2.5 Needs Selection

INTRODUCTION

To aspiring biodesign innovators, the process of selecting the right needs to bring forward into invention can feel a lot like comparing apples and oranges (and peaches, pears, bananas . . .) that all look good on the surface. One unmet need that applies to millions of patients might offer the opportunity to do little more than alleviate certain symptoms of their underlying condition. Another unmet need involving the fundamental mechanics of curing a disease might require years of research to affect just thousands of sufferers. Yet another could address a vital need common to a vast population, but in a geographic market where patients have little or no ability to pay for the remedy. With all of these trade-offs and challenges to evaluate, innovators require a systematic process for deciding which needs will provide the greatest opportunity to create and deliver value.

OBJECTIVES

- Understand how to develop a needs ranking system.
- Learn how to utilize the needs ranking system iteratively, through the incorporation of additional research, to reduce the number of needs in a stepwise fashion.
- Recognize when and how to interact with key stakeholders to validate needs.
- Know how to create a need specification for the highest-scoring needs.

Needs selection is highly dependent on all of the data collected to this point in the biodesign innovation process. The goal of this activity is to identify, from the vast list of potential needs originally under consideration, a smaller subset of needs (or sometimes a single need) that warrants further investigation. The process of needs selection is inherently subjective in that it seeks to determine which needs are in greatest alignment with the interests and priorities of the innovators, as defined by their strategic focus. However, to maximize the innovator's chances of success, needs selection also must ensure that critical data about important objective factors are considered and given appropriate weight. The information gathered through iterative and increasingly in-depth research into various aspects of each need, such as an understanding of the disease state, solution landscape, stakeholders, and market, helps to drive innovators toward needs for which significant risks can be most effectively mitigated.

There is no one "correct" way to perform needs selection. However, significant value is realized by letting needs directly compete against one another, with a combination of both subjective and objective factors used to evaluate their relative merit. This type of comparative approach, complemented by increasingly detailed due diligence as the total

number of needs gets smaller and smaller, allows innovators to ultimately decide on a few high-potential needs to pursue.

The output of needs selection is the need specification – a document that synthesizes all of the important data gathered through observations, research, and needs evaluation. The "need spec" also outlines the criteria that any solution must meet in order to satisfy the need. This information is then used as the starting point for generating preliminary solution concepts.

See ebiodesign.org for featured videos on needs selection.

NEEDS SELECTION FUNDAMENTALS

Needs selection requires the innovator to systematically compare one **need statement** against another to identify the most promising opportunities before moving into concept generation. Since most innovators transition from the needs finding stage into the needs screening stage with an abundance of **needs** and no clear sense of which ones hold the greatest potential, a formal process to select needs helps ensure that sound, unbiased decisions are made using the data gathered from 2.1 Disease State Fundamentals through 2.4 Market Analysis. Through this process, innovators can typically narrow the list of opportunities they are pursuing to between 1 and 10 top-priority needs.

The process of needs selection can be performed in many different ways, but a rigorous, structured approach usually involves six essential steps:

1. Select factors to consider in making a decision.
2. Assign ratings for each factor for each need.
3. Combine values to produce a score that can be used to rank the needs.
4. Select a smaller set of needs to be investigated further based on the rankings.
5. Perform additional research on the smaller set of remaining needs and repeat steps 1 through 4 until only a few top-priority needs remain, interspersing step 6 (below), as the number of needs decreases.
6. Engage key **stakeholders** to validate that the needs are meaningful.

Each of these steps is described in more detail later in this chapter.

Depending on how many needs innovators start with, the iterative process outlined in steps 1–4 may be repeated several times in order to get to a focused set of 1–10 top-priority needs. Some innovators move decisively through the process, revisiting these steps just once or twice, while others take a more progressive, cyclical approach, looping back through the steps multiple times and making measured cuts with each iteration.

The key to needs selection is to gather just enough information with each pass through the process to make informed choices about ranking needs without allowing the research and analysis cycle to become so burdensome that it impedes project progress. Since the biodesign innovation process fundamentally leads innovators to identify dozens (or even hundreds) of needs, it is unrealistic to think that they can spend weeks investigating each one. As noted, research, as described in chapters 2.1 through 2.4, should initially be kept at a relatively high level. As needs are screened through an iterative process and the list of those being considered becomes progressively smaller, innovators should perform increasingly more detailed and thorough research on the more focused list of needs that remain.

One technique that can help innovators appropriately limit how much time they spend on research is to set deadlines regarding when data collection for a given round of needs selection must be complete. For example, if innovators give themselves two weeks to investigate 100 needs, the research will be relatively high level by necessity. If they then take another two weeks to explore the 40 needs that "survived" the preliminary selection process, they will be able to dive deeper into understanding them, and so on.

Some innovators worry that if they do not exhaustively research each need, they might inadvertently eliminate a high-potential opportunity. But if the biodesign process is followed, innovators almost always find that the needs selection process leads them to a few excellent needs that are well aligned with their strategic focus and fully supported by the increasingly detailed needs research performed up to that point. That said, if new research uncovers information pertinent to a need that has been eliminated, innovators can always re-score the need and potentially reconsider it. Of course, this should be done empirically and not to "save" needs for which innovators have an affinity. But if innovators understand this is an option, they may be less fearful about eliminating promising needs based on their preliminary research. Re-scoring needs can even happen during the creation of a **need specification**, which occurs quite late in the needs selection process. The point is that research happens throughout the full process of selecting needs and any relevant information that is uncovered can and should be given serious consideration, even if it means adjusting prior decisions.

Again, while there is no single way to perform needs selection, Figure 2.5.1 provides a summary of how one team worked through its needs selection exercise. As the figure illustrates, this team was quite systematic in its approach to needs selection. Accordingly, this team's experience is used as an example in describing the six steps of needs selection. However, other innovators may work in a slightly less structured manner, as the two From the Field examples illustrate later in this chapter. Many different approaches can be successful as long as they: (1) allow for the rigorous evaluation of needs against a combination of subjective and objective factors that are important to the team; and (2) position needs to compete against one another, especially when screening many needs in a relatively short period of time.

Step 1 – Choose selection factors

The first step in the needs selection process is to clearly identify which factors to evaluate in comparing the needs under consideration. Each team must figure out which factors (and how many) make the most sense based on the types of needs being assessed and the interests of its members. However, choosing multiple objective factors and not more than one or two subjective factors (e.g., the team's level of enthusiasm for the need or the extent to which the need is life-saving) should be sufficient to understand and compare all of the needs on a level playing field.

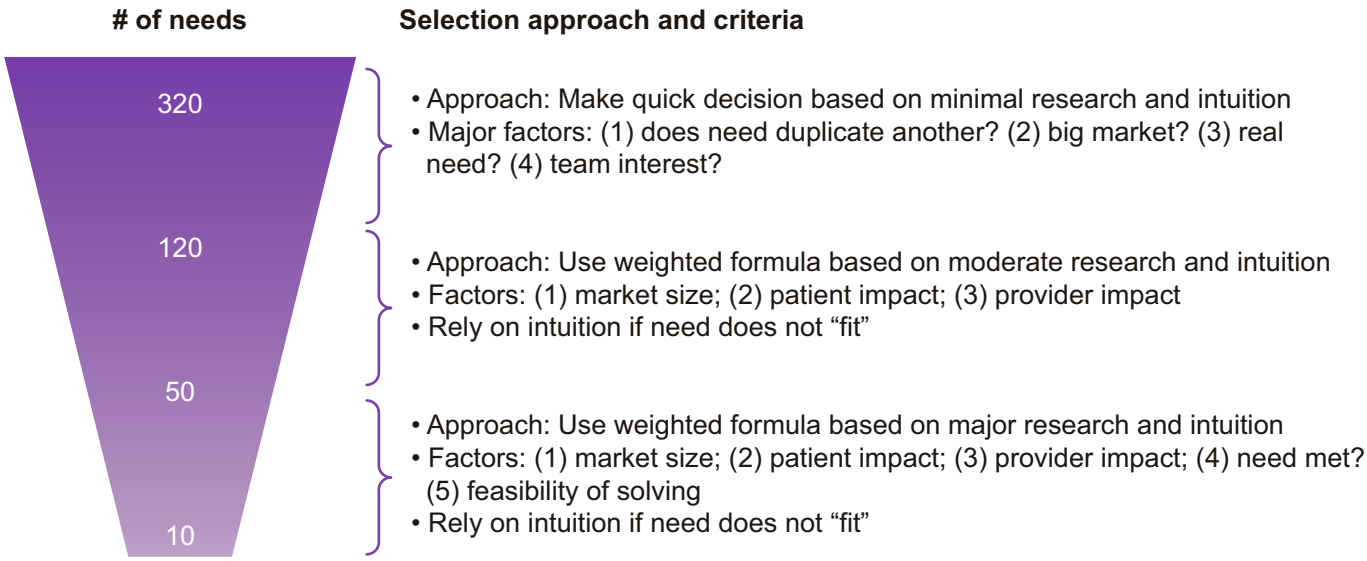


FIGURE 2.5.1

An example of the needs selection approach used by a multidisciplinary team from Stanford Biodesign. The team started with a set of 320 needs, which were cut to 120, then to 50, and finally to 10 target needs. Increasingly detailed criteria (developed through more thorough research) were used at each step in the selection process (with permission from Uday N. Kumar; developed with John White, Kityee Au-Yeung, and Joseph Knight).

Some of the most common objective factors that innovators use to evaluate one need against another are outlined in Table 2.5.1. Background research should enable the innovator to answers the questions associated with each factor (summarized in the table) for each need under consideration.

In addition to the objective factors shown in the table, innovators often find it helpful to consider the type of need that is being evaluated – blue sky, **mixed**, or incremental (see 1.3 Need Statement Development). Some innovators specifically want to evaluate a diversity of need types, while others prefer only to investigate those

Table 2.5.1 Objective factors that can be chosen to structure the needs selection process.

Factor	Question(s)	Issues/implications
Disease state mechanisms (see 2.1 Disease State Fundamentals)	Are the mechanisms of the disease state associated with the need well understood?	• Needs that are focused on poorly understood disease states may be more challenging to solve, especially with devices (e.g., autoimmune deficiencies). • Needs focused on multi-factorial disease states (e.g., diabetes) may not yield simple/direct solutions if not targeted to a specific aspect of the disease state. • Needs focused on disease states with large numbers of affected people are favorable since information tends to be available and can be discovered quickly (e.g., gastroesophageal reflux disease). • Patients in developing and emerging markets may present with later stages of a given disease state, compared to presentations in developed nations, and thus there may opportunities to shift the timing of care through earlier diagnosis and/or prevention
Solution landscape (see 2.2 Existing Solutions)	To what extent is the need currently being addressed? Is there a gap between the need and existing treatments (i.e., a "white space" characterized by no solutions)?	• If treatment options currently exist that address the need (or could be "tweaked" to provide a solution), there may be significant competition in the market. • If established treatments exist but the need is still unmet, understand their limitations or shortfalls as a source of information. • If the shortfall or limitation of established treatments may be cost-related or due to complexity, there may be opportunities to solve the need in more **value**-oriented ways, which may also be important for emerging markets. • Pay attention if no treatment options exist to address the need. This can signal both opportunities and risks.
Stakeholder impact (see 2.3 Stakeholder Analysis)	How significant would the benefits to patients be if the need is addressed? How would physicians and facilities be affected? How likely are decision makers to pay for a solution that addresses the need?	• Any perceived or real ethical issues relating to solving a need can have an impact on how that need is received by key stakeholders. • Needs focused on improving patient outcomes are generally considered particularly important. • In addition to the benefits realized by some facilities and/or physicians from addressing the need, keep in mind that a solution might adversely affect others (e.g., by taking away business or shifting care from one specialty or facility to another).

Table 2.5.1 (*cont.*)

Factor	Question(s)	Issues/implications
		• If **payers** are the decision maker, they are more likely to provide **reimbursement** if the need is related to improved safety or efficacy and/or cost reduction and increased efficiency rather than increased convenience or a better **user** experience. • Other stakeholders, including facility administrators and patients, are increasingly playing the role of decision makers for products and services not covered by insurance. In developed and emerging markets, these customers are interested in both effectiveness and affordability.
Market size and competitive dynamics (see 2.4 Market Analysis)	How large is the market for a solution to the need? Which players (and how many of them) offer or are developing therapies in the need space? What magnitude of funding will be required to develop and commercialize a solution in the need area? Is the market large enough to justify this requirement? How substantial is potential value (in terms of clinical and economic outcomes) for the need?	• Market size helps quantify the potential impact that an innovator can have by addressing the need. • Market size is also an important factor in determining the likelihood that funding can be raised. • **Blue-sky needs** tend to have greater financing requirements so they require a larger market to support them. • **Incremental needs** may have lower funding requirements and may be feasible with a somewhat smaller market. • The level and nature of competition in an area of need has significant implications for how easy (or difficult) it will be to penetrate the market. • Regardless of their type, needs that lend themselves to driving favorable economic outcomes of a reasonable scale will be more likely to drive adoption in developed and emerging markets. • Sound market data can be more difficult to amass in emerging markets and will require more time and effort from innovators.

in a particular category. Generally, the decision of what type (or types) of needs to pursue is linked to the risk–reward equation that the innovators desire. Blue-sky needs typically involve significant risks, but can lead to greater rewards; the opposite is usually true for incremental needs. For this reason, innovators sometimes chose to categorize all needs by type and then determine how many in each category to pursue based on their preferences.

When choosing objective factors to use in the needs selection process, it is essential to think about how much value can be generated by solving each need under consideration. While including one or more value-related factors in the selection process may have been "optional" years ago, it is now imperative. In cost-sensitive healthcare environments, for example, certain incremental needs that can drive favorable economic outcomes for stakeholders in decision-making roles may gain more traction than blue-sky needs that deliver greater clinical benefits at a higher cost. Regardless of need type, innovators must identify the value of their needs in both clinical and economic terms and then use this information as an objective factor in needs selection.

