leaks • Suture fixation and manual cutting are still required • Thoracoscopic approach may be complicated to develop due to size constraints • Foreign body presence and retained necrotic tissue within the chest have unknown consequences.
Endobronchial airway sealants	• Injection of fibrin glue leading to regional collapse and bronchoscopic volume reductions	• Nonsurgical/ minimally invasive • Incremental application possible with ability to perform repeated procedures • Air leaks may be reduced/ eliminated • Cost reduction could be large • Potential to be performed on an outpatient basis	• Risk of postobstructive infection • It must ensure that the occluded regions will collapse despite collateral ventilation and will not spontaneously reopen over time, which is not guaranteed • Potential for ventilation perfusion mismatch and hypoxemia if lung regions with persistent pulmonary blood flow are obstructed • Development of sterile abscesses • Unclear whether the anatomic distribution effects and physiologic response of segmental volume reduction will provide similar results to current lung tissue reduction approaches

Emerging Technology

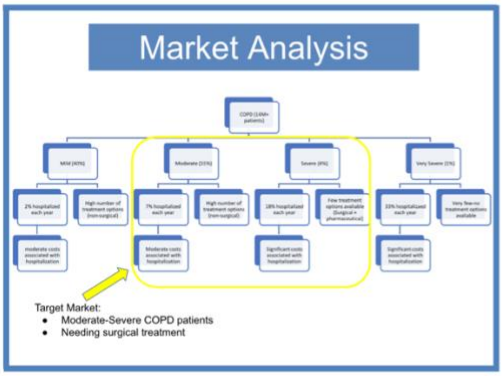
Technology	Description	Benefits	Risks
Endobronchial Blockers	• Plug that obstructs target airways, leading to distal collapse and bronchoscopic volume reduction	• Possibility of removing devices either immediately after deployment or after a delayed period of time • Nonsurgical/minimally invasive procedures could be used • Minimizes the number of usable airways	• Irreversible • Can cause upper lobe collapse • Presence of a foreign body • Risk of postobstructive pneumonia • Potential for device displacement, migration or even erosion into regional tissue • Concerns for bleeding • Does not allow for mucus clearance • With mechanical obstruction there is a risk that collateral airflow may supply the regions distal to the obstruction to the extent that distal collapse will be ineffective
Endobronchial Valves	• One way valve designed so that air can flow through the valve and out of the lung when a patient exhales, but does not allow to enter the lung compartment • Allows for clearance of mucus	• Removability and design of valves has significant advantages compared to plugs and reduce the risks associated with postobstructive pneumonia	• Issues regarding valve size and number of valves required to produce effective volume reduction • Issues regarding access to the different segments and sub-segments of the lung • Safety, effectiveness, overcoming collateral ventilation, and ease of use still requires extensive clinical investigation

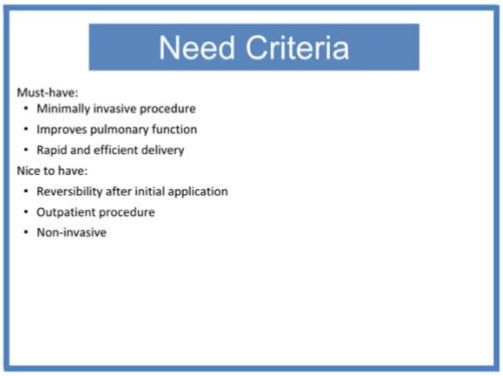
Emerging Technology

Technology	Description	Benefits	Risks
Coil Surgeries	• Metal coils are placed into the damaged tissue of the patients lung to restore elasticity to the diseased tissue	• Substantial improvements in lung function • Minimally invasive procedure • Compress damaged tissue and restore elasticity in healthier tissue s	• Does not stop the progression of emphysema • Risk of pneumothorax • Multiple have to be placed, and are placed somewhat randomly • pneumonia
Bronchial Fenestration and Airway Bypass	• Bypass the high resistance collapsing airway segments using bronchial stents to create new conducting expiratory airways	• Increased expiratory airflow and reduced expiratory resistance • Can be performed bronchoscopically with potential to reduce morbidity compared to open procedures	• There are risks of bleeding because the bronchial blood vessels run adjacent to the airways • Questions remain regarding to the ability to entrain large enough regions of trapped air for clinical benefit • Foreign body reactions and fibrosis could limit the duration and effectiveness of the bronchial fenestration method

