1.3 Need Statement Development

INTRODUCTION

Innovators are usually able to quickly identify problems during observation. The greater challenge is in understanding the associated clinical need and in translating problems into a meaningful need statement. For example, after observing the difficulties some physicians have when cutting the sternum for thoracic surgery, a well-intentioned innovator may define a need for "a more effective cutting device to perform a sternotomy." This need will lead her to investigate multiple solutions for cutting the skin and bone during thoracic procedures. However, if someone else is simultaneously exploring the need for "a way to access the chest to perform procedures on organs of the thorax," the options for innovative solutions will be much broader. In fact, the second need statement could lead to minimally invasive thoracotomy, which the first need statement would not. Ultimately, the first innovator may find that she faces a significantly diminished demand for her new cutting tool if the broader need is met by the second innovator's solution.

Needs correspond to opportunities for innovation. They are characterized by defining an outcome that currently is unmet for a problem in a particular population, which helps direct the opportunity. Too often, clever innovations fail because they have not been developed to address "real" customer and/or market needs. Creating explicit needs statements is a powerful way to prevent this mistake. By clearly and concisely articulating the needs they have observed, innovators will be in a much better position to then determine which ones represent the most compelling opportunities.

See ebiodesign.org for featured videos on need statement development.

OBJECTIVES

- Learn how to translate problems, populations, and desired outcomes identified through observations into clinical need statements that are accurate, descriptive, and solution-independent.
- Recognize the importance of need scoping and its role in improving the effectiveness of need statements.
- Understand common pitfalls in developing need statements, the impact of these mistakes, and how to avoid them.

NEED STATEMENT FUNDAMENTALS

Once interesting problems have been identified through research, observations, and interviews (as outlined in 1.2 Needs Exploration), an innovator's next challenge is to translate what has been learned into a set of meaningful **need statements**. Because need

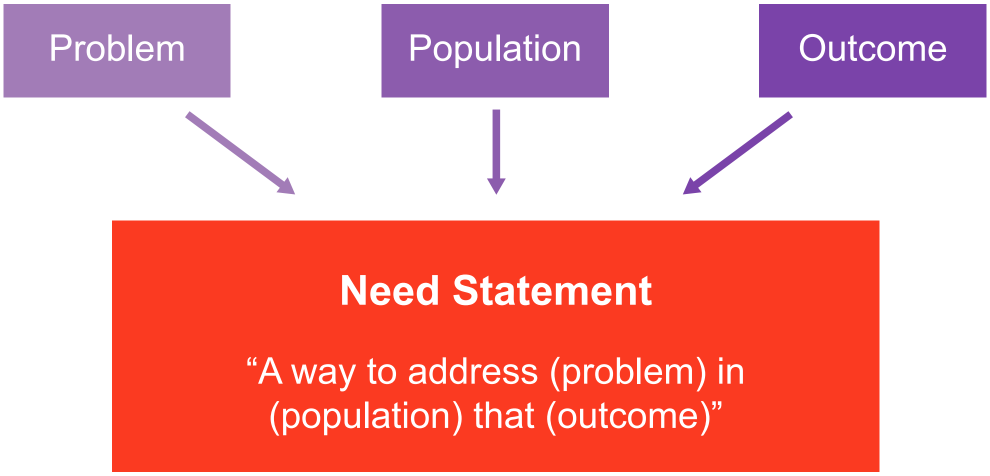

FIGURE 1.3.1
An effective need statement typically includes three essential components.

statements provide the foundation for all further steps in the biodesign innovation process, innovators should expect to invest significant time and energy in their careful construction.

Shaping a need statement has been described by seasoned innovators as something of an art form. It is an iterative exercise that starts with creating rough prototype need statements that progressively become more descriptive and refined, first through needs scoping and then through needs validation.

As previewed in 1.2 Needs Exploration, well-constructed need statements have three essential components: (1) the problem; (2) the effected population; and (3) the targeted change in outcome (see Figure 1.3.1).

The *problem* communicates the health-related dilemma that requires attention. The *population* clarifies the group that is experiencing the problem (and potentially foreshadows the market for the solution). The *outcome* specifies the targeted change in outcome, against which solutions to the problem will be evaluated.

Many innovators find that it is intuitive to include the problem and population in a needs statement, but not as natural or automatic to specify an outcome. However, being clear about the outcome up front is important in that it keeps innovators focused on the results that their eventual solutions must deliver to satisfy their target audience. For example, consider the following need statement, which is based on one of the observations described in chapter 1.2: *a way to reduce the time required for unskilled medical practitioners to place endotracheal tubes in an emergency setting*. In this statement, the specified outcome measure is the reduction in time associated with the procedure. However, further observation and research might lead an innovator to define the outcome differently, as *a way for unskilled medical practitioners to place an endotracheal tube in an emergency setting without a drop in oxygen saturation*. Both of these need statements are "correct," but they target somewhat different outcomes and therefore have the potential to lead to different solutions. The process of creating a need statement brings these differences into focus and allows the team to make a disciplined and informed decision about the opportunity it wants to pursue.

As this example illustrates, outcomes should be stated objectively so that they can easily and effectively be measured. Table 1.3.1 provides a sample of some of the desired outcomes associated with medical need statements and recommendations for how they can be assessed.

It is worth noting that a **need** may ultimately be solved in such a way that it results in multiple benefits (or a number of improved outcomes). For example, the development of a surgical procedure that can be performed in the physician's office as opposed to the operating room will likely result in measurably lower costs (primary benefit), but may also be significantly more convenient for patients and physicians (secondary benefits). In situations like this, a need statement is typically crafted to include just the primary outcome measure, rather than listing all outcomes that may be positively affected. This

Table 1.3.1 Common changes in outcomes and how they are measured in need statements.

Desired outcomes	As measured by …
• Improved clinical outcome	• Treatment success rates in clinical trials
• Increased patient safety	• Rate of adverse events in clinical trials
• Reduced cost	• Total cost of care relative to available alternatives
• Improved physician/facility productivity	• Time and resources required to perform procedure
• Improved physician ease of use	• Elimination of complex workarounds and/or the simplification of workflow
• Improved patient convenience	• Frequency and occurrence of required treatment, change in treatment venue (inpatient versus outpatient, physician's office versus home), etc.
• Accelerated patient recovery	• Length of hospital stay, recovery period, and/or days out of work

approach can be less cumbersome to innovators and keep them focused on the most important result. It also helps eliminate the perception that a need has been successfully addressed only if it performs well against *all* outcome measures (e.g., improved efficacy and safety, reduced cost, etc.) – a difficult and often unattainable challenge. Ultimately, the targeted outcome foreshadows the value that a solution would bring if it appropriately addresses the need. For this reason, innovators should make their primary focus the outcome with the opportunity to have the greatest impact.

All of this said, innovators may find that in some circumstances the outcome is implied rather than explicitly included within the need statement. For instance, consider the simplified need: *a way to prevent stroke in patients with atrial fibrillation*. In this example, stroke prevention is both the problem and the desired outcome, so restating the outcome may seem obvious or redundant. The key is to be sure the team carefully evaluates the problem, the population, *and* the target outcome when defining and assessing any need.

When thinking about how problems, populations, and outcomes come together in a need statement, it is important to carefully evaluate every word that is chosen because specific wording can potentially lead to dramatically different solutions. For example, consider the differences among the following simplified need statements:

- *A way to prevent hip dislocation in high-risk patients . . .*
- *A way to prevent recurrent hip dislocations in high-risk patients . . .*
- *A way to prevent recurrent hip dislocations in patients after surgical treatment of a first hip dislocation . . .*

All three statements address the same general clinical issue (hip dislocation in high-risk patients). Yet, each one identifies certain existing conditions (past dislocation or previous surgery for past dislocation) that would cause innovators to target different patient populations and that could potentially send them in an entirely different direction in terms of what they attempt to accomplish.