Innovator preferences should also be taken into account through a series of subjective factors that link back to the strategic focus decided upon at the outset of the biodesign innovation process. As described in chapter 1.1, **acceptance criteria** are the mechanism through which an innovator's mission, strengths, weaknesses,

and tolerance for risks in the external environment are woven together into a list of requirements that an innovation project should meet to provide a good fit. By translating the most importance acceptance criteria into selection factors, innovators can ensure that the projects emerging from the needs selection process are, in fact, aligned with their personal priorities. For teams of innovators working together, a personal interest rating provided by each team member can be used to collect and incorporate everyone's feedback on the most important subjective factors to evaluate.

The selection factors that innovators decide to use in the needs selection process can be tracked in many different ways. Some experienced innovators do little more than keep a mental list, while others record them with their notes from other steps in the biodesign innovation process. However, for most innovators, especially those who are just starting out, it can be extremely helpful to construct a spreadsheet or database to perform this tracking function. An electronic tool provides great flexibility in organizing, manipulating, and sorting information, especially when there are many needs to track. Figure 2.5.2 provides an example of the selection factors chosen by one team, as well as the method used to compile and manage this information in a database. Keep in mind that the data shown in the screen shot were collected incrementally, over multiple iterations through the selection process. Some needs were eliminated based on information related to a few key selection factors early in the process, while others that made it further in the selection process were evaluated based on research from the entire set of selection factors.

Step 2 – Assign ratings for each factor

Once a set of selection factors has been chosen, innovators next assign ratings to those factors for each need. Through this rating process, the needs under consideration begin to empirically compete against one another.

Before assigning ratings, it is necessary to decide on a rating scale that can be applied consistently across needs. Since the ratings ultimately lead to scores that should help separate strong needs from ones that may not be as compelling, innovators and their teams must be careful about choosing a rating scale. Too often, when innovators define a scale with an odd number of choices, they tend to "play it safe" by assigning ratings at the midpoint. This results in clusters of needs with scores that are similar. To help spread scores across a wider range of ratings, it may be useful to use a scale with an even number of choices so that innovators must assign scores that tip to one side of the midpoint or the other. For example, a scale of 1 to 4, where 4 is the best possible score and 1 is the lowest, often works well.

Next, the rating scale must be further defined in meaningful terms for each factor. For instance, for an objective factor related to *patient impact*, the innovator might define the scale shown in Table 2.5.2. For an objective factor related to *treatment landscape*, the scale in Table 2.5.3 might be used. For a value-related factor such as the cost/benefit of a need area, a sample rating scale is shown in Table 2.5.4.

Specific rating scales should also be defined for the subjective factors that the innovators have chosen. For example, if one of the acceptance criteria from the strategic focus is to work on projects that can have a positive effect on a large patient population, innovators may outline a factor and its rating scale as shown in Table 2.5.5.

The most difficult part of assigning ratings is that innovators must do so based only on what is known about the *need*. Because they should still be thinking in solution-independent terms, it is essential not to take into account information or **biases** related to any particular solution. Innovators have a tendency to jump ahead – for example, by rating the market size associated with a new type of catheter, rather than the size of the market associated with a better way to perform interventional procedures. The effect of this bias is to skew the rating process based on preconceived notions (e.g., "Catheter-based solutions are really hot right now, so I'm going to rate the need high," or "Medication pumps are ubiquitous commodities, so I'm going to rate the need low"). The best way to prevent this type of bias is to stay focused on rating the impact of *addressing the need* rather than the impact of a specific type of solution (see 1.3 Need Statement Development for more information about the pitfalls associated with embedding solutions within needs).

As ratings are assigned to each factor for a given need, they should be captured in the database or spreadsheet

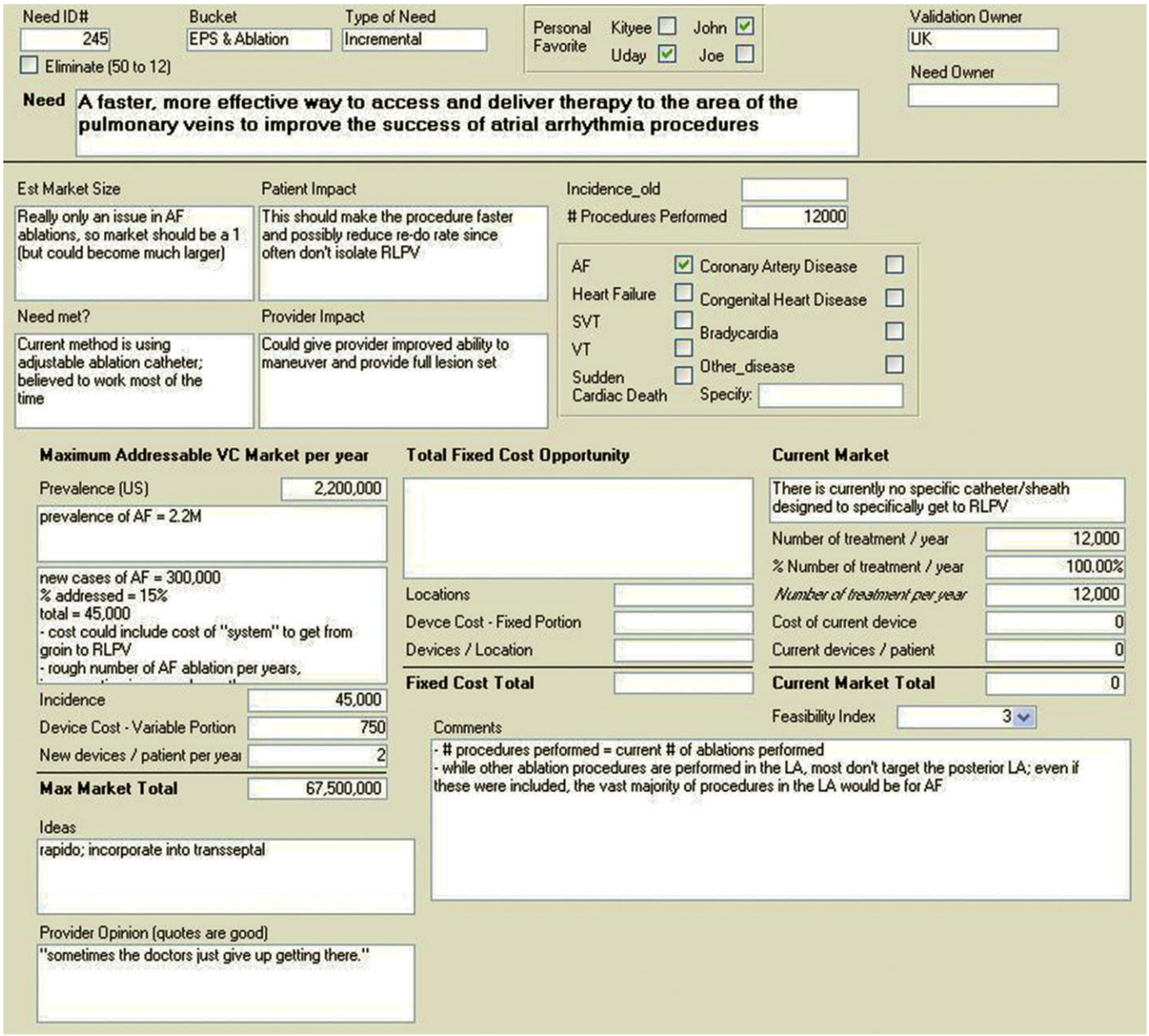


FIGURE 2.5.2

A screen shot from a database developed by a Stanford Biodesign team to support the needs selection process (with permission from Uday N. Kumar; developed with John White, Kityee Au-Yeung, and Joseph Knight).

used to manage the selection process, as shown in Figure 2.5.3.

When evaluating a large number of needs, it can be a good idea to "test" the rating system before scoring every need. Choose a small, diverse sample of the needs under consideration, assign ratings, and then combine values to produce a single score for each need, as described in Step 3 below. If the scores that result from the ratings seem reasonable and are not clustered too closely, then go ahead and apply the rating system to the remaining needs. Alternatively, if there is limited differentiation between scores and they are clustered into a few dominant groupings, innovators may want to rethink the rating scale, definition of each rating, or even the factors chosen and then try rating the needs again before pressing ahead.

Table 2.5.2 A sample rating scale for the objective factor: patient impact.

Rating	Description
4	Addressing the need would be life-saving to patients.
3	Addressing the need would reduce **morbidity** and/or eliminate the risk of serious complications.
2	Addressing the need would not have an impact on morbidity, but would positively affect **quality of life** by eliminating undesirable symptoms of the disease.
1	Addressing the need would not have a significant impact on patients.

Table 2.5.3 A sample rating scale for the objective factor: treatment landscape.

Rating	Description
4	There are no existing treatments available to address the need and the field.
3	Treatments exist to address the need but have *serious* deficiencies that must be overcome.
2	Treatments exist to address the need but have *minor* deficiencies that must be overcome.
1	Treatments exist to address the need that are generally well accepted by the target user population and address the need well.

After ratings have been made for every need, be sure to look across needs, factor by factor, to confirm that the values have been assigned consistently, fairly, and without undue bias.

Step 3 – Combine values to produce a score

The next step in the selection process is to figure out how to combine ratings in such a way that each need ends up with a single numeric score. These scores should reflect the relative strengths and weaknesses of each need to allow for their direct comparison and prioritization.

Table 2.5.4 A sample rating scale for the objective factor: potential to add value.

Rating	Description
4	Positive clinical benefit with major cost savings.
3	Positive clinical benefit with incremental cost savings.
2	Positive clinical benefit with no effect on cost.
1	Positive clinical benefit that increases cost.

Table 2.5.5 A sample rating scale for the subjective factor: desire to positively impact a large patient population.

Rating	Description
4	Need directly affects more than 1 million people.
3	Need directly affects 100,000 to 1 million people.
2	Need directly affects 10,000 to 100,000 people.
1	Need directly affects fewer than 10,000 people.

One approach is to simply add or average the ratings assigned to each factor to come up with a score for each need. If the right mix of objective and subjective factors has been developed, this simple approach to calculating an overall score may be appropriate. Another method is to assign different weights to the various factors and then calculate a total score or weighted average. Weighting the factors is important if the innovator believes that certain criteria are significantly more essential than others. For example, if an innovator is driven to build a thriving business more than anything else, it might be appropriate to assign a greater weight to a factor such as market size. On the other hand, if an innovator is motivated above all else to improve outcomes for patients, a factor such as patient impact might warrant greater weight.

The process of weighting factors is inherently subjective – there really is no right way to do it. Innovators must trust their instincts in determining the best possible approach. The weightings used to calculate scores for the example team are shown in Figure 2.5.4. Note that, in this case, team members varied their weightings by

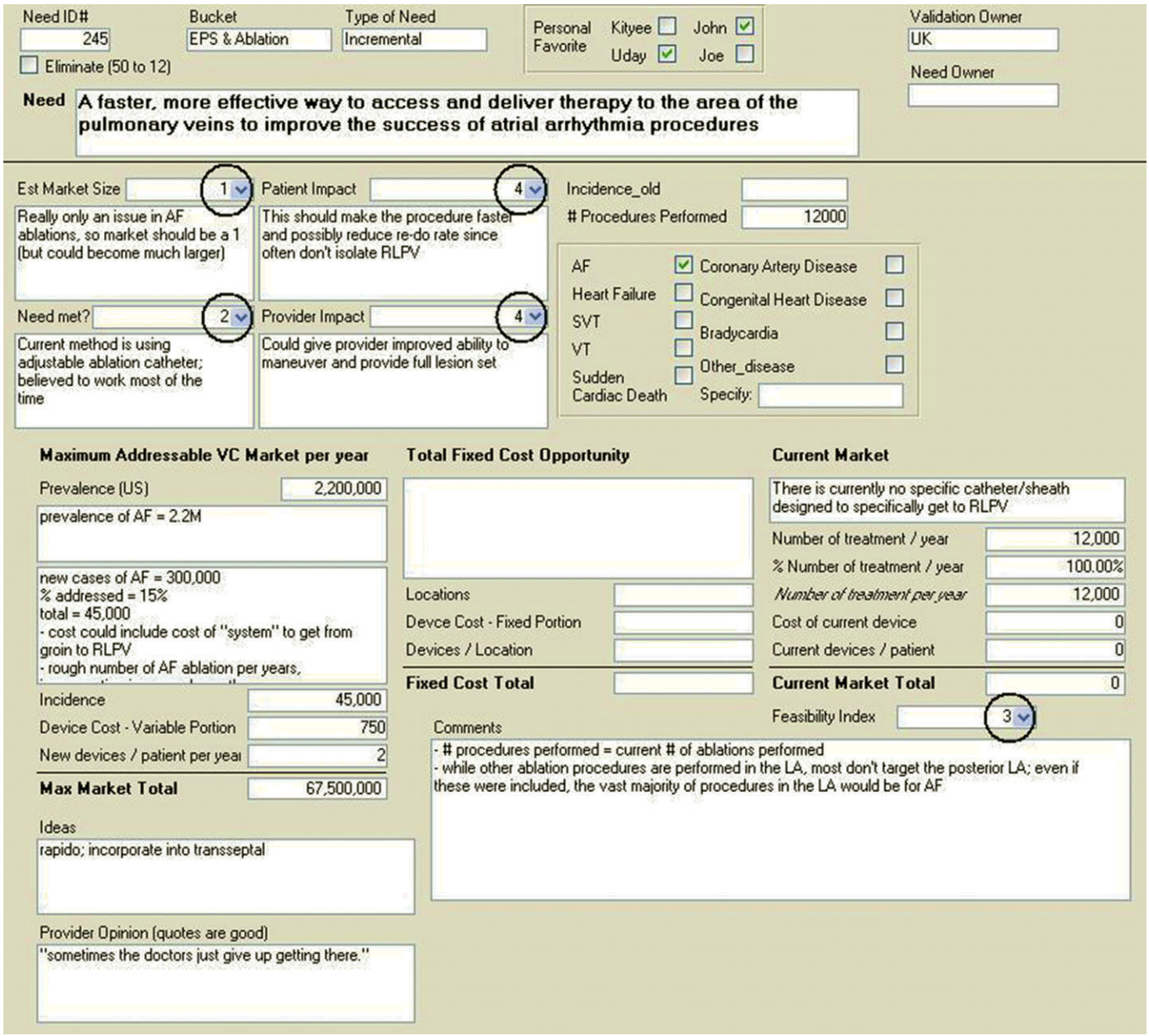
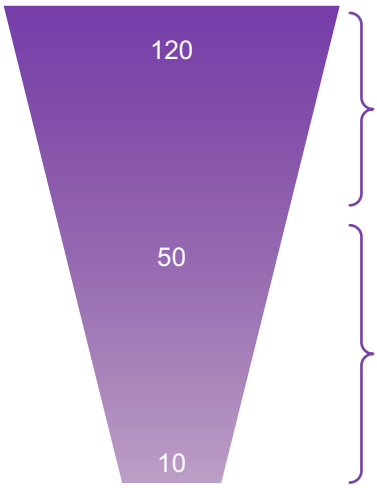