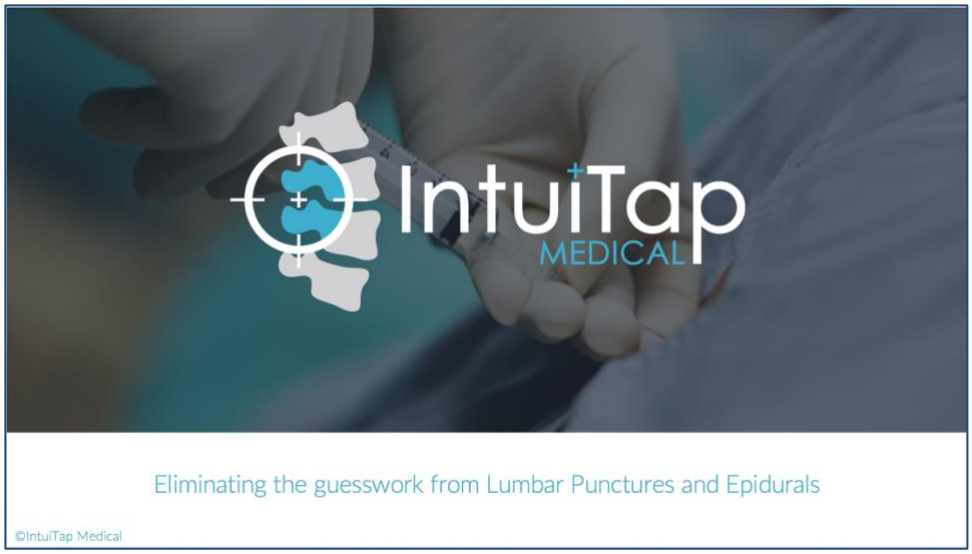

Stakeholders
Low interest, high influencing
Payers/health insurance
High interest, high influencing power
Thoracic surgeons
Pulmonologists
Severe emphysema patients
low interest, low influencing power
Employers
High interest, low influencing power
Family members/ caregivers
Power and Influence
Interest and commitment

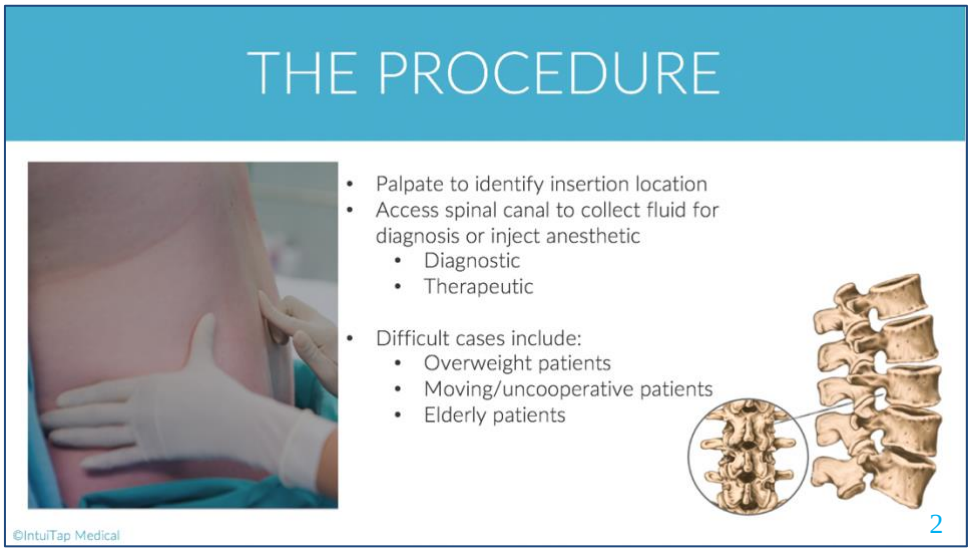
Market Analysis
According to the ALA, COPD cost the United States $49.9 Billion in 2010
49.9 Billion
29.5 Billion
12.4 Billion
8.0 Billion
Direct healthcare costs
Indirect mortality costs
Indirect morbidity costs
It is expected that by 2020 the cost of medical care for adults with COPD will be more than $90 billion

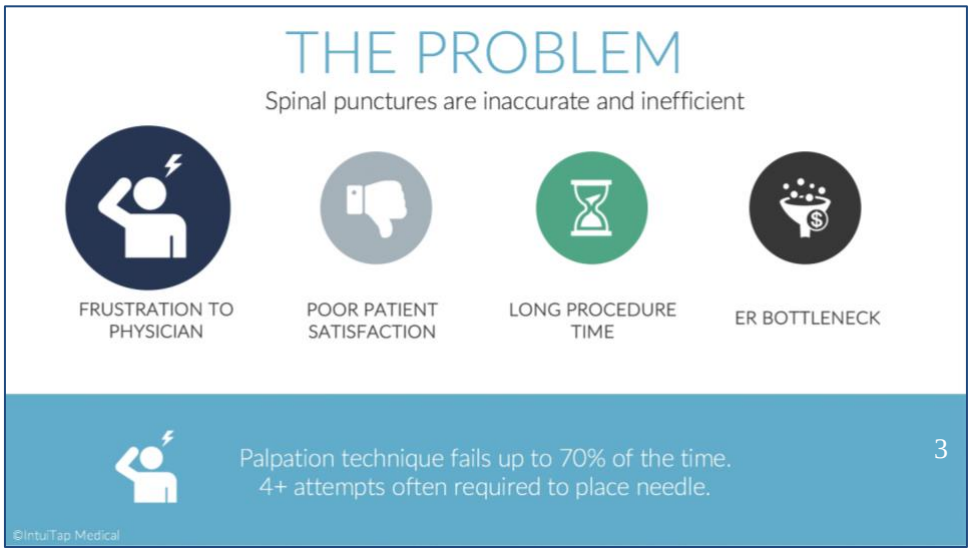

Market Analysis
Target Market:
Moderate-Severe COPD patients
Needing surgical treatment