A slightly more elaborate example further illustrates this point. Imagine that a team of new innovators has observed a problem with long-term urinary catheters causing infections in patients in the intensive care unit (ICU), and members are discussing the need statement with a mentor:

INNOVATORS: "I think I've finally defined a need statement for *a catheter that will not track infection*."

MENTOR: "Are you talking about all catheters or just urinary catheters?"

INNOVATORS: "Just urinary catheters."

MENTOR: "OK. Do you intend to address all urinary catheters?"

INNOVATORS: "No, just long-term catheters that are used for more than two weeks."

MENTOR: "Great. But is catheterization the only possible solution to this problem?"

INNOVATORS: "Well, I suppose we might be able to develop a number of other approaches. Maybe something that allows for the evacuation of urine without keeping a catheter in place at all times. Or perhaps we could come up with some sort of an implant that releases localized antibiotics in the area of the urethra . . . ."

MENTOR: "Good. Try to set aside any specific solution and focus on the need. Maybe what you're trying to address is more appropriately defined as *a way to reduce the incidence of urinary tract infections in ICU patients*. What do you think?"

INNOVATORS: "Yes. That's it."

MENTOR: "So, what value is created by reducing urinary tract infections in the ICU? Selecting a targeted outcome will better describe the value that the project can deliver.

INNOVATORS: "How about *a way to reduce the incidence of urinary tract infections in ICU patients that reduces hospital stay . . . .*"

The last iteration of the need statement expresses with much greater clarity the true nature of the problem, the metric necessary to achieve the desired outcome, and the potential value that would be created by the solution that meets the outcome. This variation is also more focused on the target audience. If the innovators were to adopt the first need statement, a number of potential (non-catheter based) solutions never would be considered. Without a specific, clearly identified target user, potential solutions could have been developed for users to whom the need was not truly applicable. The example also highlights the importance of defining an appropriate scope for the need. The goal is to establish the need as broadly as possible while keeping it linked to a specific, validated problem. More information about scoping needs is provided later in this chapter.

Drafting preliminary need statements

Drafting the first version of a need statement can seem a little daunting. The thing to keep in mind is that this version does not have to be perfect. Instead, think of it as a crude prototype. One strategy for getting started is to treat the exercise like a game of Mad Libs. Mad Libs is a word game in which one player prompts another for a list of words to substitute for blanks in a template. In this case, the team or innovator would use the need statement template (*a way to address [problem] in [population] that [outcome]*) and try substituting a variety of different words related to the observations they have made to create a cohesive need statement for each interesting problem.[1] Different variations can be tried using sticky notes or a whiteboard, for example, so it is easy to make modifications and experiment with diverse word combinations. Initially, speaking the "language" of need statements may seem awkward, but it will get easier with practice.

Ultimately, the team can select a version of the need statement that seems to most accurately, completely, and compellingly capture the need based on the current knowledge. Then, as their knowledge of the need area deepens through the activities described in chapters 2.1–2.4, they can modify and refine each need statement.

Need scoping

After innovators prototype their preliminary need statements, the next step is to begin actively testing and refining them through an exercise called need scoping. Need scoping allows innovators to further explore the problem, the population, and the desired outcome – and the interaction between these three components – through a series of thought experiments that will lead to a description for each of the components that is "just right." The point of scoping is to systematically try out different levels of focus or specificity for each of the components of the need statement while remaining centered in the general area of the need. Starting with the draft needs statement, the innovators ask themselves questions such as:

- Is the problem just the one outlined in the draft statement (e.g., from the example in the chapter introduction, cutting through the sternum) or could it in fact be broadened (e.g., gaining access to the thorax)?
- Is this issue actually relevant to a larger population than initially described (e.g., not just patients with

urinary catheters, but all patients with urinary tract infections)?

- Conversely, upon closer inspection, is this need actually most relevant and important when applied to a smaller subset of the population?
- Is the outcome described in the needs statement really the most essential one, or is there another outcome that is more compelling?
- Is the need, as scoped, consistent with the team's strategic focus?

This type of scoping exercise allows the innovators to methodically revisit the assumptions they have made in developing the needs statement in a way that results in the optimal framing for the need, so it is detailed and actionable without being too limiting.

Consider another example, starting from the draft need statement: *a way to decrease the incidence of infections associated with hip implants in the elderly in order to reduce hospital stays.* Even though this particular need has been observed in the elderly, the innovators should ask if it might be generalizable to a broader segment of the population. Through research and additional observations, they may determine that the need to decrease the incidence of infections associated with hip implants actually applies to all recipients, not just to those over a certain age. A next step, again through research and observation, would be to explore whether the need applies to other types of joint implants (e.g., artificial knees). The result could be that the potential target market is significantly larger and, thus, more compelling than originally estimated. It is also worth probing whether reduction in hospital stays is really the most important and measurable outcome for this need. Perhaps the reduction in morbidity (e.g., suffering associated with the infection rate) is really the most compelling outcome, provided it can be measured well. Finally, the innovators may want to ask whether there is, in fact, a broader problem that warrants consideration. In the example, infections associated with hip implants may be a need worth addressing. However, it is also part of a larger need to find *a better way to treat osteoarthritis*. The innovators should at least consider whether they would be well served to work on this "higher level" need.

The closer a need is to addressing the fundamental aspects of a disease state, the less likely it is that the need will be displaced by a **superseding need**; that is, a need that is proximal or upstream of the need under consideration and, if solved, would make this need superfluous. For instance, take the case of atrial fibrillation (AF), a disease in which the irregular heartbeat causes clots to form in the heart that can potentially dislodge and travel to the brain, causing a stroke. An innovator might choose to focus on how to prevent a thrombus from leaving the heart to travel to the brain (one approach would be to seal off an outpouching of the heart called the atrial appendage, where clots frequently form). In scoping this need the innovator should consider whether it could be superseded by a way to prevent clots from forming (as would be provided by a better blood thinning mediations). Even this need, though, could be superseded by a way to prevent AF from occurring in the first place (maintaining sinus rhythm through medications, surgical or catheter-based ablation). Figure 1.3.2 shows these options as progressive branches in a tree.

The further away innovators work from the trunk of the tree, the more likely it is that the branch where their innovation exists could be cut off (or superseded by another invention). As Mir Imran, serial inventor, entrepreneur, and founder of InCube Labs, summarized:[2]

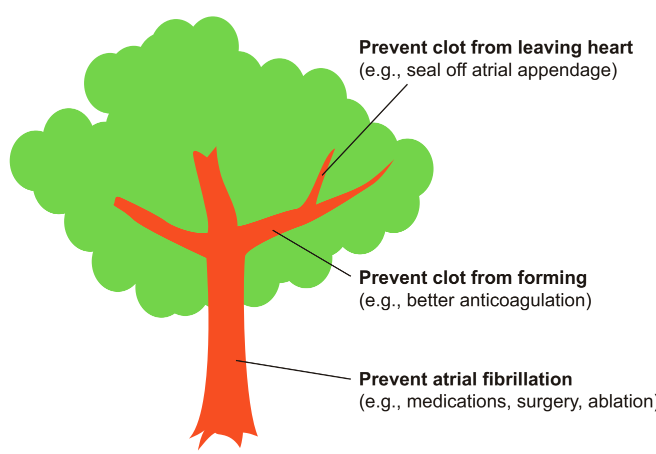

FIGURE 1.3.2
An example of superseding needs and related solutions.

One of the things that device company executives worry about most is that a technology they've worked very hard on for many years will do everything they want it to do and solve exactly the clinical problem that they figured, but by the time they actually get it to the market, it's been passed by another technology, or the clinical problem has been solved in some other way.

The point is that there is a cascade of events that create a need, and each event within the series may be associated with its own unique need. This creates a hierarchy of related needs that directly affects the risk profile associated with the issue the innovator is seeking to address. In general, broad needs (e.g., that seek to cure, eliminate, or prevent a disease) often have the potential to supersede other needs. In contrast, needs focused on changes to existing treatments are often at risk of being superseded.