FIGURE 2.5.3

A screen shot from a database developed by a team in Stanford's Program in Biodesign showing assigned ratings (with permission from Uday N. Kumar; developed with John White, Kityee Au-Yeung, and Joseph Knight).

need type (blue-sky, mixed, or incremental) to help adjust for the natural bias of certain teams towards blue-sky needs. These needs may often gain the most points simply because they are so broad and can offer the greatest clinical and market rewards if successfully addressed. However, they may not be the optimal needs to pursue if, for example, a team has a strong desire to bring a tangible product to market in a relatively short period of time or prefers not to take on the significant risk that can sometimes accompany blue-sky needs. Of note, innovators in different geographies may value needs differently based on local market factors and the overall healthcare climate in the area where they are working. Along those lines, in increasingly cost-sensitive environments, incremental needs might not be valued as highly by payers if they offer limited clinical benefit. Yet, they



Weight	Blue	Mix	Incr
Market	2	2	2
Patient	1.25	1.5	1
Provider	1	1.5	2

Weight	Blue	Mix	Incr
Market	2	2	3
Patient	1.25	1.5	1
Provider	1	1.5	2
Need Met?	1	1	0
Feasibility	2	2	2

FIGURE 2.5.4
To get from 120 to 50 and then to 10 needs, weightings were assigned to increasingly specific filtering criteria by need type (with permission from Uday N. Kumar; developed with John White, Kityee Au-Yeung, and Joseph Knight).

may be valued by potential corporate acquirers if they solving them helps differentiate a company's product or product line. It all depends on the context in which an innovator is working.

After calculating the overall scores for each need, do a "gut check" on a sample of the final scores to make sure that they accurately reflect the team's priorities and interests, as well as the more objective factors that characterize a strong opportunity. It is important to keep in mind that the scores represent estimates of the strength of each need, but are not perfectly precise. This means that a need with a slightly lower score than another need (e.g., 27 versus 28) should not be quickly discarded without first evaluating the underlying reasons why it scored lower.

Another useful exercise it to experiment with differential weightings to see how this may alter the scores. Doing this might allow the impact of key factors to be magnified, which can help spread out scores. If certain needs consistently rise to the top of the list using different scoring scenarios, these are likely to be strong needs to pay attention to as the needs selection process progresses. Additionally, as described earlier, if significant clustering of scores remains, it may be worthwhile to revisit the rating scales, rating definitions, and selection factors.

Just as with collecting data for each need, a database or spreadsheet can be used to capture the approach to weighting certain factors (if appropriate) and to calculate the overall scores for each need as shown in Figure 2.5.5.

Step 4 – Select needs

With scores assigned for each need, innovators can directly compare them and select the ones that have performed best through the process so far. One way to do this is for the team to decide how many needs it would like to take forward from this pass through the selection process, list the needs in order from highest to lowest score, and then select the target number of needs with the highest scores. Another approach is to look for a natural break in the distribution of scores and eliminate any that fall below that point. The natural break is sometimes relatively obvious – for example, if many needs have scores in the 28, 27, 26 range and then there is a jump to needs with scores of 23, 22 21, etc. Such a gap is likely to indicate that the needs below a score of 26 have certain issues or risks that may be more difficult to overcome, making 26 a natural cut-off point for this round of needs selection. Another way to identify an appropriate cut-off point is to plot the scores for each need on a graph, as shown in Figure 2.5.6.

Step 5 – Iterate the selection process

As emphasized, the need selection process should be highly iterative. The first time through the process, an innovator might cut the number of possible need statements in half, complete additional research, adjust certain ratings and scores, and then work through this process again to reduce the list by another 50 percent. This approach ensures that more and more time is

Need ID.	Need	Est Market Size	Patient Impact	Provider Impact	Type of Need	Degree to Which the Need is Met	Feasibility Index	Personal Favorite-Kit	Personal Favorite-Uday	Personal Favorite-Joe	Personal Favorite-John	Total	Rank
INCREMENTAL		3	1	2	0	0	2	0	0	0	0		
116	A method to ablate more tissue, over a larger area, with each application of energy	2	2	2	1	3	3	0	0	0	0	18	1
84	A way to change the RF energy output location along the length of the catheter without moving the catheter at all	2	1	2	1	4	3	0	0	0	0	17	3
123	A cheap, simple method with which to accurately and easily enter the arterial and venous systems	3	1	1	1	2	3	0	0	0	0	18	1
51	A better way to stabilize device lead in coronary sinus	2	1	2	1	2	3	0	0	0	0	17	3
152	A way to quickly map and ablate within a 3D structure	2	2	2	1	3	2	0	0	0	1	16	5
245	A better way to access the right lower pulmonary vein. (changed better "catheter design" to better way)	1	2	2	1	2	3	0	1	0	1	15	9
159	A way for one cath lab operator to perform all necessary equipment movements for ablation and EPS procedures	3	1	2	1	4	1	0	0	0	0	16	5
70	Lighter x-ray shielding outfits	1	1	3	1	3	2	0	0	0	0	14	11
21	A way to avoid esophageal injury during ablation	1	1	2	1	2	3	0	0	0	0	14	11
56	A way to increase the battery life in the average implanted device	3	3	1	1	3	1	0	0	0	0	16	5
52	A more effective way to close an implanted device pocket	1	1	2	1	2	3	0	0	0	0	14	11
321	A way to determine the settings of an implanted device without a programmer available	3	1	2	1	4	1	0	0	0	0	16	5
40	A way to prevent electrophysiology catheter cables from building up torque outside of the patient	1	1	2	1	4	3	0	0	0	0	14	11
191	A way to prevent thrombosis/vegetation on device leads	3	2	1	1	2	1	0	0	0	0	15	9
24	A cost effective way to remotely monitor many inpatients	3	1	1	1	2	1	0	0	0	0	14	11
22	A better handle for ablation catheters	2	1	2	1	2		0	0	0	0	11	16
MIXED		2	1.5	1.5	0	1	2	0	0	0	0		
300	A way to remove the left atrial appendage from within the left heart	3	3	2	2	4	1	0	0	0	0	19.5	1
119	A method to assess the depth of the lesion created during ablation	2	2	3	2	4	2	1	1	0	0	19.5	1
325	A way to access the pericardial space	2	2	2	3	3	3	0	0	0	0	19	3
76	A better, more reliable way to determine if an arrhythmia that was present is now gone	2	2	3	2	3	2	0	0	0	0	18.5	4
149	A better way to determine/estimate ablation site prior to the actual procedure	2	2	3	2	3	2	0	0	0	0	18.5	4
144	A way to improve and angioplasty balloon	3	2	2	2	2	2	1	0	0	0	18	6
57	A way to recharge an implanted device without removing the entire generator	3	3	1	2	4	1	0	0	0	0	18	6
226	A way to anchor the wire / lead / catheter once you are in a vessel you are interested in.	2	1	2	2	3	3	0	0	0	0	17.5	8
118	A method or a device/suite of devices that would allow one person to perform all the functions necessary to perform a complete ablation	2	1	3	2	3	2	0	0	0	0	17	9
155	A way to determine the appropriate ablation "dosage" to account for tissue variability	2	2	2	2	3	2	1	0	0	0	17	9
279	A better way to more effectively deliver energy during defibrillation	3	2	1	2	2	2	0	0	0	0	16.5	11
284	A way to change the stiffness of a balloon (complaint to non-compliant)	3	1	2	2	2	2	0	0	0	0	16.5	11
180	A better way to non-invasively monitor arrhythmias long-term	3	2	1	3	2	2	0	0	0	0	16.5	11
248	A way to treat vessel perforation during a procedure	1	3	1	2	4	2	0	0	0	0	16	14
73	A better way to keep an ablation catheter against the wall of the heart	2	1	2	2	3	2	0	0	0	0	15.5	15
298	A way to make an ablation catheter assume any shape	2	1	2	2	3	2	0	0	0	0	15.5	15
47	A better way to access the coronary sinus	2	1	2	2	2	2	0	0	0	0	14.5	17
195	A way for an EP recording system to interpret signals, not just display them.	2	1	2	2	2	2	0	0	0	0	14.5	17
314	A way to guide a catheter to the previously stored location	2	1	2	2	2	2	0	0	0	0	14.5	17
307	A way to turn different parts of a catheter (REMOVED " without having to torque at the handle")	2	1	2	2	2	2	0	0	0	0	14.5	17
131	A way to alter the properties (stiffness, softness, slickness) of the wire/stylet without exchanging it	2	1	2	2	1	2	0	0	0	0	13.5	21
86	A way to include depth perception on a fluoro image	2	1	2	2	3	1	0	0	0	0	13.5	21
99	A way to eliminate putting 12 individual ECG patches on the patient	2	1	1	2	0	3	0	0	0	0	13	23
299	A way to place permanent leads in the left heart without an increased risk of thrombus	2	1	1	2	2	2	0	0	0	0	13	23
67	A way to prevent bleeding locally in the device pocket.	1	1	2	2	2	2	0	0	0	0	12.5	25
143	A way to change the visibility of equipment on the imaging system	2	1	2	2	2	1	0	0	0	0	12.5	25
305	A way to outline the borders of the endocardium for the duration of a procedure	1	1	2	2	3	1	0	0	0	0	11.5	27
301	A way to image the left atrial appendage without using a transesophageal approach	1	1	2	2	2	1	0	0	0	0	10.5	28
163	An easier way to compare/characterize/determine the direction of waveform propagation and its origin	1	1	2	2	2	1	0	0	0	0	10.5	28
BLUE SKY		2	1.25	1	0	1	2	0	0	0	0		
326	A way to improve the contractility of the heart	3	3	2	3	4	1	0	0	0	0	17.75	1
122	An alternative to fluoroscopy that will allow visualization of internal structures in real-time which would also allow real-time procedures to be performed	3	2	3	3	4	1	0	0	0	0	17.5	2
107	A method to non-invasively image coronary and peripheral arterial plaques susceptible to rupture	3	3	2	3	3	1	0	0	0	0	16.75	3
14	A better way to treat a stenosis	3	3	1	3	2	2	0	0	0	0	16.75	3
8	A method to identify the likelihood of malignant arrhythmias in patients who are currently not symptomatic from the arrhythmia	3	3	1	3	4	1	0	0	0	0	16.75	3
112	A non-invasive method to ablate internal cardiac tissue	2	3	3	3	4	1	0	0	0	0	16.75	3
210	A way to cause scar (not iatrogenic fibrosis e.g. from a lead placement) tissue to conduct again	3	3	1	3	4	1	0	0	0	1	16.75	3
324	A better way to treat AF	3	3	1	3	3	1	0	0	0	0	15.75	8
124	A method with which to assess electrical and mechanical ventricular dyssynchrony	3	2	2	3	3	1	0	0	0	0	15.5	9
322	A way to prevent arrhythmias in post-MI patients with low EF	2	3	1	3	4	1	0	0	0	0	14.75	10

FIGURE 2.5.5

A screen shot from a spreadsheet developed by a Stanford Biodesign team showing the assigned ratings, weightings (in gray), and total scores for numerous needs. Note: the highlighted numbers indicate the weighting used for each factor (with permission from Uday N. Kumar; developed with John White, Kityee Au-Yeung, and Joseph Knight).