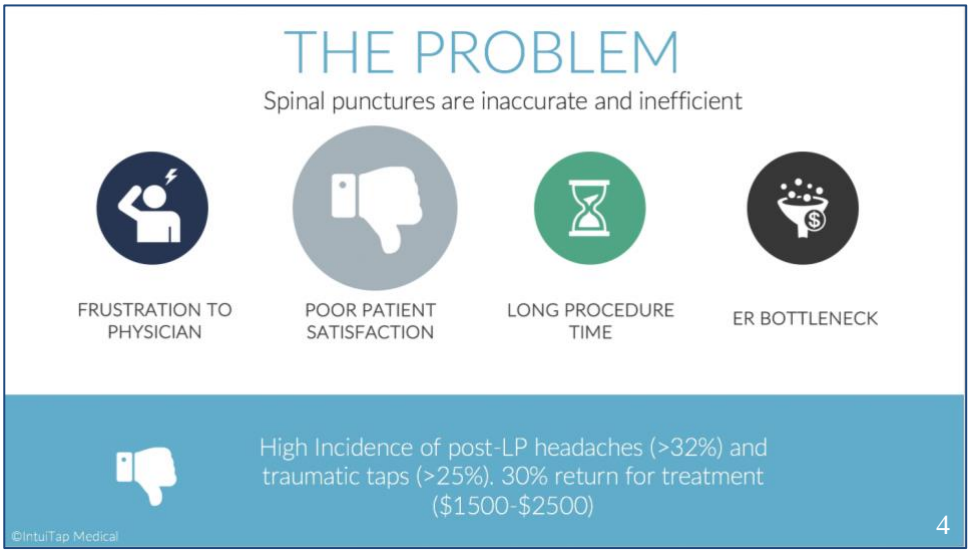

Need Criteria
Must-have:
Minimally invasive procedure
Improves pulmonary function
Rapid and efficient delivery
Nice to have:
Reversibility after initial application
Outpatient procedure
Non-invasive