Of course, there is also a risk that a need can be framed *too* broadly. In an effort to avoid unnecessary constraints, innovators sometimes over-generalize a need by making the assumption that it applies to a broader population when, in fact, it does not. In the need discussed above, *a way to decrease the incidence of infections associated with hip implants in the elderly*, the scoping exercise would, as mentioned, cause the innovators to consider whether the need should be broadened to include other joints (e.g., knee implants). However, with a bit of research and perhaps more observations, it may become clear that the nature of the infections in the two joints are dissimilar in important ways due, for instance, to differences in susceptibility, different effects of the infection on the joints, and/or different mechanisms of healing. Broadening the focus to include knees may cause the innovator to overlook that one unique insight about infections in the hip that would provide the direction for a novel solution.

Embedded solutions and other need statement pitfalls

Beyond the pitfalls of framing needs either too broadly or too narrowly, a few other problems in generating needs statements deserve mention (see Figure 1.3.3). The trickiest of these for first-time innovators is the tendency to embed a solution within the need. At the most fundamental level, a need statement should address *what* change in outcome is required to resolve a stated problem, not *how* the problem will be addressed. Too often innovators incorporate elements of a solution into their need statements because they quickly envision ideas to solve the problems they observe. This is especially tempting when a respected figure – a key opinion leader (**KOL**), for example – offers a solution for how s/he would approach the need area in question. Sometimes this occurs blatantly, sometimes subtly. In either case, embedding a solution into a need statement seriously reduces the range of possible opportunities that are explored, constrains the creativity of the team, and places unnecessary boundaries on the potential market. More importantly, it can lead to a need statement that does not truly represent the actual clinical problem and, thus, may result in solutions that do not effectively address the need.

One young company, for example, focused on a problem with stents (a mesh-like tubular scaffold that can be deployed in blood vessels to expand a narrowed region). It noted that although stents are beneficial in holding open arteries, during deployment they can cause a shower of emboli (debris that becomes dislodged, travels through the bloodstream, and potentially creates blockages by lodging in other smaller blood vessels). Centering on this problem, the company framed a need for *a coronary stent that could prevent vessel wall material from embolizing* (the implied outcome in this need is to minimize the risk of stroke). The members of the design team surmised that the relatively large gaps between the struts of the stent could allow fragments of atherosclerotic plaque or thrombus to dislodge from the vessel wall and pass through, resulting in distal embolization. They decided to develop a "covered" stent incorporating a material that would stretch over the holes and prevent the emboli from breaking free. However, after development and testing, they found that the covering prevented the natural blood vessel surface from reforming around the stent after the procedure – a phenomenon that could create other serious complications, including more embolization. Ultimately, the team failed to deliver a product to the market and the company was shut down.

Pitfall	Problematic Example	Improved Example
NEED IS TOO GENERAL	*A way to improve outcome of spine surgery* • Not clear which surgery, initial diagnosis, or how to improve	*A way to reduce risk of re-herniation after lumbar discectomy for sciatica to reduce re-operation* • Clear about procedure, diagnosis, and complication
NEED IS TOO SPECIFIC	*A way to treat bifurcation lesions in the left main coronary artery to reduce recurrence rates* • No reason to limit to this population—many patients have bifurcation lesions in other main coronary vessels	*A way to treat coronary bifurcation lesions to reduce recurrence rates* • Increases the patient population at least several-fold • Likely that same solution will work across all types/patients
NEED IS STUCK IN CURRENT PRACTICE	*A way to close sternotomy without risk of sternal-wire breaking* • Focuses on sternal-wire; closes out other approaches • Focuses on part of procedure that doesn't deliver result	*A way to close a sternotomy following CABG quickly and securely that reduces wound dehiscence* • No reference to current solution, targets procedure goal
NEED HAS AN EMBEDDED SOLUTION	*A way to ultrasonically weld suture in surgery* • Completely limits to one approach	*A way to secure an aortic valve prosthesis with minimal or no on-pump time to reduce cognitive dysfunction after surgery* • Identifies specific procedure and problem while leaving solution open
NEED IS BUILT ON A NEGATIVE	*A way to not have infections related to dialysis catheters* • Focuses negatively on one specific issue of one solution	*A way to provide long-term, high-flow vascular access for hemodialysis with reduced risk of infection* • Not so negative; focuses on the goal of dialysis catheters rather than the specific solution and is therefore less limited

FIGURE 1.3.3
Potential pitfalls in writing needs statements.

Another company took a different approach to solving the problem of emboli after stenting. This company framed the basic need as *a way to prevent the consequences of emboli in patients undergoing coronary interventional procedures*. Notice that there is no solution embedded in the need itself; this need statement leaves open a number of different potential directions to pursue. The team decided that rather than focusing on stopping the emboli from being generated, it might be more effective to catch any emboli that were created by means of a basket deployed downstream from the site of intervention. After development and successful clinical testing of a basket device, this company was acquired by one of the major medical device companies. By defining the need independent of any particular solution, the team avoided the inherent limitations of a stent-based approach and opened up a more diverse range of possibilities. Both companies were staffed with talented and

