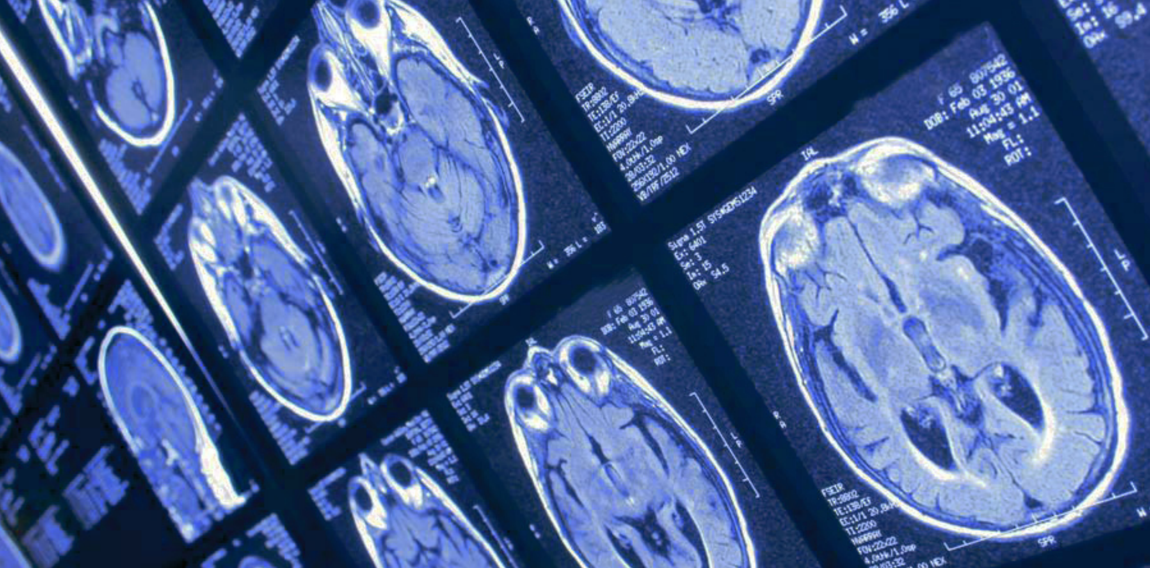


# 3.2 Initial Concept Selection

## INTRODUCTION

*A "leap of faith" is an act of accepting or trusting in something that cannot readily be seen or proved.*[1] *More than any other step in the biodesign innovation process, initial concept selection qualifies as a leap of faith. Based only on information about the need, innovators choose a handful of promising solution concepts to develop further from dozens or even hundreds of ideas coming out of their ideation sessions. At this point, they have little or no hard information about which solutions may ultimately best solve the need – just a host of questions. Is the solution truly technically feasible? Is enough understood about the underlying mechanisms of the disease that the solution targets? Is there sufficient insight into critical interactions between the different engineering elements to make the solution viable? How much time, effort, and money will it take to determine the practicality of the idea? How will doctors and other important stakeholders respond to the concept? In the face of these unknowns, innovators leap forward, setting aside the majority of their ideas to investigate the few that appear most likely to succeed.*

### OBJECTIVES

- Understand how to cluster and organize the output of ideation so it can be analyzed in order to determine whether additional ideation is needed.
- Learn to objectively compare solution concepts against the criteria in the need specification to determine which concepts to pursue.

Being selective about which concepts to take forward and further investigate from the many possibilities generated through ideation is an important step of the biodesign innovation process. Similar to the needs selection process, performing initial concept selection well increases an innovator's efficiency by helping triage concepts so that only the most favorable few move on to more detailed investigation. Spending lots of time researching many concepts in detail is not worthwhile as the bulk will be eliminated.

Initial concept selection involves comparing all of the ideas generated against the need statement and need criteria defined in the need specification to evaluate how well each solution may (or may not) solve the need. As part of this process, innovators usually organize their ideas into related groups to identify potential gaps or biases in the proposed solutions. If significant gaps are found or certain biases are discovered that unnecessarily constrain the solutions, additional ideation may be required to generate new solutions that directly target these issues. Ultimately, the output of initial concept selection is a few promising concepts to take into the concept screening stage of the biodesign innovation process.