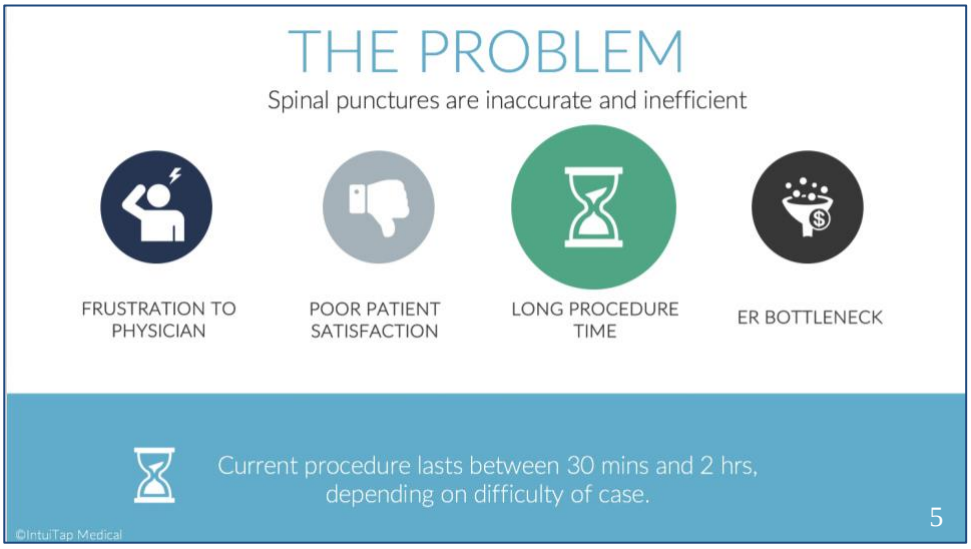
APPENDIX D: INTUITAP MEDICAL SLIDE DECK

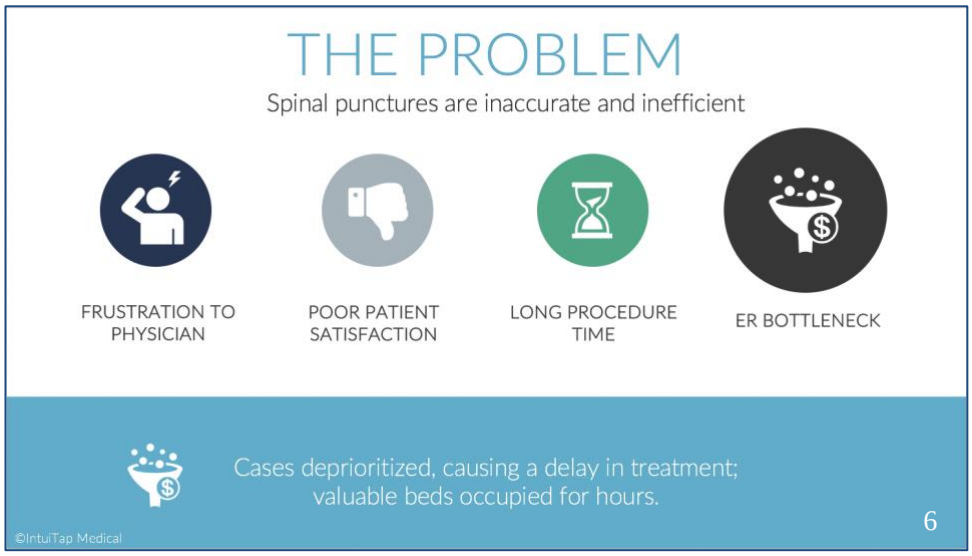


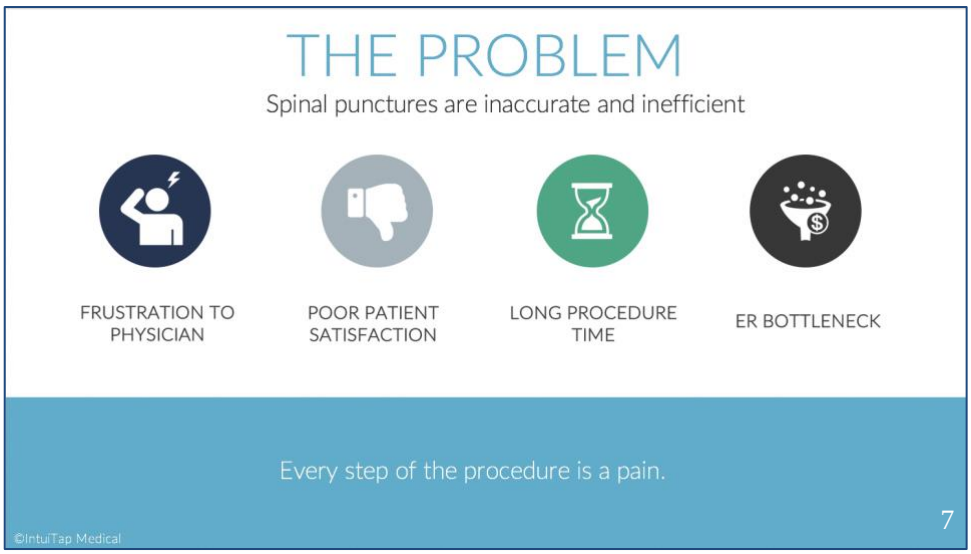


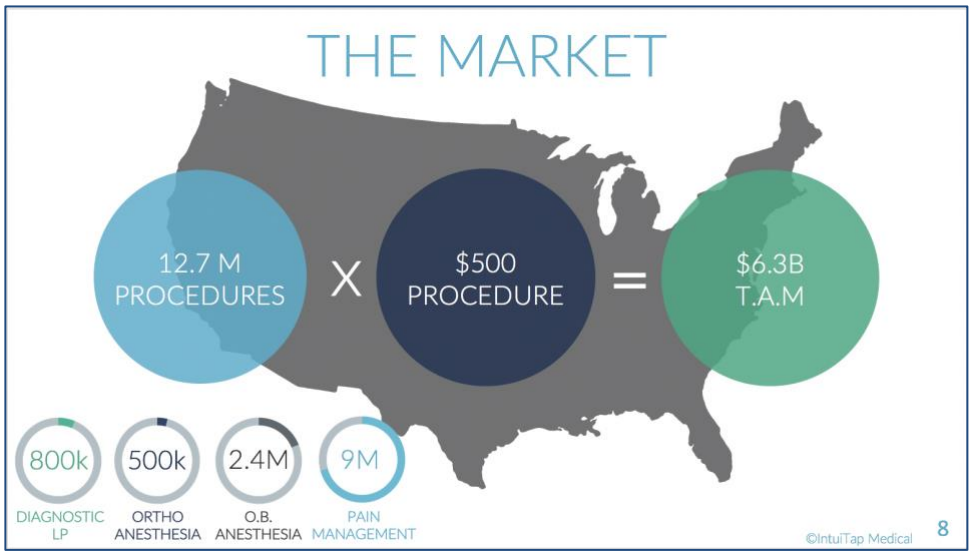

THE PROBLEM
Spinal punctures are inaccurate and inefficient
FRUSTRATION TO PHYSICIAN
POOR PATIENT SATISFACTION
LONG PROCEDURE TIME
ER BOTTLENECK
Palpation technique fails up to 70% of the time.
4+ attempts often required to place needle.
3
©IntuiTap Medical