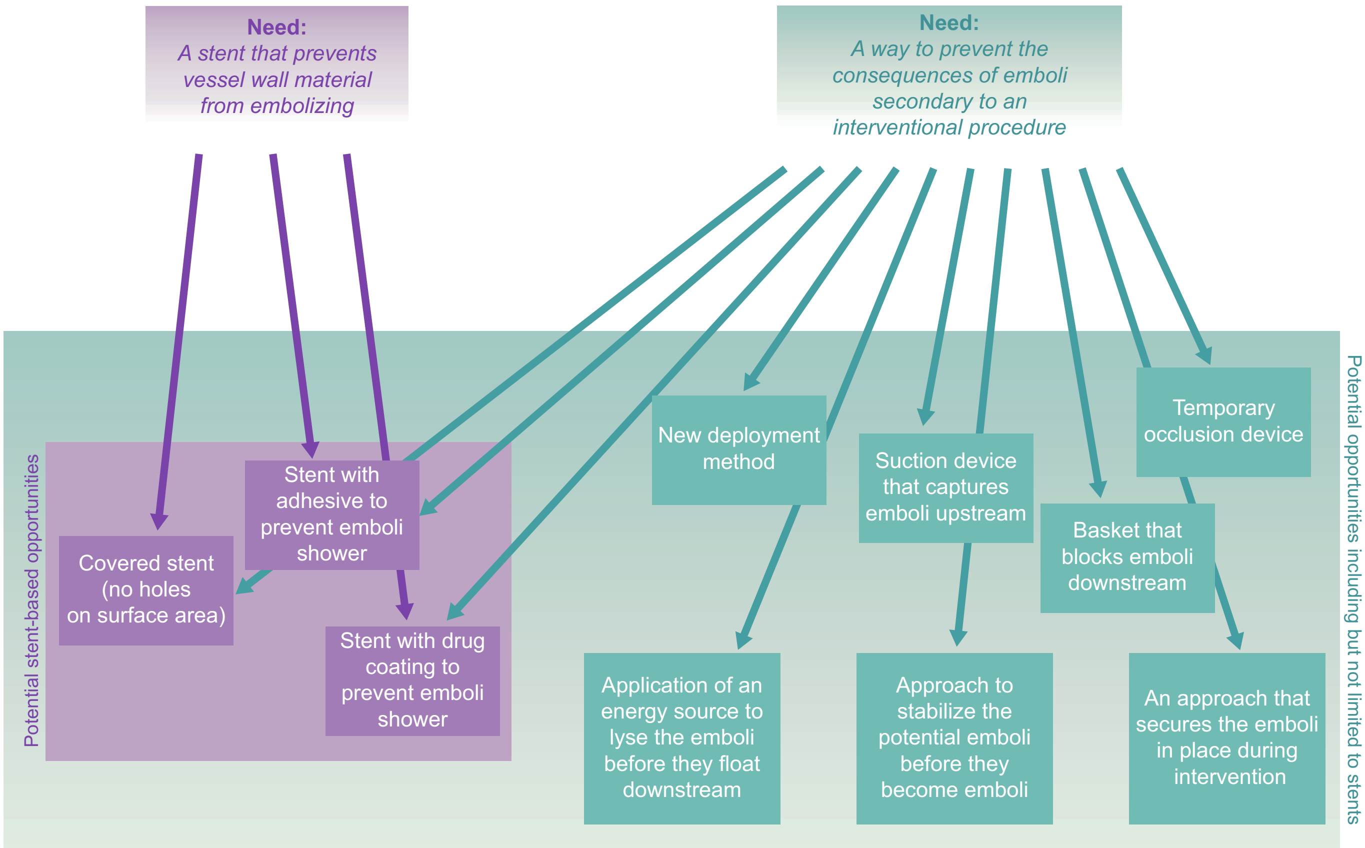

FIGURE 1.3.4
In this example, the first company restricted itself to a need with an embedded solution (a better stent) and thereby limited itself to a relatively small set of opportunities (small dotted box to the left). Removing the embedded solution of the stent and focusing on the outcome to be prevented (consequences of emboli) opened up a much broader set of possibilities.

creative engineers. The first, however, was at a disadvantage because of the solution **bias** embedded within the way the need was framed. Ultimately, taking an approach that anticipated a particular type of solution imposed artificial constraints on the team and prevented it from considering more feasible and effective approaches (see Figure 1.3.4).

Two other pitfalls in need construction deserve brief mention. The first is sticking too closely to current medical practice in formulating the need. In other words, the problem here is letting the prevailing approach or technology shape the need statement. In one of the problematic examples shown in Figure 1.3.3, the need assumes that sternotomy closure requires a sternal wire and so precludes creative thinking about other ways of accomplishing the same outcome. In a way, this problem is a variant of embedding a solution in a need in that it accepts a particular aspect of current medical practice and builds it into the need statement. It is important to point out that, in some cases, a team will (by virtue of its strategic focus) be specifically motivated to improve an existing technology rather than make a breakthrough discovery. As long as the team is clear that its goal is to create an incremental improvement, maintaining an existing paradigm is not an issue. Instead, it becomes an accepted constraint on the need statement.

The remaining pitfall is a subtle one: formulating a need in a negative way. Since a need describes a problem, the natural tendency is to frame it in a way to eliminate the problem (*a way* ***not*** *to…* or *a way to* ***avoid*** …). The challenge with a negative need statement is that it tends to constrain the open-mindedness that leads to the most creative solutions. Whenever possible, innovators should try to restate the need in a way that optimizes a positive outcome. Doing so can be tricky, but a positive need statement can lead to more open and constructive ideation sessions.

The following story, about a biomedical engineering team from Northwestern University, illustrates some of the challenges related to need statement development.

FROM THE FIELD

NORTHWESTERN UNIVERSITY BIOMEDICAL ENGINEERING TEAMS

Navigating the challenges of needs finding

Some time ago the leaders of Northwestern University's capstone course in biomedical engineering, David Kelso and Matt Glucksberg, became interested in design issues associated with global health problems. "The challenge with the equipment and devices used to address health issues in developing countries was not that they were poorly designed, but that they were not designed for the environment in which they would be used," Kelso said.[3] "If people began designing devices specifically for resource-poor settings, they could come up with much better solutions."

Motivated to make a difference, Kelso and Glucksberg initiated a program that gave senior students the opportunity to design solutions that specifically addressed medical needs in developing parts of the world. While their goal was to have students work on "real" projects for "real" end users, they initially launched the program targeting health-related issues identified by the World Health Organization (WHO) or other universities around the world. In one case, they read about a project initiated by engineers at the Massachusetts Institute of Technology (MIT) to develop an incubator that would help address the high rate of infant mortality in developing nations. In countries such as Bangladesh, the area where Kelso and a team of five students decided to focus, as many as 30 percent of all births were premature, a figure that translated into approximately 3,500 premature babies a day.

The team committed to developing *a better incubator that would be designed for local conditions to help reduce infant mortality*. Early in the process, they also defined specific **need criteria** for the solution, including the capacity of the system to operate without electricity, maintain a baby's temperature at a constant 37 degrees Celsius, help protect the infant from infections, contain a high percentage of local material, and have low manufacturing and operating costs. Over the course of the 10-week academic quarter, the team networked extensively, seeking input about incubator design from contacts with experience in healthcare delivery in South Asia as well as those with prenatal education and neonatal baby care. After developing an initial prototype in a plastic laundry basket (see Figure 1.3.5), the team decided to make the container from jute so it could be sourced and manufactured at low cost in Bangladesh.

The phase-change material they used to control temperature in the new model worked just as well as

FIGURE 1.3.5
A photograph of the team's early prototype (courtesy of David M. Kelso).

electrically powered devices. "We were really excited about this," noted Kelso, who immediately began seeking ways to take the project beyond prototype and into production.

Tapping into a Northwestern study abroad program, Kelso formed a second team of students located in Capetown, South Africa and began working with this group to make the incubator relevant for the South African market. Targeting the most prominent neonatal intensive care unit in the area, they scheduled a meeting with the head of that department at Karl Bremer hospital. Kelso and team brought with them photographs and storyboards that described their incubator project. "But as we got off the elevator, we saw incubators piled up in the corner," he recalled. "They were not at all interested in our incubator solution, but invited us to come in and see how they care for premature babies. There were 30 mothers in the neonatal intensive care unit, all caring for their newborns with something called Kangaroo Mother Care."

Kangaroo Mother Care (KMC) had been pioneered in 1978 in Bogotá, Colombia to overcome the inadequacies of neonatal care in developing countries. The basic idea is to place the infant (without clothes, except for a diaper, cap, and booties) upright between the mother's breasts.[4] The baby is held inside the mother's blouse by a pouch made from a large piece of fabric. The method promotes breastfeeding on demand, thermal maintenance through skin-to-skin contact, and maternal–infant bonding. While few large-scale studies have been conducted or published in mainstream medical journals, KMC is believed to help babies stabilize faster and to provide more protection from infection (from the antibodies gained through frequent breastfeeding) compared to babies isolated in incubators.[5] Many believe it also leads to reduced mortality rates among premature and low birth weight infants, although these results are still being studied. "Basically, it provides superior results at no cost," summarized Kelso.

"During our early discussions, we heard about Kangaroo Mother Care as a method they were trying to teach in Bangladesh," he remembered. "But the concept didn't affect the team's design." Kelso continued, "The right way to specify a design challenge is to do it in solution-independent form. By saying we would develop an incubator, we had over-constrained the need. Otherwise, almost all of the need criteria on our list were spot-on." It just so happened that KMC also met these need criteria, while offering other benefits to the infants as well as the mothers who preferred not to be separated from their babies.

Recognizing that the incubator solution was no longer appropriate for this environment, Kelso and his team quickly revisited the needs finding process. One of the associated needs they uncovered was a way to identify apnea in neonates (a problem that could have tragic consequences). Ultimately, they developed an innovative monitor that was appropriate for babies and could be used in conjunction with KMC.

As the Northwestern story illustrates, developing effective need statements is highly iterative and experiential – many innovators master this skill "the hard way" (by making mistakes and learning from them). This can be a costly process, since a poorly defined need statement usually is not discovered until the solution for that need statement misses the mark much later in the biodesign innovation process, after significant time, money, and effort have been invested.