See ebiodesign.org for featured videos on initial concept selection.

## INITIAL CONCEPT SELECTION FUNDAMENTALS

As described in 3.1 Ideation, one of the key rules of brainstorming is to "go for quantity," encouraging as many ideas as possible. This is important to ensure that many varied solutions are considered before an innovator settles on any particular **concept**. However, generating a vast number of ideas can create a challenge in that it is unrealistic for the innovator to research and develop them all. At the most basic level, the process of initial concept selection can be thought of as an objective, comprehensive method for organizing and evaluating the information generated through ideation in order to go from many concepts to a few.

### Transitioning from ideation to initial concept selection

Before beginning initial concept selection, innovators should first carefully review the raw output from their ideation sessions to make sure that all ideas are fully and accurately captured and clearly understandable (see Figure 3.2.1). If they realize that many of the ideas they generated still represent general approaches rather than concrete solutions, they may be well served to go back to ideation to expand the ideas into clearer solutions before going further with initial concept selection.

Ideally, reviewing the raw output of brainstorming should be done immediately following the session so that the innovator can seek clarification from the participants

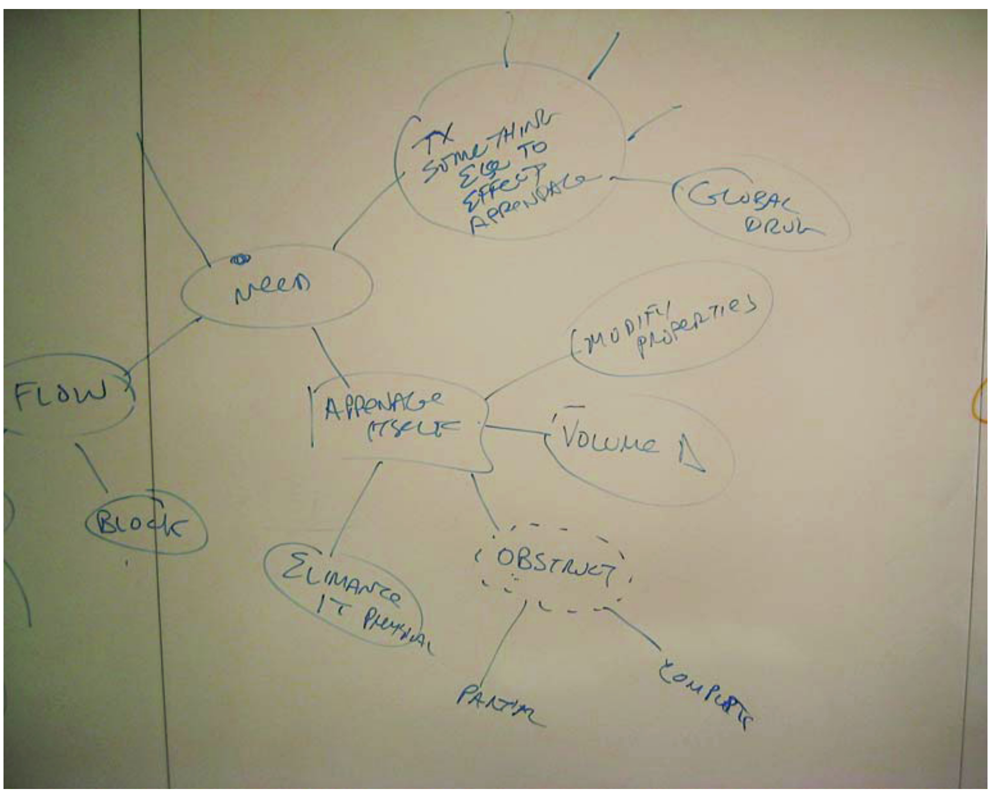



FIGURE 3.2.1
Example of the raw output from a brainstorming session (provided by Uday N. Kumar; developed with John White, Kityee Au-Yeung, Joseph Knight, and Josh Makower).

if something is unclear. Misinterpretation can be a source of error and may inadvertently lead to the elimination of potentially good ideas. If each idea is linked to the participant(s) that contributed it immediately following (or during) the brainstorm, as suggested in 3.1 Ideation, it should be relatively easy for the innovator to follow up.