THE PROBLEM
Spinal punctures are inaccurate and inefficient
FRUSTRATION TO PHYSICIAN
POOR PATIENT SATISFACTION
LONG PROCEDURE TIME
ER BOTTLENECK
High Incidence of post-LP headaches (>32%) and traumatic taps (>25%). 30% return for treatment ($1500-$2500)
4
©IntuiTap Medical


THE PROBLEM
Spinal punctures are inaccurate and inefficient
FRUSTRATION TO PHYSICIAN
POOR PATIENT SATISFACTION
LONG PROCEDURE TIME
ER BOTTLENECK
Current procedure lasts between 30 mins and 2 hrs, depending on difficulty of case.
5
©IntuiTap Medical


THE PROBLEM
Spinal punctures are inaccurate and inefficient
FRUSTRATION TO PHYSICIAN
POOR PATIENT SATISFACTION
LONG PROCEDURE TIME
ER BOTTLENECK
Cases deprioritized, causing a delay in treatment; valuable beds occupied for hours.
©IntuiTap Medical
6


THE PROBLEM
Spinal punctures are inaccurate and inefficient
FRUSTRATION TO PHYSICIAN
POOR PATIENT SATISFACTION
LONG PROCEDURE TIME
ER BOTTLENECK
Every step of the procedure is a pain.
©IntuiTap Medical
7


THE MARKET
12.7 M PROCEDURES
X
$500 PROCEDURE
=
$6.3B T.A.M
800k
DIAGNOSTIC LP
500k
ORTHO ANESTHESIA
2.4M
O.B. ANESTHESIA
9M
PAIN MANAGEMENT
©IntuiTap Medical
8

COMPETITION

	LP KIT	ULTRASOUND	L.O.R SYRINGES	ACCURO	INTUITAP
Reduced procedure time	X	X	X	✓	✓
Fewer attempts	X	X	X	✓	✓
Needle-guidance	X	X	X	X	✓
Enhanced pressure measurement	X	X	X	X	✓
Improved fluid collection	X	X	X	X	✓

OUR SOLUTION

- **TACTILE SENSING** — Accurate detection of vertebrae
- **NEEDLE GUIDANCE** — Reliable needle insertion
- **DIGITAL PRESSURE MEASUREMENT** — Digital display for improved accuracy
- **FLUID COLLECTION** — Sequential filling reduces biohazard

OUR VALUE

- LESS FRUSTRATION TO PHYSICIAN
- IMPROVED PATIENT SATISFACTION
- REDUCED PROCEDURE TIME
- INCREASE ER THROUGHPUT

Improved accuracy = reduction in pain, complications, and readmissions.
Standardizing procedure time to <30 mins saves hospitals ~$600/case

BUSINESS MODEL

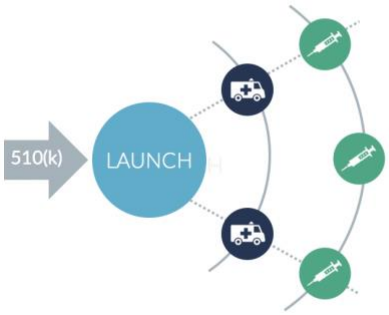
IntuiTap follows a razor/razorblade model such that the majority of revenue stems from our disposable components.

Reusables:
- Handheld device
- Display
- Microcontroller
- Sold for **$350**

Disposables:
- Tactile-sensing array
- Fluid-pressure sensor
- Fluid-collection system
- Sold as sterile kit for **$300**

Sales strategy:
- Partner with specialty distributors
- Added support from in-house clinical specialists

GO-TO-MARKET



REGULATORY
- Class II device
- Traditional 510(k) pathway
- Anticipated oversight by spine-devices branch

INITIAL LAUNCH
- Initial traction from physicians in the ER
- ER physicians tend to be early adopters
- Potential additional launch in large pain space

EXPANSION
- Grow existing markets (add sites, users)
- Establish KOLs across anesthesiology practices
- Target additional settings using initial data

REVENUE

$300/KIT | 500 HOSPITALS | 220 KITS/HOSPITAL | $33 Million

By year 3 of sales we expect to be in 500 hospitals, each using our device ~220 times/yr, totaling a revenue of ~$33M

TIMELINE

Q3'15 | Q3'16 | Q3'17 | Q1'19

TMC Biodesign ($500k)

- ✔ 250+ hrs of clinical validation
- ✔ 20+ stakeholder interviews
- ✔ Generated 220+ concepts
- ✔ Built & tested prototype
- ✔ Filed provisional patent
- ✔ Completed tactile-sensing study in humans

Seed Round ($1M)

- Animal/cadaver studies
- Hire EE & industrial designer
- Optimize imaging/guidance platform
- Form/Usability testing & validation
- Study of tactile sensing in L.P patients
- File for Utility Patent