Categorizing needs

Once defined and scoped, needs can be organized into three general categories: **incremental**, **blue sky**, and **mixed**. These three primary need categories exist upon a continuum (with incremental needs on one end, blue-sky needs on the other, and mixed need in between) based on the extent to which they operate within existing treatment paradigms. See Figure 1.3.6.

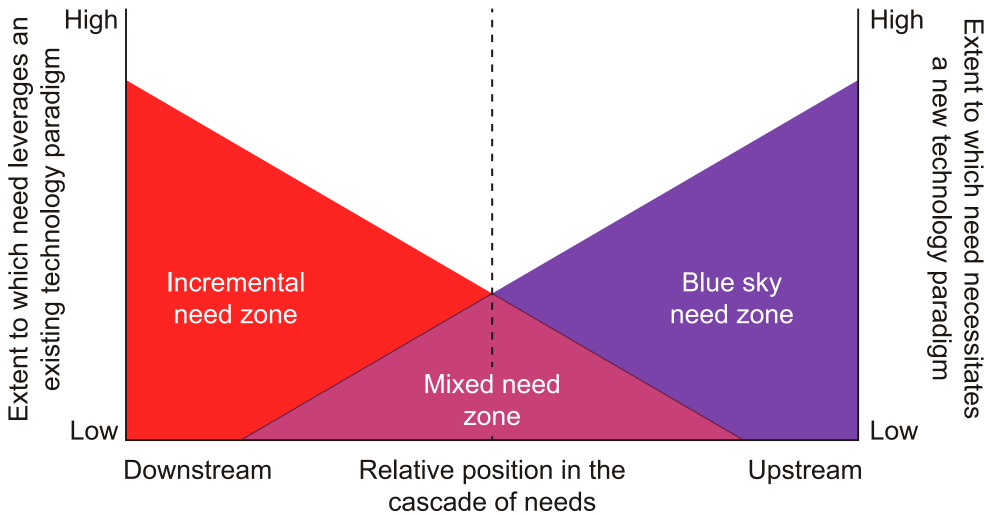

FIGURE 1.3.6
Different types of needs carry with them different benefits and risks.

Categorizing needs is useful for several reasons. First, this exercise provides a checkpoint for the team's alignment with its strategic focus – specifically, does the timeframe and budget of a given type of need fit with the priorities of the group? One team may be focused on launching a project that will support a company's goal to introduce new products within a two-year horizon (and so would concentrate on incremental needs); another group may be looking to create the biggest possible impact in the field of cancer (a blue-sky need). Second, organizing the needs in this manner can also help innovators appreciate the dependence of the potential solution on existing technology. Blue-sky needs typically are wide open for innovation, whereas many incremental needs and some mixed needs build on established practices or paradigms. Finally, by categorizing need statements at this step in the biodesign innovation process, innovators can better understand the range of needs that stemmed from their observations. Later, in 2.5 Needs Selection, they may again refer to these categories as one of several screening factors used to help them select which needs to take forward into invention. Each category is described in more detail in the sections that follow.

Incremental

An incremental need is focused on addressing issues with or making modifications to an existing solution, such as the function of a device or other technology. For example, *a way to prevent clogging of a device used to remove tumors during neurosurgery to reduce surgical time* would be considered an incremental need. It is important to understand that incremental needs typically assume that underlying treatment paradigms or technologies will continue to be used and applied. This is not the same as saying that solutions are built into the need, but rather that solutions are constrained by being further downstream in the cascade of needs. As noted, incremental needs are generally approachable, but run the risk of being superseded when new technology paradigms are introduced.

Blue sky

Blue-sky needs, on the other hand, require solutions that represent a major departure from currently available alternatives and address needs that are further upstream in the cascade of needs. As a result, they may be difficult to define. Blue-sky needs are often focused on curing, eliminating, or preventing various disease states and, therefore, are more focused on physiology and mechanisms of action than existing treatments or solutions. For example, rather than concentrating on improvements to existing machinery or procedures, a blue-sky need might be something like *a way to prevent the spread of colon cancer to improve survival*. Blue-sky needs, if solved, will often supersede most other related needs within a treatment area. A delicate balance exists in determining whether a blue-sky need is approachable at the current point in time or if it requires more study. For a blue-sky need to be entertained as something that could be solved, it is important that at least some of the underlying disease mechanisms are understood in the medical community. This differentiates a blue-sky need from a "science experiment," or an exercise for which the fundamental building blocks of a solution are not yet known and are unlikely to be solved.

Mixed

A mixed need exists somewhere in between an incremental and blue-sky need on the continuum. With a mixed need, most of the problem may be defined, yet the solution requires expansive thinking. *A better way to surgically remove breast cancer at the time of surgery to ensure all of it has been eliminated from the site while minimizing breast tissue loss* is an example of a mixed need.

Importantly, the scope of the problem or type of need does not necessarily correspond to the size of the business opportunity or potential market. Incremental needs can be solved by solutions that can result in sizable business opportunities if undertaken at the right time. Conversely, blue-sky needs may result in solutions that are direction-changing in the industry but may not necessarily translate into significant commercial opportunities.

Early needs validation

After actively scoping each need statement, it is essential to gather more information by talking directly with potential users, customers, and other stakeholders about the problem that has been observed and the need(s) associated with it. These discussions are important because the change outlined by a need *must* be driven by what the target audience wants and/or requires. If innovators seek to solve a problem that is not important to the target population, then the innovation may not be widely adopted. If the problem identified through observation is an issue about which the target population is not readily aware, it can be more challenging for the innovators to validate the need.

Consider an example. In approximately 5–20 percent of colonoscopy procedures, the cecum (the pouch at the base of the ascending colon) is never reached due to the difficulty in navigating the endoscope through the entirety of the colon.[6] As a result, some instances of colon cancer that exist deep within the colon are not detected. Using current technology, it is difficult for physicians to know with certainty whether or not they have reached the cecum. However, despite the fact that published colonoscopy completion rates vary substantially, when endoscopists are interviewed many say that this is not a problem that they personally experience. In cases such as this, innovators may be successful initiating a productive dialog if they identify the problem in a generalized manner, based on research, without asking if a physician has personally ever experienced it. With this approach, physicians can acknowledge and discuss the need for more reliable colonoscopy completion results, whether or not they feel comfortable admitting any personal familiarity with the problem. Moreover, if a solution is introduced that makes the procedure more failsafe for all physicians, with no additional cost or risk, most would be likely to adopt it.

In talking with members of the target population, it is essential to ask them exactly *what* results they would want, not *how* to achieve them – at least at this stage. The point is to keep the discussion focused on the need and not potential solutions. (*How* comes later, when team members decide they want to include an expert in ideation or they want to bring concepts or prototypes to stakeholders for feedback and/or talk with them about product features.) Deconstruct the problem, breaking it down to each component to ensure that it is understood at every level. Make sure to understand any possible interactions between the various components of the problem and develop hypotheses for the root causes of each component that can be validated or refuted by the target audience. Then, using input from the target population, seek to identify the key elements that an ideal solution would have to include to satisfy them (ideally, these elements should be linked back to the root causes they are likely to address). Individuals can be asked to not only identify these elements, but also prioritize them in order of importance. Keep in mind that experts may have different requirements than "common users," but that common users often represent the greater market. They may also have different biases based on their own experience and perspectives that should be considered when gathering feedback from them about an observed clinical problem.

Needs validation begins right after need statement development but is repeated in an iterative fashion throughout needs screening. Efforts to validate needs play an essential role in refining the need statements and also in needs selection (see chapter 2.5 for more information).