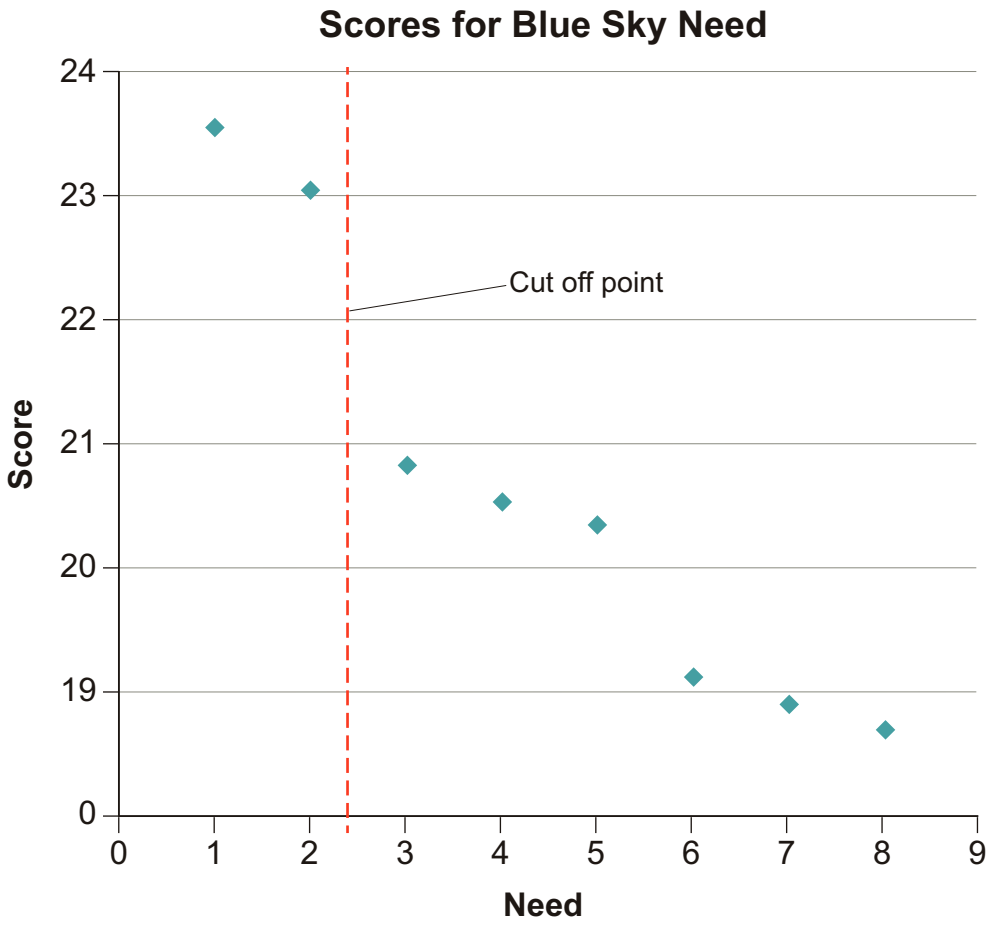


FIGURE 2.5.6
By plotting the score of nine different needs, one team was able to identify the two most promising needs to take forward (courtesy of Rena Dharmawan, Prusothman Sina Raja, Benjamin Chee Keong Tee, and Cecilia Yao Wang).

invested in researching only the most promising needs that continue to "make the cut."

Typically, the quantitative scores developed through this process provide an excellent way to make the "easy" decisions about which needs to eliminate. For example, some needs clearly will not be as compelling as others in terms of the potential opportunities they represent, and their scores will cause them to be quickly set aside. However, most innovators find that, as the list of needs gets smaller and smaller, the quantitative scores become less helpful and they must rely on more qualitative decision-making criteria, potentially building of some of the subjective criteria used earlier to reduce the list to 1–10 top-priority needs. This is a natural part of the process, demonstrating that there is fundamentally no substitute for an innovator's professional judgment. But, if the process is followed consistently, this will help maintain some level of structure and objectivity to the exercise.

Step 6 –Validate needs with stakeholders

An important step that can help innovators arrive at a list of 1–10 top-priority needs is to reengage stakeholders for their input. Validating needs with key influencers and decision makers (as initially described in 1.3 Need Statement Development) helps ensure that the needs are, in fact, interesting and important. Traditionally, innovators have predominantly validated their needs with the physicians and other care providers they observed during needs exploration. However, it is essential to revisit a team's stakeholder analysis and validate needs with decision makers (often payers or purchasing managers), as well as influencers (like physicians).

Innovators can choose to validate specific aspects of their needs with stakeholders at any time during the needs selection process. However, they usually get good results when they do so on a smaller set after significant cuts have been made (e.g., from 320 to 50 needs). Asking stakeholders to consider dozens of needs is far more

manageable than asking them to consider hundreds. On the other hand, if the list gets too small, there may not be enough choices among the needs to enable stakeholders to compare/contrast in order to identify the ones they truly find most compelling.

When approaching stakeholders for feedback on a list of needs, it is often advisable to quickly go through each one (or perhaps provide the list ahead of time for review) so that the full set of needs is understood before the stakeholder provides input. If each need is reviewed sequentially, invariably more time and effort is focused on the first few that are discussed. Another potential issue is that needs presented early may seem artificially interesting in the absence of information about more compelling needs that show up later on the list.

Another useful technique is to provide stakeholders with a few relevant selection factors and their associated rating scales and then ask the reviewers to objectively compare the needs. Importantly, these factors and their rating scales should be carefully customized to the perspective of each stakeholder. For example, a patient impact or physician impact selection factor might be appropriate when speaking with physicians, whereas a cost-effectiveness selection factor would be more appropriate for a payer or purchasing administrator. In addition to generating interesting insights, this approach can provide an efficient way for innovators to directly populate ratings for a stakeholder-oriented rating factor that can be used in the next round of needs selection.

Once stakeholders have validated the needs, this step usually does not need to be repeated in getting to the final list of top-priority needs since stakeholder opinions are unlikely to change significantly as the list of needs gets smaller.

Although stakeholder validation is a valuable technique and an effective way to keep needs selection linked to the interests of key stakeholders, innovators must strike a careful balance. It is absolutely critical that the input provided from stakeholders is used only as one data point in the ongoing needs selection process. All stakeholders have their own biases, and no single individual or group should be allowed to unduly influence the selection process. Ultimately, the team should choose its top-priority needs based on *all* of the input it has gathered and the research it has performed through the biodesign innovation process so far. Depending on the relationship between the innovators and the people they approach to validate their needs, it may be helpful to explain this in advance so that there are no misunderstandings if a need that appeals to a stakeholder is eventually set aside.

More needs selection examples

Given all the different ways to execute the six steps described above, there are countless variations of the needs selection process when it is put into practice. The factors, rating scales, weights, and scores chosen by each team will be unique. For example, one team from the Stanford-India Biodesign (SIB) Program followed the basic process when screening needs in pediatric medicine and maternal health, but ended up with an approach that was distinctive from the one shown in Figures 2.5.2 through 2.5.5 in several notable ways. Figure 2.5.7 summarizes the SIB team's needs selection approach.

This team entered the needs screening stage of the biodesign innovation process with more than 370 needs and went through four iterative selection rounds to eventually get to three top-priority needs. For each round, they used different factors, each with a specialized rating scale, as a mechanism for eliminating some needs and selecting others for additional research and evaluation. The SIB team did not explicitly assign weightings to the factors it used in each round. However, the rating scale chosen to support each factor implied a prioritization of the factors. For instance, in round 2, a need could earn up to five points for patient impact, but only a maximum of three points for the number of affected patients, understanding of the disease state and problem area, and treatment landscape. Such a system inherently assigned greater weight to the patient impact factor. Similarly, a mixed or incremental need was rated a one while a blue-sky need was given a zero, effectively weighting the selection process against blue-sky needs based on the team's preferred focus.

370+ Need Statements

Round 1 : Gut Check Screening						
Factor 1	Team passionate about need	Yes = 1	No = 0			
Factor 2	Need type (blue-sky, mixed, incremental)	Mixed/ Incremental = 1	Blue-Sky = 0			
If Factor 1=0 or Factor 2=0, need is eliminated						

~175 Need Statements

Round 2 : Screening Based on Moderate Research						
Factor 1	Number of affected patients	Large = 3	Moderate = 2	Small = 1		
Factor 2	Understanding of disease state and problem area	Clear understanding of a well-focused problem area = 3	Reasonable understanding of a somewhat defined problem area = 2	Limited understanding of an ambiguous problem area = 1		
Factor 3	Treatment landscape	No good options available to address need = 3	A few available options but need is still largely unmet = 2	Numerous options available to address need although they may be may be suboptimal in some way = 1		
Factor 4	Patient impact	Life saving = 5	Eliminates serious complications = 4	Eliminates undesirable outcomes but no impact on morbidity = 3	Improves patient experience, but has no clinical impact =2	No major impact = 1
Factor 5	Positive feedback from informal advisors	Yes = 1	No = 0			
Rank order needs based on total score and take top 50 needs						

~50 Need Statements

Round 3: Screening Based on More In-Depth Research and Expert Validation						
Factor 1	Market size	Greater than INR 50 Cr (USD $10 million) per year = 3	Between INR 50 Cr (USD $10 million) and INR 10 Cr (USD $2 million) per year = 2	Less than INR 10 Cr (USD $2 million) per year = 1		
Factor 2	Expert opinion	High preference = 3	Mid preference = 2	No preference = 1		
Factor 3	Provider value (cost savings to hospitals, reduced procedure time, lower skill requirements)	Changes 2 or more factors = 3	Changes at least 1 factor = 2	Changes no factors = 1		
Rank order needs based on total score and take top 15 needs						

~15 Need Statements

Round 4: Final Screening						
Factor 1	Competitive landscape	Intense = 1	Moderate = 2	Low = 3		
Factor 2	Industry/partner opinion	Yes = 0.5	No = 0			
Factor 3	Department of Biotech (and other govt. agencies) opinion	Yes = 0.5	No = 0			
Identify natural breaking point, then discuss remaining choices as a team to choose final set of top 3 needs						

FIGURE 2.5.7

An overview of the factors, rating system, and general approach used by a team from the Stanford-India Biodesign program to move from 370 to 3 top-priority needs (with permission from Ritu Kamal; developed with Nitin Sisodia and Pushkar Ingale).

Another interesting aspect of this approach is that the team validated needs with four different types of external experts at three different times during the selection process. In emerging markets like India, which do not have mature medical device industries, it is difficult to gather relevant and reliable market data. Accordingly, multiple levels of feedback from a diverse set of experts can help teams understand the relative merits of different needs. In round 2, SIB team members gathered feedback about a relatively sizable list of needs from informal advisors such as former Fellows and the physicians they interacted with during observations. In round 3, they validated their top 50 needs with department heads in pediatric medicine and other key opinion leaders. In round 4, the innovators gathered feedback on their final 15 needs from prospective industry partners, such as representatives from major **medtech** firms and foundations working in India. They also validated these needs with the Indian Department of Biotechnology and representatives from other government agencies to gauge their interest in having specific needs addressed. This input into the needs selection process reflects the desire of innovators in countries like India to partner with industry and government to increase their chances of success in developing new medical technologies. While there are certainly no guarantees, if a need is aligned with the interests of a prospective partner and/or the priorities of the government, it can potentially eliminate some barriers to funding and commercialization. In this case, one of the industry partners, Siemens Healthcare, went on to provide seed-stage funding for the SIB team's top need (*a better way to screen neonates for hearing loss in resource-constrained settings*) as it was closely aligned with the company's area of focus.[1]

Generally speaking, the needs selection process as described in this chapter works in any geographic environment. However, as the SIB example demonstrates, the factors, rating scale, weightings, and approach toward validation may vary depending on where the work is being performed. The team at Indian medtech accelerator InnAccel, which includes Jagdish Chaturvedi, Siraj Dhanani, and A. Vijayrajan, emphasized two main differences innovators should anticipate in working in a low-resource setting. First, they underscored the lack of available secondary data to use when conducting needs selection. As Chaturvedi, a former SIB Fellow and clinician, explained, "Gathering data in India can be very unpredictable, and many times we get information from research that is unreliable or irrelevant to the Indian setting." Accordingly, innovators at InnAccel use a factor in their needs selection activities that allows them to take into account the caliber of the data used to evaluate each need. If the need is supported by information that is India-specific and credible, meaning that it comes from **peer-reviewed** journals or reputable analyst reports, it is given a score of 1. Data that is not unique to India or comes from less reliable sources (or is mixed) is scored with a 0. In this way, data quality is lightly reflected in the overall scores for each need.

The InnAccel team also stressed that the needs selection process should be weighted toward factors linked to the cost of potential solutions and stakeholders' willingness and ability to pay for them. Given that most healthcare in India is funded using a self-pay model and, as a result, nearly all stakeholders in this environment are price sensitive, innovators must prioritize high value solutions that can be delivered at an affordable cost in order for them to have a reasonable chance of being adopted. Solutions that affordably deliver desired improvements are becoming increasingly important in all markets, but they are an absolute necessity in resource-constrained settings. InnAccel always includes a factor in its needs selection process that assesses the capacity of key stakeholders to pay. Another factor that the group sometimes evaluates is the extent to which needs can potentially be solved by shifting care to lower skilled care providers, since this is one way to effectively reduce cost and make solutions more affordable.

Independent of geography, a great deal can be learned from understanding the different ways that teams of innovators work through the needs selection process. The following story describes the approach used by the US-based medical device incubator, The Foundry.

FROM THE FIELD THE FOUNDRY

An incubator's approach to selecting needs

As described in chapters 2.1 and 2.2, The Foundry is a medical device incubator that helps innovators "rapidly transform their **concepts** into companies."[2] Because of the large number of needs the company evaluates each year, Hanson Gifford managing partners and Mark Deem are constantly in the needs selection process as they decide which projects to pursue and which opportunities will translate into the most promising solutions.

Gifford and Deem are inundated with new ideas every day. Some of these needs arise organically from related projects they are working on, while others are brought to them by entrepreneurs and inventors. With limited resources and even more limited time, Gifford and Deem are forced to make tough and relatively quick decisions about which needs should proceed to concept generation and which should not. While Gifford and Deem appreciate the merits of a well-defined, clearly structured needs selection process, they admit that their approach is only partially systematic. As Deem commented, "I'd like to say our project analysis is completely calculated, but each opportunity is different. At the end of the day, you have to take the facts around each of them and make a judgment call. Sometimes, as we move along, one need starts to make more sense. We've got better ideas and information in one area than we do in another and it becomes the lead horse," he explained.[3]

Despite their informal characterization of The Foundry's process for selecting needs, further discussion revealed that Gifford and Deem do, in fact, evaluate many of the objective and subjective factors described within this chapter. While they may not formally assign quantitative ratings and explicitly weight the factors via rigid analysis to come up with an overall score, they do much more than depend simply on their gut instincts. When pressed for information on how The Foundry makes decisions regarding which needs to pursue, Gifford highlighted the main factors that they consider: "The market opportunity, the clinical benefit, and the overall investment landscape – is the need attractive to investors? Are we going to be able to get there within our lifetime and with less cost than the national debt? We also carefully consider how likely something is to really succeed in the market." These criteria, consistently applied across needs, provide a basis of comparison that lends objectivity to the selection process. If there is only a small market for a product, or if the intellectual property is already substantially owned by others, The Foundry may be inclined to pass on the opportunity. Likewise, Gifford and Deem may steer away from a need if the referral and reimbursement patterns are unduly complex, or if prior research suggests clinical feasibility may be low.