Remember that it is important to consider all of the notes, pictures, drawings, diagrams, and three-dimensional mock-ups that were created during the brainstorm, and not just the documentation produced by the scribe. The goal is to review all ideas, in their entirety, so that they can be adequately assessed.

Once innovators feel comfortable that they have accurately identified and interpreted all of the raw data from ideation, and that the ideas seem to represent well-defined concepts, the information can be recorded in some meaningful and easily understandable way. One approach is to tag each idea with a short phrase or name to make it quickly identifiable. By standardizing the way ideas are described, an innovator can more efficiently compile and organize the concepts. For example, in the obesity space, an idea to put an implant in the stomach that elutes a substance to simulate satiety, or the sensation of feeling full, might be named "drug-eluting implant."

## Grouping and organizing ideas

Once the raw data from ideation have been reviewed, "cleaned up," and labeled, innovators can group and organize the concepts. There are many methods for accomplishing this, but the most effective techniques usually involve clustering the ideas according to some organizing construct, such as the mechanism of action or presumed technical feasibility, and then visually organizing them into a **concept map**.

Organizing concepts is important because it allows innovators to identify gaps, biases, and synergies among the ideas. Identifying gaps among groups of solutions is necessary so that additional ideation can be performed to address any opportunities that may have been missed. For example, if an innovator working on the **need** for *a way to prevent strokes due to clots coming from the heart* generated a preliminary set of solutions that did not include any concepts involving the blood vessels that convey clots to the brain, this would be an obvious gap to focus on during subsequent ideation sessions.

The innovator should also watch out for biases in the types of solutions proposed. For example, if all the concepts initially generated to solve the stroke need were heavily focused on mechanical engineering solutions, involving individuals from other engineering disciplines might lead to different approaches and concepts (e.g., chemistry or drug-based solutions).

An effective approach to organizing concepts also allows the innovator to identify commonalities and complementarities between concepts so that they can be merged to create synergistic, combined concepts. For example, for the same stroke need, one group of solutions might focus on meshes to capture clots while another set focuses on medications to dissolve clots. By putting these clusters together, a new set of ideas, centered on a mesh that elutes a substance to dissolve a clot, may emerge. In many cases, the combination of concepts can result in a stronger overall solution.

### *Clustering*

The notion of arranging ideas into groups is simple in theory, but can be difficult to accomplish in practice (requiring more art than science). At its most basic, clustering requires the examination of ideas to identify common themes or similarities and then grouping them based on their related characteristics. For instance, the roughly 100 ideas generated in a brainstorm may fit within 10 general clusters based on the most dominant traits they have in common.

The first step in the grouping process is to identify the primary organizing principle for creating the clusters. Some examples of common ways to group ideas in the **medtech** field are outlined in Table 3.2.1. The challenge to the innovator is to find the most meaningful organizing principle for the solutions being evaluated. Factors like anatomical location and engineering area are simple to understand and provide easy comparisons, but they may not be relevant for some needs. Factors such as mechanism of action may be harder to define and apply, but potentially could be more significant in terms of identifying the similarities and differences between ideas and for assessing the likelihood of success. Innovators