Need criteria

Need criteria are an essential component of the need specifications that the team will develop as part of 2.5 Needs Selection. When the innovators begin to feel relatively confident in their preliminary characterization of need statements, they can begin to think more deeply about the need criteria that any solution must meet to address the need as defined. Need criteria should be based on a team's research and observations, as well as information collected in interviews and discussions with providers, patients, and other stakeholders. For instance, for the need *to reduce the incidence of urinary tract infections in ICU patients to reduce hospital stay*, the need criteria might include the following:

- Whatever the solution may be, it must be deployable by personnel that are already available within the ICU.
- It has to last for at least two weeks (since this is how long the average patient spends in the ICU). And if it is limited to two weeks, it needs to be repeatable, if necessary, with no adverse consequences.
- It must have a similar safety profile to existing treatment (traditional urinary catheters) so as not to introduce the risk of a consequence more dangerous than a urinary tract infection.
- The cost of the solution should be comparable to the cost of a traditional catheter (or only slightly more, based on the incidence of urinary tract infection and the costs associated with its treatment in those who become infected) in order for it to be commercially viable.

Although the most important need criterion is integrated into the need statement itself in the form of the desired outcome, innovators will have learned a great deal about other supporting principles that are of value to the target population. These principles might include "softer" solution attributes, such as ease of use, speed, patient convenience, etc. After conducting observations and working through the development of need statements, innovators may be able to start a list of potential need criteria to support some of their needs. Just like the need statements themselves, these criteria will be refined over time as additional information is gathered. The key is to make note of any essential insights about preliminary requirements associated with a need to ensure they do not get overlooked.

Importantly, if at any point the need criteria cause the innovators to consider modifying the need statement, it is essential that they reconfirm (with data and additional observations) that the revised need statement is still valid. In this way, the early need criteria can provide innovators with additional "boundary conditions" that can be used to stimulate further investigation during need screening.

Because needs emerge from observations, innovators should keep in mind that the need criteria may vary based on where the observations were performed. For instance, when exploring needs in low-resource facilities in areas with emerging healthcare ecosystems, innovators may find a greater imperative for solutions that are:

- Inexpensive.
- Locally manufactured (using relatively simple manufacturing methods).
- Able to withstand tough environmental conditions (dust, humidity).
- Operational despite inadequate infrastructure (irregular power supply, poor maintenance).
- Usable with minimal specialized skills or training.
- Easily repaired (with accessible replacement parts).

However, across all settings, need criteria will become more specific and actionable as innovators perform additional research.

A final word on insight

As mentioned in several places in this text, the core "mantra" of the biodesign innovation process is that *a well-characterized need is the DNA of a great invention.* One of the wonderful characteristics of the medtech field is that if an innovator or team is able to identify a truly promising need, there is a high likelihood that they can find a solution to bring into patient care to address it. In fact, there are many times when the real *insight* behind an important technology innovation is in the recognition of the need, not in the solution. The case study of Acclarent that follows this chapter provides a good example of this point. The founding team recognized that a whole category of sinus surgery could be performed with catheter-based tools that are similar to those developed to treat vascular blockages (balloon catheters, guides, etc.). Developing the tools for this application was by no means trivial, but the core insight lay in appreciating the need for this less invasive approach.

Sometimes the key insight behind an important need is camouflaged by years of medical practice (an opportunity like this is called a "latent need"). For instance, in the early days of coronary angioplasty (catheter-based opening of arterial blockages), patients were subjected to 20–30 minutes of a "groin hold" following a procedure (i.e., manual pressure applied by a doctor or nurse to help seal the femoral artery site where the catheter had been inserted). Patients routinely complained that the hold was by far the worst part of the procedure from the standpoint of pain and discomfort. But, presumably because physicians were so focused on the dramatic outcome of opening the coronary arteries, this complaint did not register as a significant problem. Finally, some 15 years after angioplasty began, the medtech community woke up to the insight that managing the entry site in the femoral artery was an important need. A number of different approaches were invented to seal the arteriotomy site and a major new sector of the industry was born.

Unfortunately, innovators cannot solely count on finding a need where, within the need itself, there is a radical or transforming insight. But by taking a systematic approach to creating a need statement, innovators will clarify their understanding of what they have observed and be able to identify the best possible opportunity residing within the need area. Time spent on crafting effective, meaningful need statements is an invaluable investment that will pay off throughout the biodesign innovation process. And, it represents a discipline that, with some practice, will become an essential part of the innovator's skill set.

Online Resources

Visit www.ebiodesign.org/1.3 for more content, including:

Activities and links for "Getting Started"

- Translate problems, populations, and outcomes into need statements
- Confirm that needs are solution independent
- Scope each need
- Perform early needs validation
- Categorize needs and define need criteria

Videos on need statement development

CREDITS

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Acclarent Case Study

Throughout the biodesign innovation process, innovators face a continual stream of interconnected challenges and opportunities as they move from needs finding to integration, and then on to commercial launch. New information becomes available at every stage of the process, which can require them to revisit previous decisions, address new risks, and consider complicated trade-offs. Moreover, the biodesign innovation process takes place within the competitive medtech field, against the backdrop of the increasingly demanding and complicated domestic and global healthcare environments.

Nothing demonstrates the difficult, ever-changing, yet potentially rewarding nature of this process better than a real-world example. The following case study tells the story of a company called Acclarent, Inc. as it moves through each stage of the biodesign innovation process toward the commercial launch of its innovative new technology.

Stage 1: Needs Finding

After completing the sale of his most recent company, TransVascular, to Medtronic, Josh Makower was at a crossroads. With Makower's leadership, TransVascular had pioneered the development of a proprietary catheter-based platform to facilitate existing and emerging intravascular procedures. The new technology could be used to bypass occluded vessels in the coronaries and peripheral vasculature, rescue failed attempts to navigate total occlusions, and deliver therapeutic agents (e.g., cells, genes, and drugs) to precise locations within the vascular architecture.[1] One potential application for the system was to repair the damaged heart tissue that resulted from the more than 1.5 million heart attacks suffered annually.[2] In September 2003, Medtronic acquired substantially all of TransVascular's assets for a deal valued up to $90 million, leaving Makower in a position to decide what he wanted to do next. While the sale to Medtronic was a positive financial outcome for the investors and employees, it fell short of the much higher expectations the TransVascular team had for the business when its members set out to "pioneer the vascular highway" in 1996, the year in which the company was founded.

1.1 Strategic Focus

"Anytime you have an opportunity to stop, step back, and reassess, it's just a great time to check in on your priorities and the things that you want to try to accomplish in life to make sure that you're heading in the right direction," Makower said.[3] Recognizing the chance to define a fresh strategic focus in his career, he initiated a personal inventory and started by thinking about his mission. "For me, it was about trying to make sure that I learned from the mistakes that I had made in the past. And I also wanted to stay true to what I initially set out to do, which was to work on medical problems of a magnitude that, if solved, would result in a significant improvement of quality of life for thousands, if not millions of patients," he recalled.

In terms of his strengths, Makower, who holds a SB in mechanical engineering from MIT, an MD from the New York University School of Medicine, and an MBA from Columbia University, had now delivered successful liquidity events for investors from his first two companies. This gave him not only a valuable educational background, but the battle-scars of real-life experience on which to depend. In addition, "I felt that a skill I could rely upon was the ability to sift out important things to work on, and create projects that were compelling enough to draw extremely talented people together. I also knew that I had selling skills that would help me raise money and communicate enough enthusiasm to others that they would see the vision, commit themselves to a project, and join me in giving it all we have," he commented. Makower further recognized that he had an advantage in his close relationship with venture capital firm NEA, which had invested in TransVascular and his prior start-up, EndoMatrix.[4] His ties with this entity bolstered his belief that he would be able to secure enough funding to get his next idea off the ground. Based on his past experiences (with start-ups as well as Pfizer's Strategic Innovation Group), his education and, most importantly, his mastery of the biodesign innovation process, Makower also felt confident in his ability "to venture with a blank sheet of paper into any clinical field and come up with something that was meaningful to improve the lives of patients."