Series A ($4M)

- Low volume manufacturing
- Integrated device animal/cadaver studies
- Small single-center efficacy study
- Safety testing
- 510(k) Submission
- E.R Launch
- Market expansion activities

THE TEAM

JESSICA TRAVER, CEO
Mechanical engineer with a range of experience in product design and development

NICOLE MOSKOWITZ, CTO
Biomedical engineer with extensive experience in hardware and software development of medical devices

XAVIER GARCIA-ROJAS, CMO
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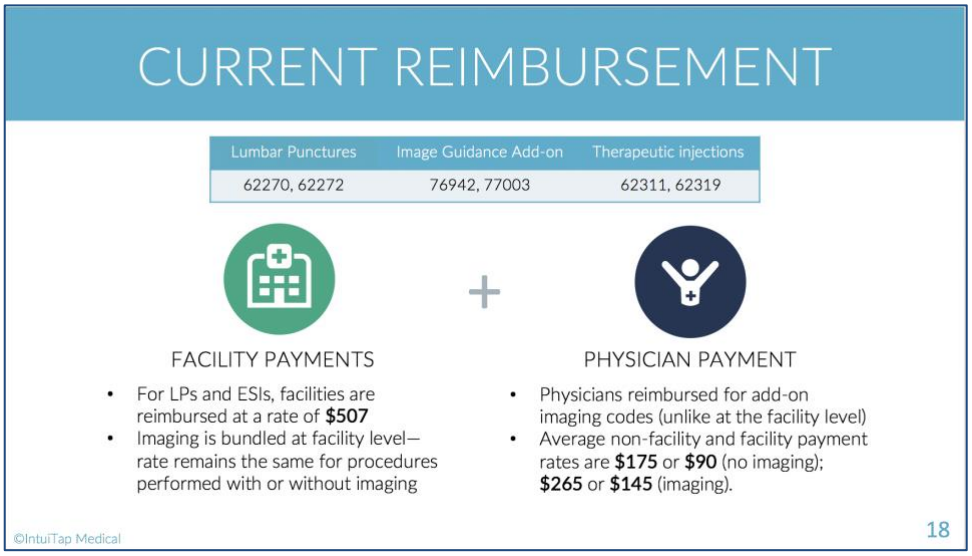
CURRENT REIMBURSEMENT
Lumbar Punctures
Image Guidance Add-on
Therapeutic injections
62270, 62272
76942, 77003
62311, 62319
+
FACILITY PAYMENTS
For LPs and ESIs, facilities are reimbursed at a rate of $507
Imaging is bundled at facility level—rate remains the same for procedures performed with or without imaging
PHYSICIAN PAYMENT
Physicians reimbursed for add-on imaging codes (unlike at the facility level)
Average non-facility and facility payment rates are $175 or $90 (no imaging); $265 or $145 (imaging).
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APPENDIX E: RESULTS FROM IRB STUDY

OVERVIEW

Our initial study was designed to explore the feasibility of a new technology aimed at improving spinal-needle placements (i.e. for lumbar punctures, spinal anesthesia, and epidurals). The current method used for identifying an entry site for proper needle insertion into the spinal canal is very difficult and inaccurate, particularly in patients with high BMI. Physicians must palpate the lower back and estimate the location of the vertebral gap. This often requires multiple needle insertion attempts and results in physician frustration, patient pain, and ER bottleneck.

Our non-invasive, tactile-imaging solution consists of a sensor array, which senses underlying bony landmarks when placed against the patient's lower back. This information is presented to physicians as a real-time pressure map, allowing them to better identify an entry site.

Having tested our system on spine models, we were hoping to evaluate its feasibility (particularly, as a function of BMI) on human subjects. In doing so, we recruited healthy subjects, over the age of 18, to undergo three common, non-invasive clinical techniques for spinous process localization (manual palpation, tactile imaging, and ultrasound).

A ruled tegaderm dressing was used to allow investigators to identify coordinates for each determined entry site. For each technique, investigators found one gap while being timed, and then went on to find as many other gaps in the lumbar region as possible.

First, we compared the entry sites identified by a physician using palpation to those identified by a co-investigator using tactile sensing. We then used ultrasound as the gold standard, to verify the entry site identified by tactile imaging, and provide true data on underlying landmarks and anatomic measurements (e.g. depth and midline location).

Additionally, we collected basic subject demographics to provide additional data-points to correlate with study outcomes (e.g. how technique accuracy compares with BMI or weight status).

Finally, a feedback questionnaire related to the comfort and speed of each technique was administered to obtain qualitative information on potential patient outcomes related to the localization component of our device.

RESULTS

Subject demographics

6 males and 9 females took part in this study. The average age was 27, with an average BMI of 24. Figure 1a breaks down subject age and BMI by gender; 1b depicts the breakdown of weight status among subjects. It should be noted that we did not specify BMI as an in/exclusion criterion for this study; rather, we anticipated enrolling a range of BMIs, such that we could better extrapolate the results to outcomes for our target, higher-BMI population.