Continuing to describe the factors they take into account in selecting needs, they emphasized the importance of stakeholder analysis, abiding by the saying that "A new therapy needs to be attractive to patients, physicians, and payers." Typically, the Foundry investigates the **value proposition** to all three groups before making a decision.

Gifford explained that it is also important to take the innovator's interests and motivations into account in the needs selection process: "This isn't just a one-time decision about whether projects A, B, or C are interesting to work on. It's a decision followed by several years of blood, sweat, and tears to make it happen. We have to take a good, hard look at ourselves and ask which opportunity we want to commit a portion of our lives to." That is not to say that they always stick with what they know and like best – as Deem pointed out, The Foundry has taken on highly diverse projects over the course of its history. Rather, he said, they must be excited about any need they decide to pursue. Over time, they have learned that a project only succeeds if the people involved want to work on it and not simply because it looks financially promising. If they are not enthusiastic about and truly interested in addressing the need, Gifford and Deem are more than willing to shelve it

and move on. They recognize that it is this sense of passion that has kept them excited about coming to work every day through many start-up experiences since 1998.

One of The Foundry's former companies, called Cierra, Inc., provides an example of how the group's needs selection criteria were applied to a new opportunity. Cierra was founded to develop a novel approach for the treatment of patent foramen ovale (PFO). This condition results from the incomplete closure of the septal wall between the right and left atria (upper chambers) of the heart, an opening that exists before birth to allow oxygenated blood to circulate throughout the fetus without having to pass through its lungs. In 75 percent of those with the condition, the foramen ovale closes naturally after birth. In the remaining 25 percent, it does not seal completely, allowing blood to flow directly, under certain conditions, from the right atrium to the left atrium.[4] As a result of the existence of a PFO, the natural filtration that the lungs provide is partially bypassed. Consequently, blood clots and other agents in the blood can go directly into the arterial system, potentially causing paradoxical embolism, cryptogenic stroke, and right to left nitrogen embolism in severe decompression illness.

Early in the innovation process, when Gifford and Deem first began looking at PFO, they did so at the urging of cardiologists in their network who anticipated that this was going to become an increasingly important need. At the time, there was no clearly defined **standard of care**. Many physicians believed there was no reason to treat for PFO unless a patient experienced cryptogenic stroke (a stroke with unknown causes). In these cases, patients often were prescribed chronic anticoagulation therapy. The condition could also be addressed through open surgery or a transcatheter intervention that used an implantable closure device to address the problem. Two transcatheter devices had received approval from the **FDA** for the treatment of PFO under a humanitarian device exemption (**HDE**), a category of FDA clearance that applies to devices designed to treat a population of less than 4,000 patients.

After initially studying the disease and evaluating stroke-related PFO opportunities against their selection criteria, Gifford and Deem were somewhat less than enthusiastic about the need. The market opportunity was relatively small, the attractiveness to investors was dubious, and the clinical benefits were not compelling relative to the amount of effort and investment required to conduct a stroke trial (which were notorious for being costly, lengthy, and difficult to enroll). "We just couldn't get excited about signing up for a project where we were going to have do a one-thousand patient **clinical trial** to try to show an improvement in stroke rates from one single digit number to another single digit number," recalled Deem. "We were about to shelve it," he continued, "when we came across some of the first articles that were being published on the migraine-PFO association." As Erik Engelson, who later became CEO of Cierra, described, "There were observations and some single-arm studies that were published. In deep-sea divers who were having PFO treated for decompression illness and in stroke patients who also had migraines and had their PFO closed, the observation was that the frequency of migraine decreased after the procedure." "That caught our interest, and we started studying it a little bit more," said Deem. "It was still a relatively unproven association, but we felt like there was probably something there that could transform this into a huge opportunity." Although there was still a fair amount of uncertainty surrounding the linkage between migraines and PFO closure, as well as the amount of time and cost required to develop a solution, Gifford and Deem became passionate about pursuing the need.

When Gifford and Deem reapplied their selection criteria to the migraine-related opportunity, it was more appealing, in part, because it seemed that the market could potentially be more easily and quickly accessed than the stroke market. While the symptoms of this larger population of migraine sufferers were not life threatening, they could be severely debilitating so Gifford and Deem perceived the clinical benefit of a solution to be significant in terms of improving quality of life. Moreover, Gifford and Deem anticipated being able to more effectively get

investors interested due, in part, to recent activity in the field. “All of a sudden this market was hot,” recalled Engelson. “There was this public company called NMT Medical, the market cap of which doubled on the buzz of upcoming completion of their UK-based migraine study [the MIST-I study].”

The apparent attractiveness of the opportunity was also enhanced by the novel concept of closing PFO with a non-implant solution (rather than leaving behind an implant in the heart). As a result, The Foundry team refined its **need criteria** to include this design requirement. “An implant is all well and good if you’re a 75-year old patient who has already had one or two strokes and you’re trying to prevent another one,” Deem said. “But if you’re a 25-year old migraine sufferer who is otherwise reasonably healthy, having a metal implant in your heart for the rest of your life is a completely different value proposition due to known [and yet-to-be known] complications associated with some of the PFO implant devices. The notion of a non-implant solution played positively to cardiologists, patients, neurologists, and investors. So, we decided that we needed a solution that left nothing behind in the heart.” It would have been a lot easier and faster to simply pursue a better implant. But, as Deem summarized, “We felt like the benefit of leaving absolutely nothing behind versus having the next best clip warranted the decision to go forward there.”

When Engelson was recruited to head Cierra, the company had 12 employees. The team had evaluated clips, snaps, staples, sutures, and patches to build a broad IP position, but ultimately decided on an implant-free system that closed the PFO using suction and “tissue welding” performed percutaneously using radiofrequency (RF) energy (see Figure 2.5.8).

Under Engelson’s leadership, Cierra refined its product, completed animal testing, treated eight human patients in Germany (with an initial 75 percent PFO closure rate), and raised $21 million in next-round funding (incremental to the previous $8 million). The team also had a series of promising meetings with the FDA. In order for the PFO-migraine solution to be successful, the company needed to be able to design a clinical study that would address the agency’s safety concerns related to applying RF energy to the heart. “The FDA really seemed to like the non-implant solution. They gave us a verbal thumbs-up on our safety data,” Engelson recalled.

FIGURE 2.5.8
The Cierra device (courtesy of Cierra, Inc.).

Shortly thereafter, however, Cierra faced a reversal of fortune. “When we formally submitted our **clinical protocol**, the written feedback we received seemed to differ significantly from the verbal feedback on the conceptual study design we had previously discussed

with the FDA," said Engelson. The FDA's written feedback (questions and suggestions) directed the company to conform its study design to that of the other migraine studies, which were not enrolling. Around the same time, the company found itself achieving mixed technical results. "We had learned to segment by size and we were getting good PFO closure in smaller PFOs, but still had work to do in the larger ones. Closing the large PFOs was becoming an insurmountable challenge with the RF technology," noted Engelson. Additionally, when NMT released partial results of the MIST I trial in spring 2006, the buzz around PFO-migraine opportunities diminished. In that study of 147 patients, there was no difference in headache cure between migraine sufferers receiving PFO closure and those receiving the sham procedure.[5] Despite these challenges, Engelson noted, "We believed in this." "We had signed up and we were fighting this war together. So we carried on." The company's efforts continued until late 2007, when it finally discontinued its operations. Interestingly, NMT Medical announced that it was halting its MIST II (US-based migraine) trial one month later, citing difficulty in enrolling patients in the study and the need to redirect the millions of dollars necessary to sustain their stroke investigation.[6]

Reflecting on the Cierra experience, Engelson commented that some of the challenges faced by the company could be traced back to steps in the needs selection process. While the team's market analysis demonstrated that migraine was, in fact, a bigger and potentially more easily accessible market segment, it later became clear that neurologists, not cardiologists, were the key stakeholder group since they would be the ones to control study enrollment. And, unfortunately, they were generally not supportive of PFO-migraine studies. "It wasn't a cardiology deal," said Engelson. "It was a neurology deal. Compared to cardiologists, neurologists tend to be less aggressive – they were not enthusiastic to try new, interventional technologies. They're used to using drugs to manage their patients," he noted. While initiating an interventional procedure to address a quality of life issue might have been broadly accepted in cardiology, the concept was viewed skeptically in neurology.

The definition of a need criterion to develop a non-implantable solution also may have unnecessarily constrained the company's efforts and eventually contributed to its difficulties in overcoming the technical challenges associated with closing large PFOs. According to Engelson, "We spent a lot of time and money developing a totally non-implantable solution when, in hindsight, I'm not sure that this was as critical as initially thought. We may have been better served by developing a succession of products for PFO closure: first a very small implant such as a clip, which would be much smaller than the existing implants, followed by the non-implant technology. This technology-product tradeoff decision (or product portfolio planning) process might have been more effective had we had a visionary and inventive physician as part of our internal thinking process."

Overall, summarized Engelson, "It was the FDA's high study-design hurdle, the lack of support by migraine neurologists, and the remaining technical challenge in closing larger PFOs without an implant that collectively led to our shut-down decision." Similar issues had proven to be challenging for numerous other device-based companies working in the field. Ultimately, the combination of having to demonstrate the safety and effectiveness of the intervention in parallel with addressing basic science questions about the PFO-migraine link that remained unanswered presented too much risk for the company to proceed.

Need specification

Once a small set of top-priority needs has emerged from the needs selection process, a need specification should be created for each one. A need specification is a detailed, but succinct stand-alone document that (1) presents the need statement, (2) summarizes the data gathered through the needs screening process (chapters 2.1 through 2.5), and (3) outlines the need criteria that

any solution must address in order to satisfy the need. These criteria should be organized into "must-haves" and "nice-to-haves," with typically 4–6 key requirements in each category.

The information in the need specification serves as guiding principles for the next stage of the biodesign innovation process – concept generation. For this reason, it is essential that each specification is prepared thoroughly. However, this should not be viewed as an exhaustive task. Innovators should apply roughly the same level of effort and rigor to creating a need specification as they would to developing a research paper.

Keep in mind that the need specification is not a static document, presentation, or outline, but rather evolves and changes as the data that goes into it is updated and revised. Ultimately, the need specification has to be finalized prior to entering the concept generation stage but, as with many parts of the biodesign innovation process, getting to that final document is itself iterative.

In creating a need specification, innovators may also uncover information that throws the needs selection process into a new light. For example, when compiling more detailed data about various treatment options, they may realize that one solution, previously thought to be unimportant, is actually of significance. If elements about competitive landscape were included in the selection process, new information could suggest that certain ratings may need to be adjusted. Although minor adjustments are not likely to have a significant impact on the overall ranking of needs, it is important to confirm this by revisiting the needs selection process. Major adjustments in rankings will typically only occur if important information was somehow missed in the initial screening process or if the research performed at each stage of needs selection was kept too superficial, even as the number of needs was being reduced. This interaction of the needs selection process with the creation of the need specification once again highlights the iterative nature of the biodesign innovation process.

Sometimes innovators may try to shortcut need specification by preparing one background document for multiple needs that overlap, particularly when they all focus on a given disease state. However, in doing this, the innovator runs the risk of creating confusion about the key drivers of each need, especially if those are not clearly separated. Additionally, since a need specification provides a key input into upcoming ideation sessions, it is undesirable for information about competing or alternate needs to distract participants or bias their thinking if it is included in a combined need specification. Additionally, even with only a few needs remaining, some will continue to fall off the list of the innovator's top priorities as more information becomes known. If each need has its own specification, this can more easily be accomplished.

In terms of content, a need specification provides a summary of the most important and relevant information gathered in support of the need. It is often organized into the sections outlined below, although the document does not have to follow this outline exactly. Innovators have the freedom to experiment with different headings and ways of organizing their need specification, as long as all of the most relevant and informative content is included. See online Appendices 2.5.1 and 2.5.2 for two real-world examples of need specifications that have quite different forms, but cover most of the same fundamental information. The format of the need specification can also vary. Need specifications usually are created as either several-page papers, slide presentations, or bulleted outlines.

One final point is that a need specification should incorporate quantitative data that support the need. In describing the problem area to which the need is related and the market that could be addressed by a new solution, innovators should reference relevant facts and figures to add specificity and credibility to the document. Need criteria are often used to help quantify ideas captured in the need statement. For example, if a need statement refers to a requirement for something smaller, a need criterion might provide a specific size, limit, or target range. Need criteria can also clarify why certain requirements exist; for instance, a solution should be small so it can placed through a specific type of incision.

The need statement

The need statement can be used as originally written (see 1.3 Need Statement Development) or refined based on what has been learned through researching. Sometimes innovators and teams refine their needs progressively, as

research is performed. In other cases, they make adjustments when creating the need specification. Both approaches are acceptable, as long as there is not a fundamental altering of what was actually observed. Refining and clarifying the need helps ensure the team shares a common understanding and can position it for greater success during ideation.

The problem

The summary of the problem should address affected anatomy and physiology, disease mechanisms of action, disease progression, past and current approaches to addressing the problem, outcomes, complication rates, and a gap analysis of existing and emerging treatments, including costs relative to the improvements they deliver (see 2.1 Disease State Fundamentals and 2.2 Existing Solutions).

Market description

The market overview should cover high-level market-related information from the needs research process, including data about the target market, procedure volume, treatment penetration, competitive landscape, and burden on the healthcare system (see 2.3 Stakeholder Analysis and 2.4 Market Analysis). Additionally, important insights related to the potential value of a solution to the need should be included.