As far as assessing his weaknesses, Makower tried to be brutally honest with himself. "One weakness," he recalled, "was that I knew that I did not want to be a CEO again, at least not for a long period of time. While I understood the skills required for management, appreciated its value, and probably could do it, it just wasn't fun for me. I knew managing large groups of people was not for me and it was not until I brought a new CEO into TransVascular, Wick Goodspeed, that I started enjoying my role again. I liked being a part of finding the solution, being a problem-solver, and providing a vision of the future. But I didn't enjoy having to manage people by milestones, conduct performance reviews, and all the other things that good managers do to manage and lead a company." This brought him to the conclusion that he preferred working with small teams during their start-up phase and growing the business to the point where he could reasonably hire a CEO to lead the dozens or even hundreds of employees that might come afterwards.

In addition, "I realized that while I deeply enjoy pushing the edge of medicine and exploring completely new concepts in medical areas that are not well understood, basic research is not a good place to operate a venture-backed company," he said. Due to the highly theoretical nature of this kind of work and the extreme levels of uncertainty that innovators face, Makower recalled, "I had strong feelings about not wanting to get people – employees and investors – on board with a vision and then have them be disappointed because our theory was wrong after so much good effort and hard work. We had been there before with TransVascular, and I just didn't want to do that to myself and the people that I worked with again. I wanted to look for opportunities that were much more concrete and could be realized commercially in a reasonable time frame."

After evaluating his strengths and weaknesses, Makower thought about specific project acceptance criteria that would make a new project attractive to him. "I viewed EndoMatrix and TransVascular as good learning experiences, but not tremendously successful. I wanted to have the opportunity to deliver on a project that was very successful. I felt like it was time to take what I had learned and really apply it." This led him to focus on opportunities with a reasonably high chance of success. "No more science experiments" became a mantra of sorts as he and his eventual team began evaluating possibilities.

Another key acceptance criterion was Makower's desire to work on problems that affected a large number of people. Finding a compelling market – opportunities with the potential to reach millions of people and achieve $1 billion in revenue – was another important factor. "We knew we needed to create a company that within a 10-year timeframe could have $100–$200+ million in annual revenues with a reasonable growth rate to achieve our investor's return expectations," he recalled.

Finally, he decided to commit himself to projects that would not involve patient deaths. According to Makower, "At TransVascular, we worked on a technology targeted at critically ill patients. Our interventions risked patient lives in an effort to try to save them. This kind of project requires a certain level of intestinal fortitude and a willingness to accept dire consequences for miscalculating the unknowns. I respect it. I've done it. But I didn't want to do it again, at least not as my next big thing. It's just too much emotion and stress, worrying about the patients."

With these (and a handful of other) acceptance criteria defined, Makower set out to identify one or more specific strategic focus areas that would meet his requirements. To help accomplish this, he restarted medical device incubator ExploraMed. ExploraMed I, which was originally founded by Makower in 1995, spawned EndoMatrix

FIGURE C1.1
Makower and a skull sinus model pose with Chang on his first day of work with ExploraMed (courtesy of Josh Makower).

and TransVascular. In its new form, ExploraMed II (as it would be called) was intended to become a platform for launching two to three new medical device businesses.

Makower's first move was to secure trusted team members in key roles within the incubator. Karen Nguyen signed on to oversee the finances and Maria Marshall agreed to continue on this new ExploraMed venture as his executive assistant. His first technical hire was John Chang, a seasoned R&D veteran who had been a core part of the engineering team at TransVascular (see **Figure C1.1**). In fact, Makower accelerated his plans to restart ExploraMed in an effort to help Chang avoid having to accept another job. "I think one of the important parts of my model is an emphasis on people," he said. "At the end of the day, the value of a business is in the people. Ideas are great, but the people who make it all work are the reason why you're successful. I wanted to work with John again because he's just the most positive, energetic, happy, hard working, smart, dedicated, loyal, and trustworthy guy anyone would ever want to have on a team. So I restarted ExploraMed sooner than I wanted to, so we could have a chance to work together again."

Together, Makower and Chang decided to explore four key areas. Two of these areas were orthopedics and respiratory disease. Another was focused on trying to find a niche within the congestive heart failure (CHF) arena that would meet Makower's acceptance criteria. This field was interesting to the two men because of their prior experience at TransVascular, but they needed to define a scope and focus that would be more applied. "The thought was, 'Is there anything that we can do that would be simpler than what we were working on at TransVascular – something that's not going to require us to create new science?'" Makower recalled. They started to focus on pulmonary edema associated with CHF (the effect that causes patients to become starved for oxygen during the night and unable to sleep). They noticed it was an important side effect that dramatically affected patients' quality of life, yet it seemed to have some interesting mechanical implications.

The fourth potential focus area was in the ear, nose, and throat (ENT) specialty – a space in which Makower had already performed some preliminary research and generated some ideas. As someone who suffered from chronic sinusitis, a condition involving the recurring inflammation of the cavities behind the eyes and nose commonly caused by bacterial or viral infections,[5] Makower was intimately familiar with the inadequacies of existing treatment alternatives for this condition. Patients usually were treated with over-the-counter and prescription medications, including antibiotics, when severe infections occurred. In fact, sinusitis was the fifth most common condition for which antibiotics were prescribed in the US.[6] Steroids were another type of therapy employed when these other treatments failed to produce or sustain results. In a relatively small number of the worst cases, chronic sinusitis patients qualified for surgical procedures, the most common of which was functional endoscopic sinus surgery (FESS). Frustrated with the efficacy and nature of his treatment alternatives, Makower had informally begun exploring new approaches in this area. When Chang joined ExploraMed, the time was right to more formally evaluate the strength of potential opportunities in ENT. "We set aside my previous work for the time being to try to treat this like any of the other projects," said Makower. "We needed to start with the basic clinical problem, develop a deep understanding of the real clinical needs, and do our due diligence to see if we would arrive at the same general conclusions and ideas that I had going in."

1.2 Needs Exploration

According to Chang, the two men developed a plan to spend their first few weeks collecting general information about what was going on in the areas of orthopedics, respiratory disease, CHF, and ENT. "I scheduled a number of meetings with physicians I knew, and I attended several conferences," he said. In these meetings, Chang remembered, "We said, 'So, tell us about what you do. Tell us about some of the patients you see. Tell us about the challenges you face as a physician. What are some of your greatest needs?'" Sometimes the physicians had specific ideas to share but, more often than not, they simply shared their experiences and discussed whatever frustrations were giving them problems. The team knew that the real insights would come from observing physicians in the operating room, with their patients in the clinic, and at clinical meetings as they debated and discussed current therapy.

Accordingly, the next step was to schedule first-hand observations. Makower explained: "We needed to find clinicians that would allow us to see a large volume of cases, get a lot of patient experience, and quickly come up to speed on the space." Makower had already begun teaching at Stanford University's Program in Biodesign and, as a result, had a rich network at the university's medical center to tap into for contacts in certain specialties. However, in some fields, such as ENT, he and Chang had to "cold call" the hospital. "We called and asked, 'Who's the rhinologist at this hospital?'" Makower remembered.

Once they made the appropriate connections, a formal observation process was launched. Again, in the ENT space, "We spent a couple of days following a surgeon around in clinic, getting an appreciation for his day-to-day routine – what patients were coming in, and why. Was it an initial visit, a post-operative follow-up, or some other type of appointment?" said Chang. "We also spent time in the OR asking 'dumb' questions like, 'Hey, I notice you did that four times. Is there a reason why you have to do that?' The idea was to keep the eyes and the mind open."