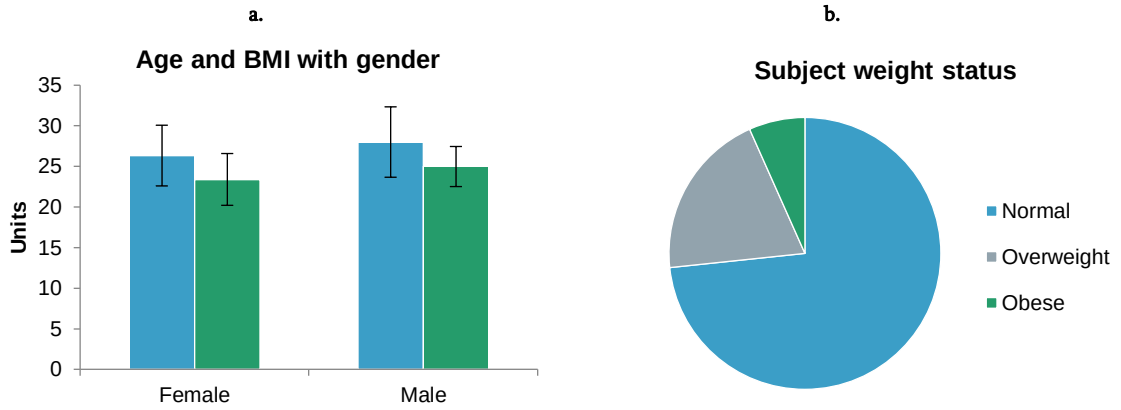

Figure 1. Subject demographics, including a. age and BMI; b. weight status.

Localization time

To evaluate the effects of our technology on localization time, a correlated, one-way ANOVA was performed. Results demonstrated that the times required for each localization method did not statistically differ ($p = 0.9$). Figure 2a depicts the average and standard error for time across techniques; 2b demonstrates the trend in time with increased subject BMI.

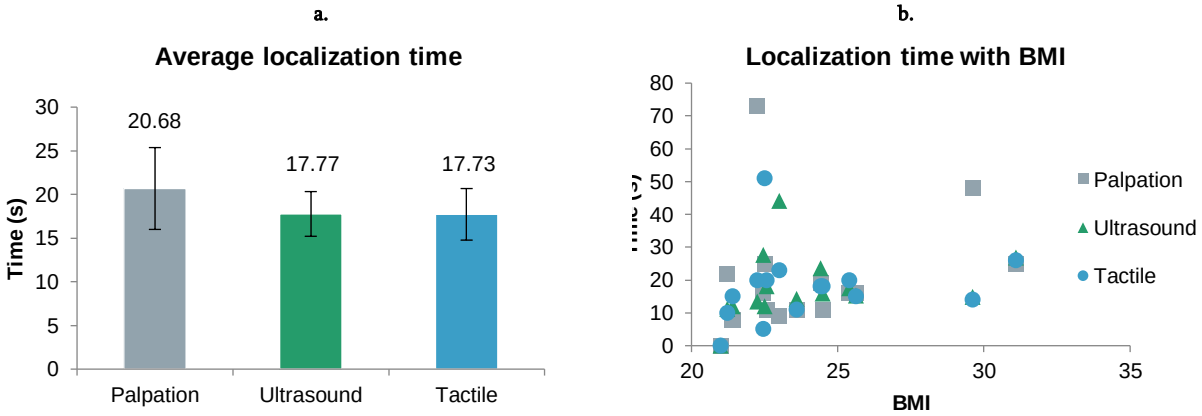

Figure 2. Localization time, a. mean and standard error; b. trends with BMI.

Interestingly, while the null hypothesis was not rejected in this case, there were some distinguishing characteristics across methods. Namely, palpation was found to have the greatest variation in localization time, largely due to its having been most strongly affected by increased BMI. It should be noted that we did not anticipate providing timesaving value with our localization component; rather, we aim to indirectly standardize procedure times through a reduction in required needle-insertion attempts, and with the ease-of-use components of our system.

Midline detection

To verify that our technology could adequately detect the midline of subjects' spines, a correlated, one-way ANOVA was performed on the midline coordinates identified by each investigator. Results demonstrated that the techniques did not statistically differ ($p = 0.55$) in lateral localization.