Need criteria

As noted, need criteria are the key elements required and/or desired from any new solution by the stakeholders with an interest in the need (e.g., efficacy rates, compatibility with other devices, ease of use). Must-have criteria are essential to addressing the need and should correspond include the core requirements of decision makers. Nice-to-have need criteria are not imperative but would make the solution more attractive. They often correspond to the requirements that are most important to influencers.

A preliminary set of need criteria requirements is usually developed as the need statement is defined (see 1.3 Need Statement Development). However, unlike these initial requirements, which are primarily based on observations, the criteria in the need specification are significantly influenced by the data gathered from research about the problem and the market. These data allow innovators to more deeply understand the key issues that must be met for a need to truly be addressed.

For example, consider the need for *a way to perform testing for skin lesions at the point-of-care to enable accurate, inexpensive diagnosis of malignant melanoma by a dermatologist*. The team members working on this project developed four must-have need criteria that they believed were critical to the adoption of any potential solution, along with a comparable set of nice-to-have criteria that would potentially increase the attractiveness of an offering (as shown in Table 2.5.6).

As this example illustrates, need criteria (particularly the must-haves) should be specific and measurable. Quantitative criteria are especially useful in helping the team be as unambiguous as possible in understanding what is required to adequately address a defined need. Quantitative need criteria can usually be developed relative to benchmarks uncovered through the team's observations and research in the need area. For example, after learning that the national average for the length of a dermatology appointment was approximately 15 minutes, this team determined that dermatologists must be able to administer a new point-of-care diagnostic *and*

Table 2.5.6 Defining strong need criteria is essential for guiding concept generation and selection (with permission from Varun Boriah, Tiffany Chao, and Ryan Krone).

Must-haves	Nice-to-haves
Point of care: < 10 minutes at dermatology clinic	< 1 minute interface time with patient
Accurate: Sensitivity > 98 percent Specificity > 50 percent	Interface component is physically small (can hold in one hand)
Inexpensive: < $190 (which is the current reimbursement rate biopsy + pathology)	Disposable component
Portable	Can be performed by a mid-level provider

deliver the test results comfortably within this time frame. They derived requirements around the sensitivity and specificity of a new solution by assessing the current performance of tests typically performed by primary care physicians and dermatologists, as well as standards set by the state-of-the-art technology available in the field. They then chose accuracy targets that were likely to be viewed favorably relative to the increased convenience and affordability of a new solution, and so on.

Developing need criteria can be more art than science, but it is important that the information gathered through needs research be used to help refine and specify the criteria in such a way that imperative requirements can be distinguished from those that are desirable but not on the critical path. However, recognize that creating too many absolute criteria (more than 6–8) will place too many constraints on concept generation and screening. Innovators should stay focused on the few criteria that are absolutely essential to address the need.

Finally, while some need criteria may specify product attributes (e.g., small, able to be placed via a blood vessel), these more specific attributes should still be kept at a high level. The point is to avoid the implication of a solution while reflecting the accepted constraints for the need (e.g., developing a solution for a problem accepting the fact that it should optimally leverage a catheter-based platform). Need criteria should also continue to evolve and become increasingly concrete as innovators iterate the need specification.

References

All quantitative informative included in the need specification must be cited using commonly accepted conventions for footnotes or endnotes. Quotes from stakeholders should also be cited in the list of references.

The following story describes how one team went through the process of selecting a need and developing a need specification.

FROM THE FIELD BLOOD STREAM INFECTION TEAM

Selecting a need and developing a need specification

As part of their experience in Stanford's Biodesign Innovation course, Eric Chehab, Carl Dambkowski, Jon Fritz, Siddartha Joshi, Brian Matesic, and Julie Papanek began thinking about the incremental need for *a way to reduce catheter-related bloodstream infections*. Recognizing that they would have to refine the need statement to be more actionable and focused, they simultaneously initiated needs scoping and needs research. They started by investigating blood stream infections and the different types of catheters used in the hospital setting, such as dialysis catheters, central lines, PICC lines, chemotherapy ports, and pediatric catheters. After gathering preliminary disease state, treatment, stakeholder, and market data in each area, they defined four preliminary factors to help them compare the opportunities and narrow their focus: (1) infection rate; (2) utilization/volume; (3) the extent to which existing technologies effectively targeted the problem; and (4) the fit with the team's interests.

Through the first selection round, the team converged on pediatric catheters and related blood stream infections (BSIs). In particular, infections rates with pediatric catheters were much higher than in the other areas. "We were drawn toward the highest infections rates where we could really make a difference and where showing an improvement would be easier," said Papanek. They were also struck by the lack of existing technologies designed specifically to address pediatric needs and the fact that few (if any) companies seemed to be working on unique solutions to reduce catheter-related BSIs in neonates.

With this refined focus, they dove back into research to go deeper into pediatric-related disease, treatment, stakeholder, and market characteristics. "Basically," said

Chehab, "we redid our research each time we refined the need." Papanek added that, "As we were pulling in more and more data, our understanding of the needs improved significantly." In total, the team completed two additional rounds of needs scoping and refinement, each time using the same four factors to help them make a decision. Coming out of the second round, they narrowed their focus to catheter-related BSIs in premature babies. The third round led them to umbilical cord catheters and the need for *a way to prevent bacteria from entering the blood stream in neonates with umbilical cord catheters in order to reduce the rate of BSI infections*.

In validating the need statement, many of the experts they spoke with drew attention to the fact that the market for neonatal umbilical catheters was relatively small. The team had uncovered this in its research, but decided that it offered some attractive trade-offs. Although the market was not likely to support a stand-alone business, it was an important need that could have a substantial impact on neonatal health. In addition, they believed a solution could be developed quickly and with limited technical risk because non-neonate-specific devices already existed. The team members did not have to come up with something completely novel, they just had to figure out how to adapt available technologies to the unusual morphology of the umbilical catheter and this unique patient population. For these reasons, it would be a good "first project" for the group to undertake, with the hope of licensing the solution to a larger firm and then moving on to other, potentially more lucrative opportunities.

Another important insight from the team's research and its need validation activities had to do with the value that any solution would have to deliver to the healthcare system. "From the get-go we knew that we were trying to reduce overall cost for the hospital, especially since hospital-acquired blood stream infections are expensive and no longer reimbursed by Medicare," said Chehab. For each infant that contracted a BSI, costs to the hospital increased by approximately $40,000. That said, catheter-related BSIs affected 5–15 percent of babies admitted to the neonatal intensive care unit (NICU). For a facility like Lucile Packard Children's Hospital, which typically administers umbilical catheters to less than 250 NICU patients a year, the annual cost of the related BSIs was approximately $260,000. As Papanek summarized, "The majority of babies never get a blood stream infection, so a solution essentially has to be a cheap insurance policy for the hospital."

Taking this information into account, the team defined another factor that would affect the success of a solution. To be widely adopted, the members believed that any solution they designed would have to seamlessly and easily integrate with existing catheterization protocols. "We could not expect to reinvent catheter placement or change the current procedure. This solution had to be an add-on to the current catheter placement method – possibly bundled with the current catheter set – to reduce catheter-induced infections," said Dambkowski.

With these factors clearly in mind, the team was able to define clear need criteria as part of developing its need specification. Issues related to value and adoption were placed prominently on the list of "must-have" criteria,

Need criteria

A way to reduce BSI infections caused by umbilical catheters in premature neonates without increasing additional side-effects

Must Haves

- BSI rate <7.1/1k patient days
- No significant increase in small artery elasticity
- Deliver required TNP, drug, and fluid and enable blood monitoring available in competing products
- Can be used immediately after birth
- Can be used in babies with APGAR score <7
- Integrates into existing procedure
- Does not increase net healthcare expenses to system

Nice to Haves

- Safely and effectively utilized for >14 days
- Can be used in very low birth weight infants (<1000g)
- Does not increase antibiotic resistance
- Can be inserted without X-ray confirmation
- Can be legally placed by a nurse
- Simple training to facilitate rapid adoption

FIGURE 2.5.9

Need criteria as defined by the team (with permission from Eric Chehab, Carl Dambkowski, Jonathan Fritz, Siddhartha Joshi, Brian Matesic, and Julie Papanek).

along with a variety of additional clinical and technical requirements, supported by quantitative guidelines. Other requirements to improve the patient and physician experience and make an easy-to-use solution were included among the "nice-to-have" criteria as shown in Figure 2.5.9.

Eager to transition into concept generation, Chehab, Dambkowski, Papanek, and their colleagues committed themselves to using these need criteria as a guide through ideation and eventually in choosing a solution. A variation of the team's complete need specification is available in online Appendix 2.5.1.

Ultimately, the innovators designed a product called the LifeBubble – a small rigid bubble that is placed around the umbilical catheter insertion site to secure the catheter and reduce BSIs by covering and isolating the area, to prevent the migration of bacteria from the skin to the stump. LifeBubble is still in development.

Online Resources

Visit www.ebiodesign.org/2.5 for more content, including:

- Activities and links for "Getting Started"
  - Choose selection factors
  - Assign ratings
  - Calculate scores
  - Validate and select needs
  - Create need specification(s)
- Videos on needs selection
- Appendices that provide sample need specifications for two projects

CREDITS

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NOTES

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STAGE 2: NEEDS SCREENING

At the same time that Makower and Chang were investigating the chronic sinusitis need, they continued to press forward with investigating needs in orthopedics, respiratory disease, and congestive heart failure (CHF). However, delays in gathering information and gaining access to perform observations allowed chronic sinusitis to become somewhat of a "lead horse" in their efforts to identify which project to work on.

Importantly, they developed more than one need in this area. For instance, in addition to finding a potential alternative to FESS surgery, they also saw the need for improved, more dynamic diagnostics that would allow ENT specialists to more accurately assess a patient's condition. As Chang explained, "In ENT surgery, they use endoscopy and computer tomography (CT) scans to assess symptoms. But the results from these measures don't necessarily correlate. CT scans are static – they provide a snapshot in time, just like endoscopy. So, you can have a picture-perfect CT scan from a week ago, but the patient feels terrible today, and vice versa. So it's pretty obvious that the surgeons are working virtually in the dark and going on their best clinical judgment rather than a single conclusive diagnostic test."[1]

With an understanding of the clinical problems in the area and a working hypothesis for addressing more than one important need, the next step in the process was to perform more detailed research regarding the disease state, existing solutions, stakeholders, and market. Once this was completed, they would be in a much better position to screen the needs and decide which one should become their chief focus.

2.1 Disease State Fundamentals

To understand the disease state, Makower and Chang threw themselves into a thorough literature search. They sought to understand the anatomy and physiology of the sinuses by looking at surgical textbooks, cadaver dissection books, and hundreds of CT scans (see Figure C2.1).

In terms of understanding the pathophysiology of chronic sinusitis, they did more book research and combed peer-reviewed clinical articles, paying particular attention to the disease's mechanism of action. However, as Sharon Lam Wang, a consultant to the ExploraMed II team, pointed out, "Chronic sinusitis is not a given. It's not like we understand what this is. Even the physicians in the field don't agree on the definition. Is it a syndrome? Is it a disease? How do allergies play into it? How does the anatomic makeup of the patient affect the condition? It's a multi-factorial disease that seems to have a life of its own." Lam Wang was an experienced device professional who had worked with Makower and Chang at TransVascular and had played an important early role at both Kyphon and Hansen Medical.

Given the complexity of the disease, Makower and Chang felt that secondary research would not be enough to ensure an adequate understanding of it. Their primary research strategy would involve direct physician input, as well as cadaver dissections. However, they wanted to be highly selective about interfacing with ENT specialists so early in their process. "We needed somebody who we really felt was a safe person, who understood this space very well, but ideally was someone who did not work directly as a rhinologist," explained Makower. "This kind of person would be able to provide great clinical feedback and training for us, but we wouldn't have burned a bridge or potentially mismanaged a relationship with anyone in our target market. We needed someone without a vested interest in what we were doing." The team found such an individual in Dr. Dave Kim, who was an ENT physician, but a specialist in facial plastics for cosmetic and post-traumatic applications. The referral to Dr. Kim came through one of ExploraMed's board members. According to Makower, "We went to him and basically started from scratch. What's a sinus? Where are they located? Why do they remove that structure? We revisited all of the basic physiology, how it functions, and so on. And then we went into the anatomy lab and

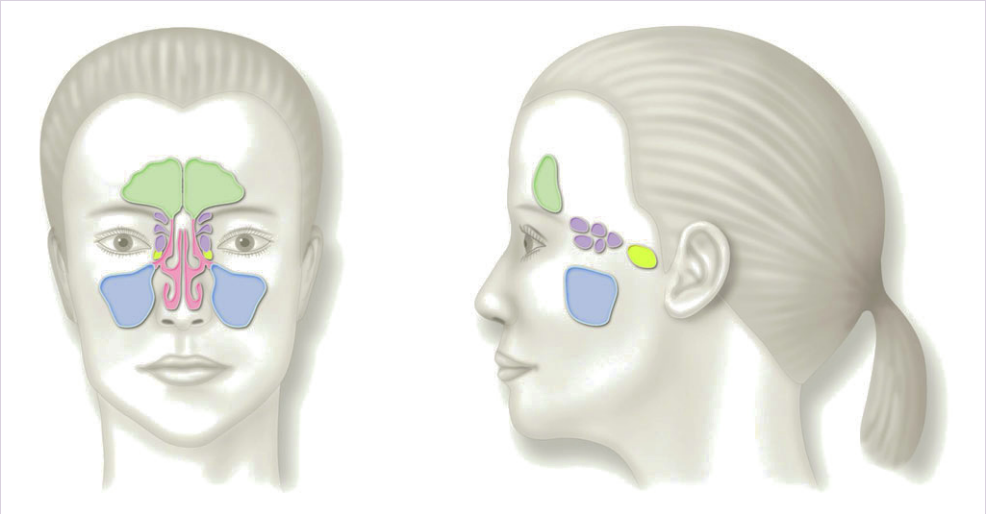


FIGURE C2.1
The sinuses are four bilateral sets of air-filled cavities with ostia that connect to the nose. The frontal sinuses are in the forehead, the ethmoid sinuses are groups of small air pockets located between the eyes, the sphenoid sinuses are behind the eyes, and the maxillary sinuses are in the cheek area. Each sinus has an opening through which mucus drains. The drainage of mucus is a normal process that keeps the sinuses healthy. Mucus moistens the nasal lining and protects the inside of the nose from impurities such as dust and bacteria (provided by Acclarent).

did a detailed dissection with him where he pointed out all the structures, which was very helpful." In terms of a key take-away from the investigation, Makower stated, "For most people it seemed that when you have good flow out of your sinuses, you have healthy sinuses. That seemed to be the bottom line" (see Figure C2.2).