"We went to clinic, we watched cases, we talked to patients, and we observed surgeries," Makower reiterated. "And basically, the more we heard and saw, the more we began to feel that we really had something here." FESS surgery to treat severe cases of chronic sinusitis became the dominant form of sinus surgery in the mid-1980s, led by the introduction of the endoscope to the field. This approach involved the insertion of a glass-rod optic, called an endoscope, into the nose for a direct visual examination of the openings into the sinuses. Then, under direct visualization, several cutting and grasping instruments were used to remove abnormal and obstructive tissues in an effort to open the sinus drainage pathways. In the majority of cases, the surgical procedure was performed entirely through the nostrils (rather than through incisions in the patient's face, mouth, or scalp, as was previously necessary).[7] "Conceptually, the specialty made this huge leap forward 20 years ago from large open incisions to FESS, which was considered to be minimally invasive and atraumatic," commented Chang. "But when observing a FESS procedure, the video image coming off the endoscopic camera was often a sea of red. As an outsider, you just think, 'Gosh, maybe that's better than it used to be, but that doesn't seem so atraumatic to me. Ouch!"

According to Makower, one of the reasons the process was so bloody was because a significant amount of bone and tissue was being removed in every procedure. As an example, he explained:

> *The uncinate process is a bone that sits at the edge of the maxillary sinus. It is never diseased, yet it is completely removed in almost every conventional sinus surgery. To me, it was amazing that they were removing a structure solely because it was in the way. I had to ask the question two or three times: "So, the only reason why you're taking it out is because you can't see around it?" "Yes." "But it's not diseased?" It was kind of incredible. And that was the beginning of us coming to the realization that there was a lot more cutting involved in the procedure than ideally needed to be done. We used to joke that it was analogous to someone deciding that they needed to make their bedroom door a little bit bigger and then choosing the method of driving a bulldozer through the entry doorway, through the living room, and demolishing the kitchen along the way just to get to the bedroom door, because all those things were just "in the way."*

Other major problems identified through their observations included post-operative scarring, mostly related to the trauma imparted during surgery that often led to suboptimal outcomes and a need for repeated procedures solely to address the recurrence of their scars. Additionally, "There were other potential complications, like cerebrospinal fluid (CSF) leaks, as well as a high level of complexity of the procedure, not to mention the significant post-operative pain and bleeding," Makower added. The team perceived that these factors, in combination, presented an opportunity to create significant value in the space by offering a better solution.

1.3 Need Statement Development

Using the information gleaned from their initial observations, Makower and Chang defined a need statement and a preliminary list of need criteria. Summing up their takeaways, Makower said, "We saw a need for a minimally invasive approach to treating chronic sinusitis that had less bleeding, less pain, less bone and tissue removal, less risk of scarring, and that was faster, easier, and safer to perform. We tried hard to put aside the ideas that we had come up with already and stay true to the process, but our excitement about the opportunity was clearly building."

NOTES

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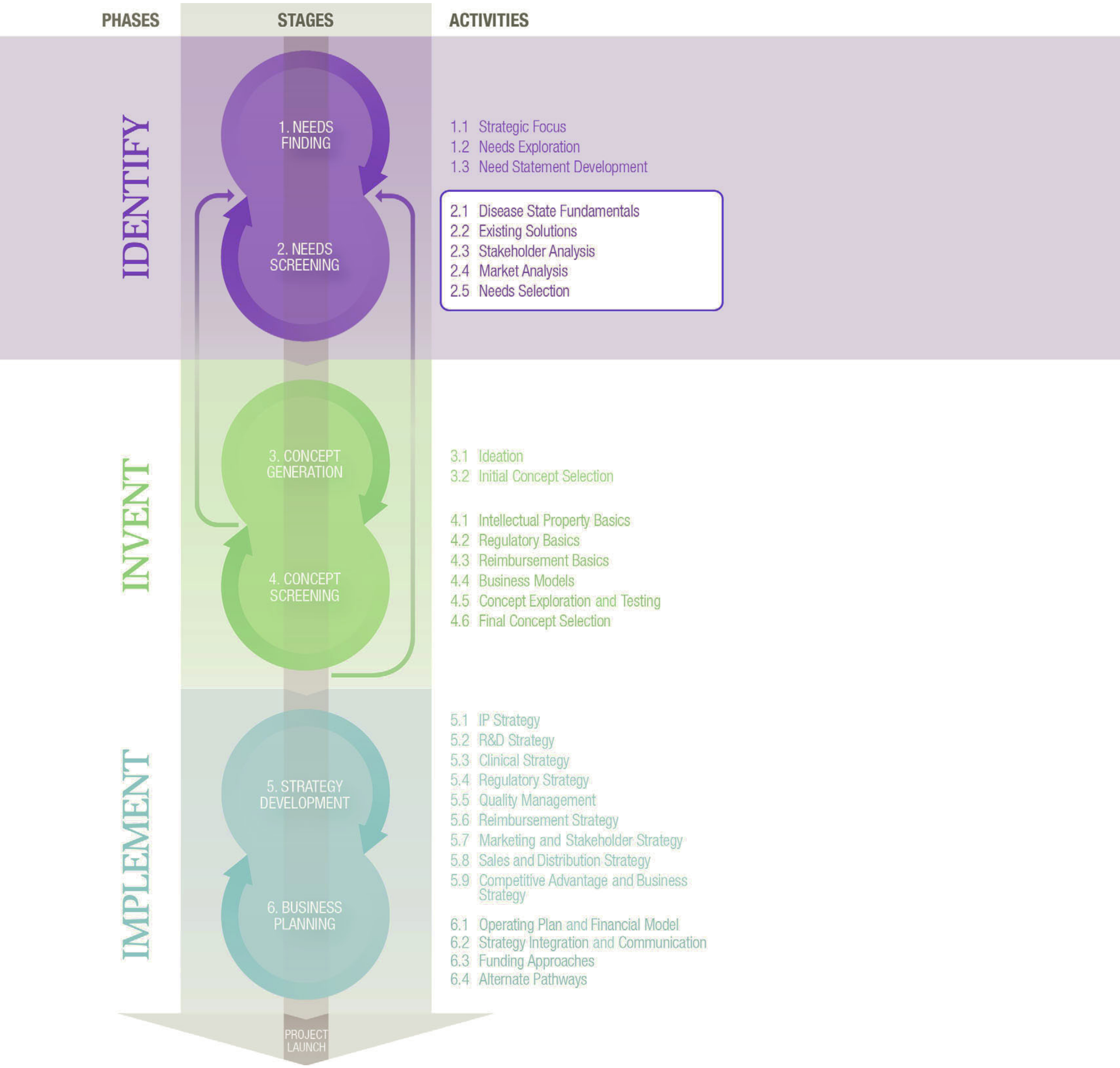
IDENTIFY Needs Screening



Successful entrepreneurs do not wait until "the muse kisses them" and gives them "a bright idea": they go to work . . .. Those entrepreneurs who start out with the idea that they'll make it big – and in a hurry – can be guaranteed failure.

Peter Drucker[1]

I find out what the world needs. Then, I go ahead and invent it.

Thomas Edison[2]

IDENTIFY

2. NEEDS SCREENING

After collecting many needs, a rigorous, follow-on process of screening and specification is required before you begin inventing – the deep dive. This is not an intuitive skill for most; typically, bright people will encounter a clinical need and proceed directly to devising solutions without first validating whether that need is *really* the most important one to take on.

In fact, careful scrutiny of all facets of the need is essential. While serial innovators may do this intuitively, a formal process is highly useful for those with less experience. The iterative process of "walking around the problem" may be enhanced by an occasional cooling off period. There is a perfectly natural human tendency to fall in love with a need and remain anchored to it. Dispassionate review and reflection can prevent a WOMBAT experience (Waste of Money, Brains, and Time).

By the end of this deep dive, the innovation team should have become absolutely expert on the problem, with a detailed specification of the need including clinical characteristics, market dynamics, competitors and their current solutions, and stakeholder requirements – both "must haves" and "nice-to-haves." The all-important headline is the need statement, a single sentence that contains the essential features of the need: the problem, the population affected, and the outcome desired for the new solution. This is the genetic code for the entire project to come.

NOTES

[1] Peter Drucker, *Innovation and Entrepreneurship: Practice and Principles* (HarperCollins, 2006).
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