As depicted in figure 3a, observations of the mean absolute error with respect to the gold standard—ultrasound—suggest greater deviations with palpation, as well as larger standard error with that method, overall. As per figure 3b, initial regression attempts suggest that there may be an inverse correlation between accuracy and BMI; however, a greater amount of data (particularly for subjects with higher BMI) will be necessary to lend confidence to this observation.

a. **b.**

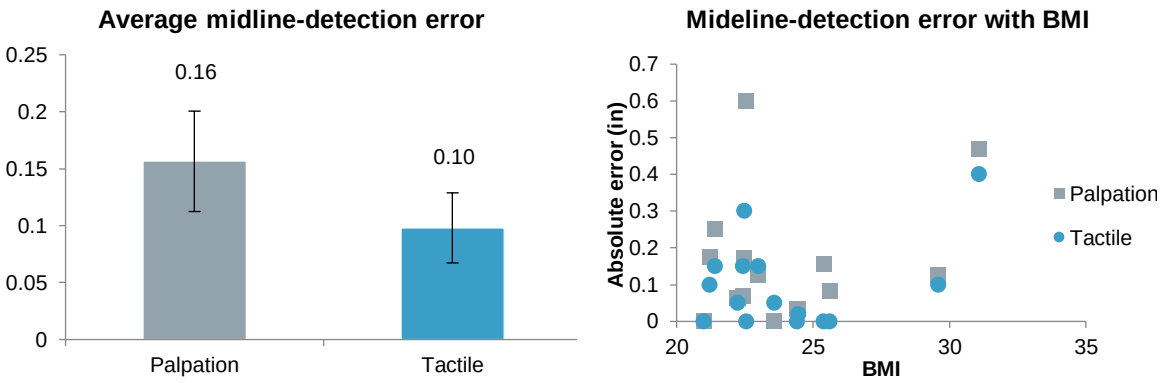

Figure 3. Mideline-detection data, showing a. mean absolute error (with standard error); b. trends with BMI.

Gap detection

A critical endpoint of this study was the comparison of our platform to the existing techniques in identifying insertion sites along the midline. We were able to analyze >2 gaps per subject, given that investigators were instructed to identify >1 potential sites. Gap locations were sorted and subsequently matched to identify corresponding sites across methods.

A correlated, one-way ANOVA was performed on all gaps identified by all three investigators ($n = 22$). Results suggested that the means across the three techniques statistically differed ($p < 0.05$); a Tukey HSD test confirmed that while palpation statistically differed from both ultrasound and tactile sensing, tactile, there was no significant difference observed between tactile sensing and ultrasound.

Sites were then compared using mean absolute and percent errors. As shown in figure 4a, when compared to coordinates based on ultrasound, the mean absolute error with tactile sensing was found to be less than half of that with palpation, falling well within the investigator's stated experimental error. Related to this, mean percent error was found to be 6.44% for palpation, versus 1.94% for tactile sensing. As shown in figure 4b, palpation error was relatively high at all BMIs, but was especially so with overweight and obese weights statuses.

a. **b.**

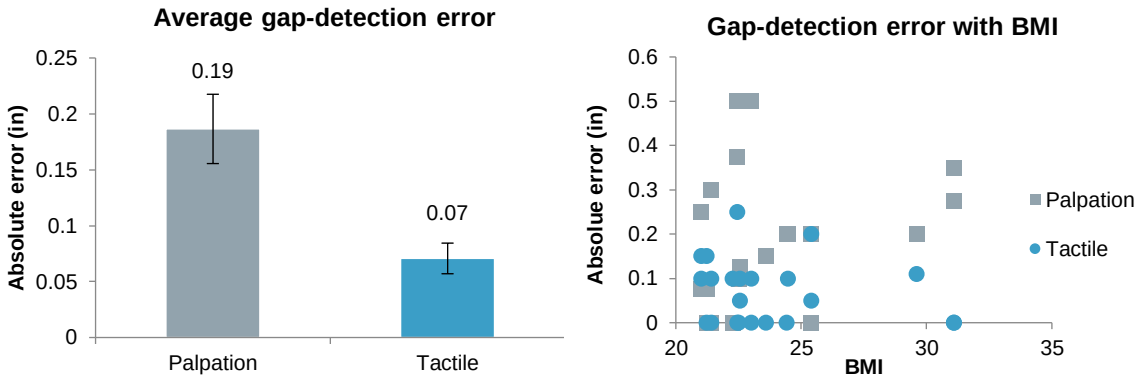

Figure 4. Gap-detection data, showing a. average absolute error; b. trends with BMI.

Feedback

On a more qualitative note, the feedback questionnaires demonstrated that subjects ranked tactile-sensing the highest for comfort and overall preference (at nearly 75%); and found both palpation and tactile-sensing to be quicker than ultrasound. It should be noted that, in going into this study, there was an understanding that substantial, quantitative value propositions for patients will likely not be achieved until efficacy testing of the integrated system.

The study also gave us the opportunity to receive additional important feedback on our imaging platform, user interaction, and algorithms.

Future

At a later stage, we aim to return to the collected ultrasound data, in an effort to improve our needle-projection algorithm. We also hope to use the collected datasets in order to run a usability study with physicians, to optimize the signal-processing schemes used in visualization (e.g. colors; interpolation), in an effort to arrive at an ideally readable and intuitive interface. Finally, having considered the output of this study, we have identified additional metrics that may be important to collect and/or demonstrate in future clinical studies (e.g. patient positioning).