Other important information gleaned from the team's disease research is shown in Table C2.1.[2,3,4]

2.2 Existing Solutions

In parallel with learning about the disease state of chronic sinusitis, Makower and Chang studied existing and emerging solutions in the field. "This is where being a patient myself came back into play," said Makower, "because I had been very frustrated with my choices." He elaborated on the progression of clinical treatment:

> *First, there are a variety of over-the-counter drugs, like Sudafed and other allergy medications, to reduce mucus and relieve minor symptoms. At the next level, under doctor's prescription are antibiotics and sprayable steroids, such as Flonase. These always scared me – I never liked the idea of spraying steroids into my nose. Then, before someone would qualify to get surgery, a lot of doctors prescribed high doses of oral steroids, which can introduce significant side effects. Finally, in the worst cases, functional endoscopic surgery was performed. Over the years, I had seen multiple ENTs regarding the possibility of surgery. But each time, they would look at my CT scans and say, "You know, you just don't have bad enough disease in your sinuses for us to do anything." And that never really made sense to me, because I was really suffering. But, after watching these surgeries, I finally understood why they were steering patients away. They were protecting me from the potential complications of surgery, which are severe when they happen. The surgical tools they use to perform FESS [see Figure C2.3] can sometimes cause scarring, which actually can create a whole new level of disease itself. For a recurrent sinusitis sufferer like me, without surgery, I might have had months of symptoms from swollen sinus that would eventually subside. But after FESS, it would be possible to end up with a permanently scarred ostium that would have had little or no chance of draining, with the possibility of even worse symptoms than I had before.*

Table C2.1 Chronic sinusitis is a serious medical condition that affects a significant number of patients.

Sinusitis facts
Sinusitis affects approximately 39 million people each year (or 14 percent of the adult US population), making it one of the most common health problems in the US.
It is more prevalent than heart disease and asthma and has a greater impact on quality of life than chronic back pain, diabetes, or congestive heart failure.
Common symptoms, which can affect patients physically, functionally, and emotionally, include facial pain, pressure and congestion, discharge and drainage, loss of one's sense of smell, headache, bad breath, and fatigue.
Direct healthcare expenditures due to sinusitis total more than $8.1 billion per year.
Patients with chronic sinusitis have symptoms that last more than 12 weeks (patients with acute sinusitis usually have their symptoms resolved in less than four weeks).
Approximately 1.4 million patients are medically managed for chronic sinusitis each year.
Patients with chronic sinusitis make 18–22 million annual office visits per year and have twice as many visits to their primary care doctors and five times as many pharmacy fills as those who do not.

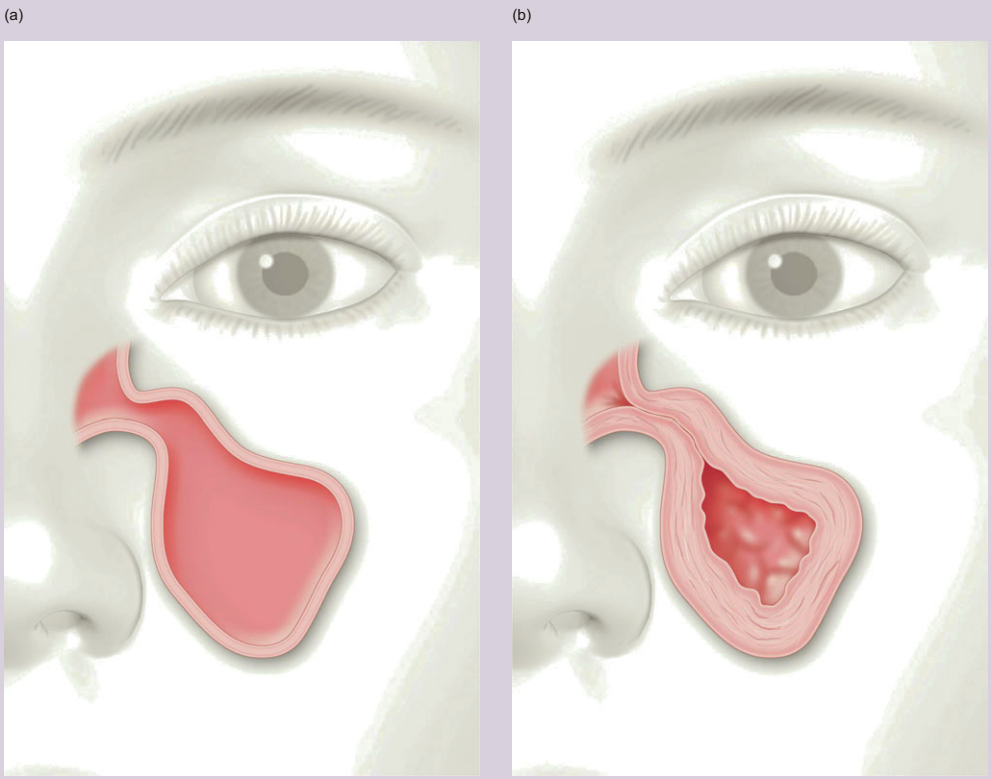


FIGURE C2.2
Sinusitis is an inflammation of the sinus lining most commonly caused by bacterial, viral, and/or microbial infections, as well as structural issues such as blockage of the sinus opening (ostium). If the ostium becomes swollen shut, normal mucus drainage may not occur. This condition may lead to infection and inflammation of the sinuses (provided by Acclarent).

Of the 1.4 million people who are medically managed for chronic sinusitis each year, approximately 970,000 are considered candidates for FESS surgery. The goal of this procedure is to remove bone and tissue to enlarge the sinus opening and restore drainage. Yet, a surprisingly small number of the qualified surgical candidates – just 500,000 per year – undergo the FESS procedure.[5] Some of the most common reasons patients declined the surgery are summarized in Table C2.2.[6]

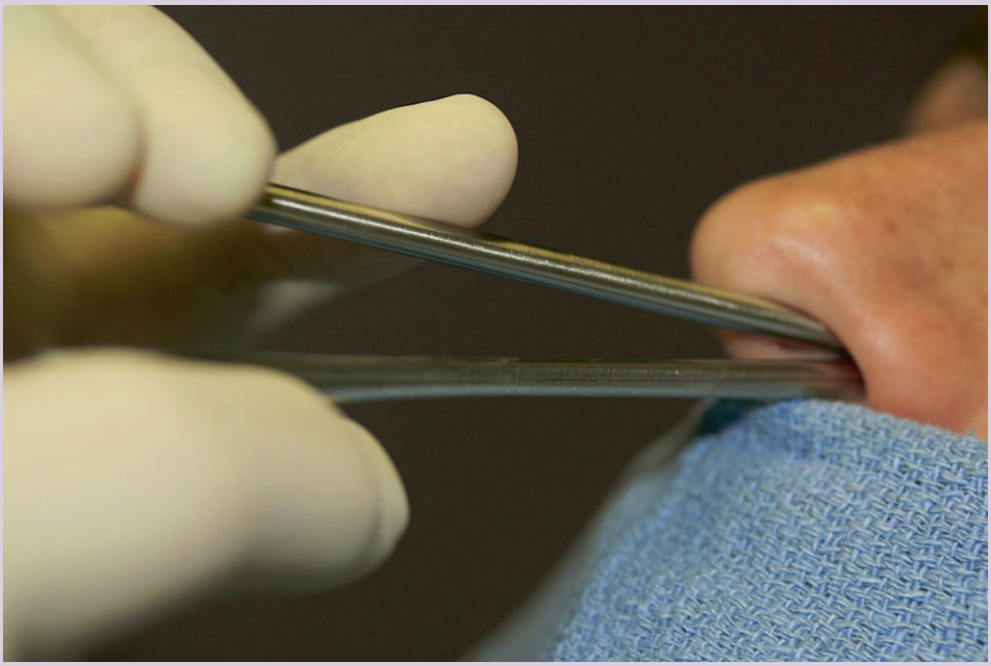


FIGURE C2.3
Functional endoscopic surgery uses straight, rigid tools in the tortuous sinus anatomy. As a result, surgeons are often forced to remove healthy tissue and bone simply to reach the infected sinus(es) (courtesy of Acclarent).

After investigating these risk factors, Makower noted, "It was clear that this procedure had not been completely fixed yet." Chang added, "Patients described feeling terrible for a week or two post-operatively, as if they were recovering from being hit in the face with a baseball bat. This was often accompanied by swelling and the occasional black eye. But, even worse is the fact that there can be a significant revision rate. That's horrible! How do you ask patients to go through such a painful surgery and recovery with an almost one-in-four chance that they will need to go through it again?"

2.3 Stakeholder Analysis

Understanding the risks involved with FESS helped provide Makower and team with insights into how the patients felt about the procedure. As a result, they spent the majority of their time during their preliminary stakeholder analysis evaluating the perspectives of physicians. Research was also performed on payers and facilities, but this work will be described in more detail in the stage 4 section of this case (under reimbursement).

Lam Wang performed much of this physician research, joining the team to determine if the group could realistically make a business in this area. When she got involved in the project, she believed that ENT specialists would respond positively to new innovations in the area of chronic sinusitis:

> *I thought that they were open to new technology, primarily because of the FESS revolution that had occurred in the 1980s. Before then, sinus surgery was done open through cuts on the face or through the gums to get to your sinuses. They would literally peel away the skin on your face to get to your sinuses. With the advent of the endoscope, physicians switched over to accessing the sinus through the nose. It was almost like an overnight switch, and they adopted the new approach with no clinical data indicating that it worked better. Even when we were researching the problem, there was very little data out there. And so that told me these folks are willing to be practical and open-minded to new ways of doing things.*

To confirm this point of view, she conducted interviews with four or five well-respected doctors in the ENT specialty – those physicians who routinely performed FESS. "In these initial discussions, nothing led me to believe that they would be resistant," she recalled.

Table C2.2 FESS procedures can be fraught with pain and risk.

About FESS
FESS is successful in approximately 76 to 98 percent of all procedures[7] (with revision rates up to 24 percent).
Post-operative visits to remove debris, clots, and scars from the surgical site are often needed and can be painful.
Rigid steel surgical instruments are used to perform the procedure through the patient's nostrils, which creates the need to remove bone and tissue so that the physician can reach target sinus and open the ostium to facilitate drainage.
The procedure is conducted under general anesthesia.
Given the proximity of the sinuses to the skull and eyes, there is a small chance with every surgery (one in 200) that the surgeon will inadvertently remove a piece of thin bone between the sinus and the brain, which can cause a spinal fluid leak and can introduce the risk of meningitis.
Blindness is another possible complication from the procedure if the wall of the sinus against the eye socket is breached.
Due to the highly vascular nature of the nose and sinuses, the nasal cavity can sometimes require packing with gauze to absorb bleeding from the procedure, and its subsequent removal can be painful.
Although the procedure is usually performed on an outpatient basis, it is often described by patients as one of the worst experiences of their lives.
Following surgery, it can take weeks for the ancillary effects (e.g., swelling) to subside in order to determine whether the procedure was successful in opening the ostium.

From Chang's perspective, however, there were some mixed signals coming from their physician stakeholders. He explained:

> *On the one hand, we'd talk to them and they'd claim to be "gadget guys." They'd tell us how much they loved new toys, like powered instrumentation and surgical navigation. This gave us the feeling they might be excited to adopt new technology that did things a little better. On the other hand, as we peeled back the onion, we recognized that most of what they were talking were about incremental innovations taken from other specialties – powered shavers from orthopedics and surgical navigation for neurosurgery. Procedurally, they were still cutting and removing bone, where the shaver and navigation system allowed them to do it more efficiently and safely. These were certainly improvements, but not huge leaps forward in their approach to surgery. They were also very proud of keeping the same instrument set for the last 12 years. They would handle these steel instruments with the utmost care because they didn't want to break them and subsequently have to pay for a new set. This did concern us.*

Despite the uncertainty raised by the conflicting feedback gathered by Lam Wang and Chang, the team felt reasonably comfortable pressing forward with their investigation of the needs in this space.

2.4 Market Analysis

The next step was to perform a more detailed assessment of the market. The team believed that to get a truly accurate estimate of the market, it would not be enough to rely on the broad-brush estimates published in the available literature. So, they started from scratch. To determine the incidence of people affected by chronic sinusitis each year, Lam Wang researched the clinical literature and found a study that used ICD-9 diagnosis codes to estimate the true number of adults diagnosed with the condition.

Next, she worked through a cycle of care analysis to identify the "low hanging fruit" – people who do not benefit from drug therapy, are considered candidates

Estimated Market Potential for Exploramed

U.S. Market Model for 2004

	294.2	M	U.S. population 2004
	1.96%		annual incidence rate of CRS as indicated by ICD-9
	5.8	M	individuals diagnosed with CRS
	87.0%		non-pediatric
	5.0	M	adults diagnosed with CRS in 2004

X	90%		**≥ 12 wk symptoms**	X	10%		**recurrent acute**
	4.5	M			0.50	M	
X	20%		refractory to medical therapy	X	30%		due to unfortunate anatomy/ostial obstruction
	0.9	M	referred to ENT for surgery consult		0.15	M	candidates for surgery
X	90%		positive CT scan	-	0.03	M	FESS on recurrent acute pts today
	0.8	M	really have CRS				
-	0.3	M	FESS procedures on CRS pts today				
	0.5	M	refractory to meds but don't get surgery today		0.12	M	recurrent acute pts with unmet clinical need
	515,705		**CRS pts with unmet need for Exploramed**		**117,501**		**recurr acute pts with unmet need for Exploramed**

Potential initial target market	**117,501**	**Recurrent acute pts with ostial obstruction but no surgery today**
Potential target market	**515,705**	**CRS pts refractory to meds and no polyps but no surgery today**
Potential expansion populations	**330,000**	**Cannibalize FESS** **Pediatric** **Undiagnosed pts who do not seek treatment**
TOTAL Potential Market	**963,206**	

FIGURE C2.4
The market analysis for chronic sinusitis pointed to a large unmet medical need (provided by Acclarent).

for surgery, but elect not to undergo the FESS procedure. After diving into all the numbers, validating them with practicing physicians in the field, and testing all the assumptions in the model through an iterative process, she had a preliminary answer. "It turns out it was a phenomenally high number, like 900,000 patients per year, who might be candidates for an alternate procedure," Lam Wang recalled. "So that spoke to a huge unmet need." Importantly, this figure included the more than 300,000 patients per year currently undergoing FESS (assuming they might eventually move toward an alternate procedure). It also took into account a certain type of chronic sinusitis called recurrent acute sinusitis, which met the definition of sinusitis but was "considered a different animal." According to Lam Wang, "These are folks who have frequent episodes, possibly because of their anatomy – a narrowing in their passageway. Getting at these numbers required a lot of iteration with the doctors." See Figure C2.4 for the basic model.

The fact that there were "tons and tons of possible patients, but not a lot of procedures being performed," indicated to Lam Wang, Makower, and Chang that the current and future opportunity was highly attractive. If they could create a less invasive solution that could be performed in the specialist's office rather than in the operating room, they had the potential to create even greater value by reducing costs in the process of providing an improved solution.

2.5 Needs Selection

By the time the team members had determined that the total potential market for an alternative technology for FESS surgery could reach nearly a million patients per

year, they had all the information necessary to confidently commit to this opportunity in ongoing innovation efforts. Enough was known about the disease state to make new solutions feasible, the solution landscape was ripe for innovation, patients were eager for an alternative technology for FESS, and physicians seemed to be generally open to considering new ideas. It was also a strong fit with the defined strategic focus and Makower's related acceptance criteria.

While the team was still investigating needs related to orthopedics, respiratory disease, and CHF (as well as other chronic sinusitis needs), the 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* had strongly overtaken any of the other opportunities being considered. As Makower explained, rather than performing all of their needs screening activities at one point in time, the team had been filtering its needs on more of a rolling basis as new information became available:

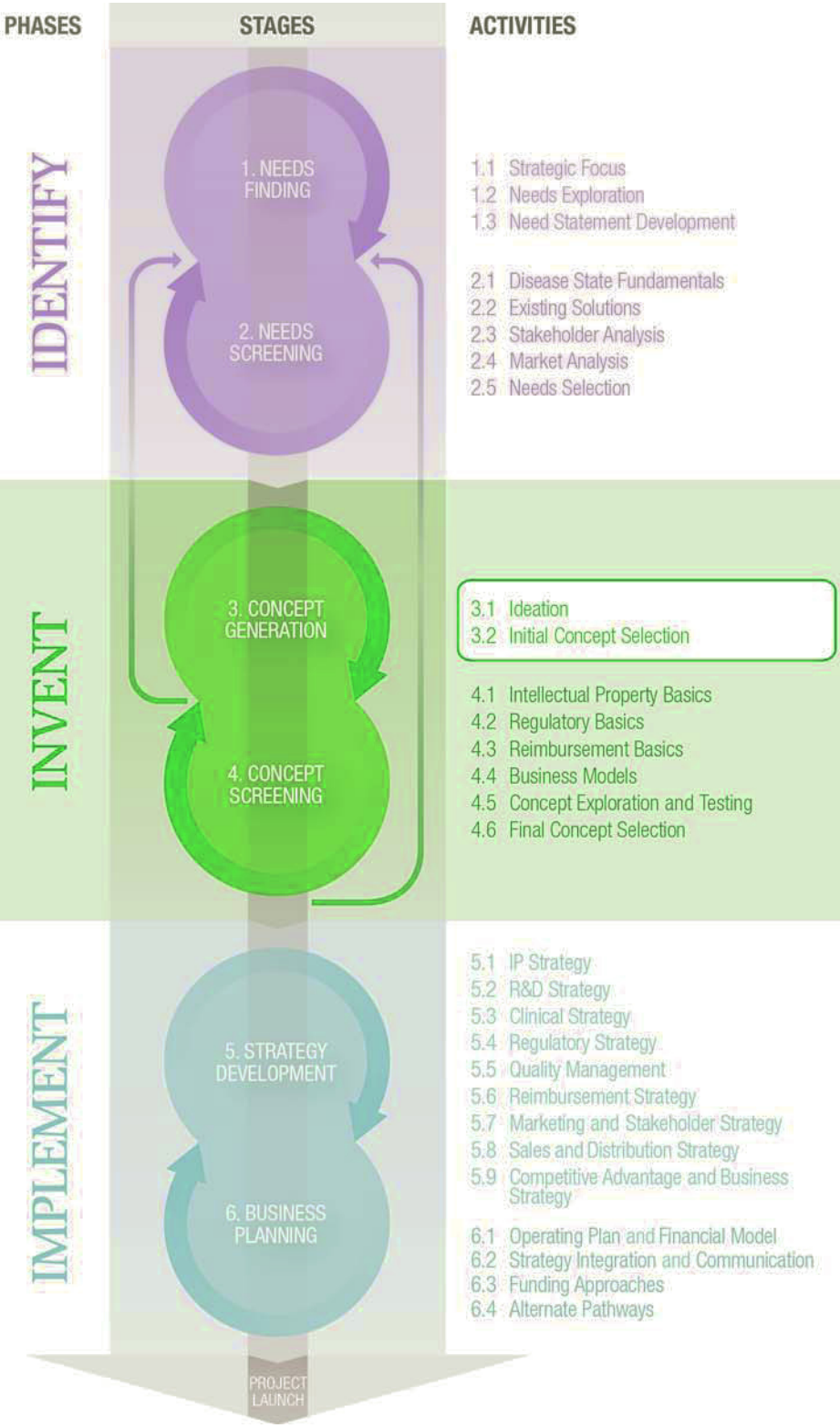
> *We did our filtering along the way. When we teach the biodesign innovation process, we focus on isolating the fundamentals of how people innovate to make each step clear, but in doing so, it can make the process seem like all of these activities occur in sequence. In practice, they can happen almost simultaneously. There's an analogy that I like to use with my project architects: Getting to the finish line with a winning project is like a horse race. You can put the need areas or ideas (horses) in at any time during the race, and they can get knocked out at any time, too. Some horses start at the beginning of the race and go very far before being knocked out by other screening criteria. Others don't make it very far at all. Eventually there's one horse that keeps on going and gets out ahead of the others, clearing each screening hurdle with ease. Once you see one getting far ahead of the others, you solely focus on that one horse and you try to ride it to the finish line.*

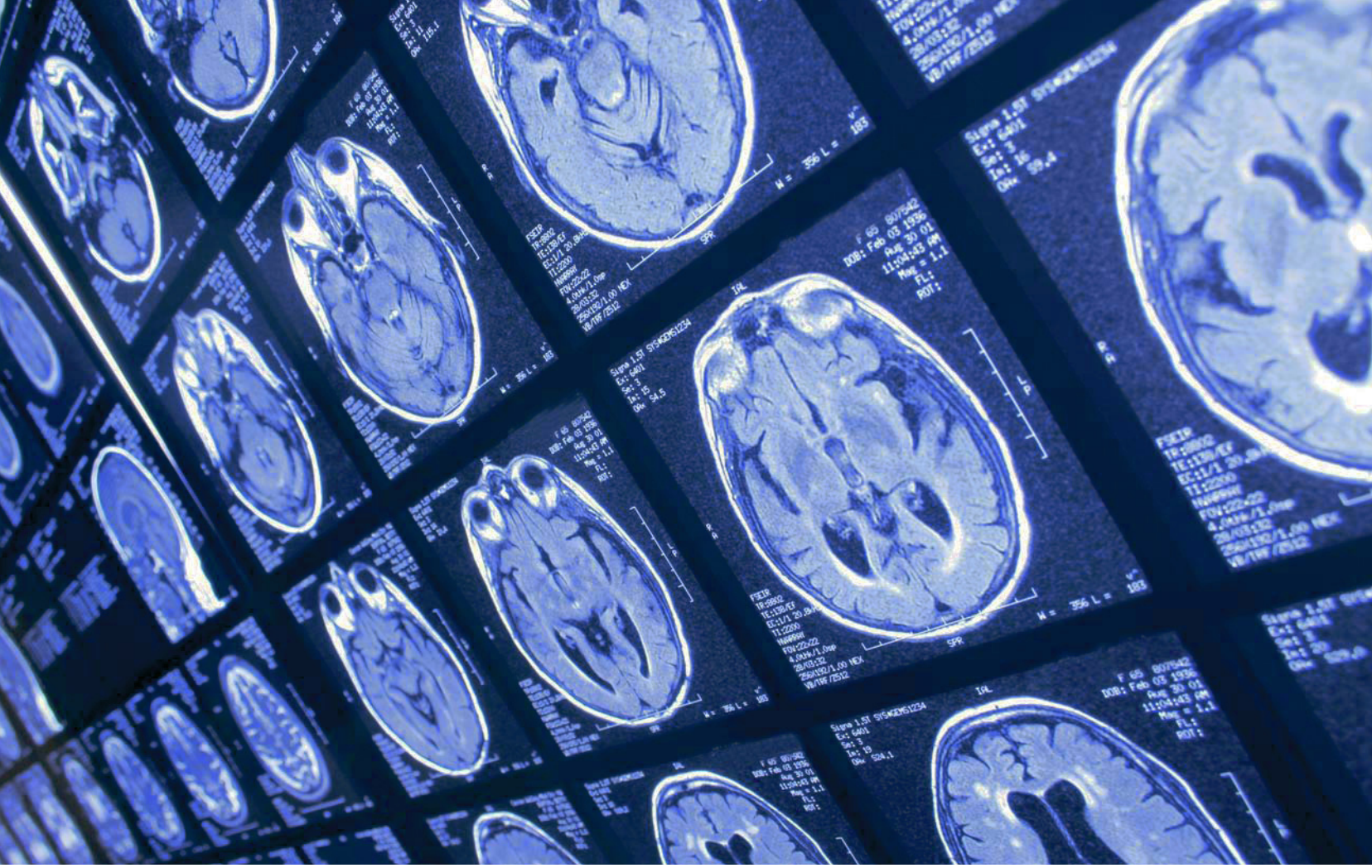
As a seasoned innovator and entrepreneur, Makower was comfortable leaving some opportunities behind when others seemed more promising. "You can only win by eventually focusing on one thing at a time. If you spread your efforts too thin, you'll be too distracted to execute well on any one need, and you'll never get there."

NOTES

1 All quotations are from interviews conducted by the authors, unless otherwise cited. Reprinted with permission.
2 "Sinusitis Overview," Balloonsinuplasty.com, http://www.balloonsinuplasty.com/learn-about-sinusitis (September 16, 2013).
3 Carol Sorgen, "Sinus Management Innovation Leads to an Evolution in Practice Patterns," *MD News*, May/June 2007, http://www.clevelandnasalsinus.com/webdocuments/Acclar-Cleveland-md-news.pdf (September 16, 2013).
4 Stephen Levin, "Acclarent: Can Balloons Open Sinuses and the ENT Device Market?," *In Vivo*, January 2006.
5 Ibid.
6 Ibid.
7 R.S. Jiang and C.Y. Hsu, "Revision Functional Endoscopic Sinus Surgery," *Annals of Otology, Rhinology and Laryngology*, February 2002, pp. 55–59.

INVENT Concept Generation





Innovation is now recognized as the single most important ingredient in any modern economy.

The Economist[1]

The devil's advocate may be the biggest innovation killer . . .

Tom Kelley[2]

3. CONCEPT GENERATION

If invention/innovation is so important, why are there so many devil's advocates? Can we banish them . . . at least early on?

Once an important clinical need is clearly identified, it's time to have some fun. It's time to invent. The recurring theme of constant iteration developed in Phase 1 of the biodesign innovation process (Identify) continues as an essential component, during both the concept generation and concept screening stages.

Concept generation, getting the ideas, begins with ideation. One common approach is brainstorming, which originated half a century ago in Alex Osborn's *Applied Imagination*[3] and launched the study of creativity in business development. Its premise is clear. There are three things to work with – facts, ideas, and solutions; *each* deserves quality time. The natural tendency is to leap from facts to solutions, skipping over the play and exploration that should be at the heart of finding new ideas. Most of us are experienced with fact finding; it's a consequence of contemporary education's preoccupation with facts. We're also familiar with solutions; most of us like to solve problems and move on. Idea finding may seem childlike (and it should be) but at its core is the exploration of possibilities *free from as many constraints as possible*. If nothing revolutionary, weird, or goofy surfaces during concept generation, then this stage has failed. The vibe should be upbeat – a chance to try things out, to free associate, and to challenge the wisdom of the present.

NOTES

[1] As cited in Tom Kelley, *The Ten Faces of Innovation* (Doubleday Business, 2005).
[2] Ibid.
[3] Alex F. Osborn, *Applied Imagination* (Charles Scribner's Sons, 1957).