**Table 3.2.1** Organizing principles that can be used to help cluster ideas initial concept slection.

| Organizing principle | Description | Example |
|---|---|---|
| Anatomic location | Group ideas according to the part of the anatomy they pertain to and/or target. Differences between groupings might be small if all solutions are in a highly focused area (e.g., the vertebral discs). Alternatively, groupings might span entire regions/organ systems if the solutions focus on a need pertinent to a significant portion of the body (such as the various places to which emboli dislodged from the heart can travel). | For solutions to address the problem of obesity, ideas might naturally cluster around the mouth, esophagus, stomach, pylorus, small intestines (duodenum, jejunum, and ileum), large intestines, and the various valves in the GI tract. |
| Mechanism of action | Group ideas according to how the solutions are intended to work. | Increasing energy expenditure, regulating food intake, reducing nutrient absorption, and reducing the motivation to take in energy (or eat) are all different mechanisms of action for reducing weight. |
| Engineering or scientific area | Group ideas according to the type of engineering or scientific approach underlying the solution. | Solutions could be supported by three main types of engineering: *chemical* (pharmacological weight control), *electrical* (gastric pacing), or *mechanical* (laparoscopic banding, bariatric surgery, liposuction). |
| Technical feasibility | Group ideas according to their likelihood of coming to fruition. This is based on understanding what is feasible using current engineering and scientific methods, which implies some knowledge of the science behind the solution and/or the engineering development timeline required. | Solutions such as reprogramming fat cells might have low feasibility; a drug-eluting implant might have moderate feasibility; a space-occupying stomach device would have high feasibility. |
| Funding required | Group ideas around the amount and/or source of funding required to develop them. While this may be difficult before researching the funding landscape, a "best guess" based on prior information (see 2.4 Market Analysis and 2.5 Needs Selection) may suffice. | For obesity, a solution such as filling the stomach with a space-occupying device would likely require less money to develop than a drug-eluting implant. |
| Appeal to influencers | Group ideas around the interests of important influencers involved with the need, typically the patient or healthcare provider. While this may result in rather general groupings, it can provide insights into which concepts are more likely to be attractive to these **stakeholders** (see 2.3 Stakeholder Analysis). | For obesity, solutions focusing on medications might be more appealing to patients than those requiring surgeries. In contrast, surgeons used to performing bariatric procedures may favor other surgical interventions that are more effective and/or easier to perform but allow them to maintain procedure volumes. |

**Table 3.2.1** (*cont.*)

| Organizing principle | Description | Example |
|---|---|---|
| Appeal to decision makers | Group ideas around the interests of decision makers who will potentially pay for a solution to the need, which is often a facility or **payer**. These stakeholders are usually interested in the cost-effectiveness of new solutions relative to available treatments. Remember that in some cases, patients may be the ultimate decision makers if a solution must be paid for out-of-pocket, which can have slightly different implications. | For obesity, solutions requiring a one-time payment may be more attractive than solutions requiring recurrent **payments**. Solutions that reduce costs by moving a procedure out of the operating room and into the clinic or from a specialist to a primary care physician may also be viewed favorably. |

are encouraged to experiment with several different organizing methods before choosing the one or two that make most sense and best capture the potential value of the ideas generated.

Another approach for clustering ideas is to create a hierarchy of organizing principles where, for example, concepts are first clustered according to one factor (e.g., anatomical location) and then, within each of the resulting clusters, arranged into subgroups according to a different organizing principle (e.g., mechanism of action). The innovator can then continue this process, incorporating additional organizing principles at deeper and deeper levels. For instance, in the example focused on preventing strokes due to clots from the heart, the first level organizing principle might be anatomical (solutions could be broken down by location: heart, blood vessel, and brain). The concepts within each anatomical location could next be organized by engineering area (mechanical solutions, chemical solutions, or biological solutions). Alternatively, the innovator might start by organizing concepts according to engineering area and then create subgroups based on anatomical location. Again, the key is to try several different approaches, watching for patterns that illuminate important gaps or commonalities among the concepts.

*Concept mapping*

After one or more organizing principles have been chosen and ideas have been placed into groups, they can be documented in a concept map (also called a mind map). A concept map visually illustrates how ideas relate to one another and to the need itself. As noted, these maps are meant to help the innovator recognize patterns and build connections between solution concepts, as well as between the concepts and the need. Concepts maps are especially useful for highlighting gaps in the solution set – for example, innovators who are well versed in the chosen organizing principle (e.g., all the anatomical locations relevant to the chosen need) can quickly spot what might be missing if it is not represented in the concept map.

When developing a concept map, the need is placed at the center, with the clusters of ideas spanning out in different directions. Figure 3.2.2 shows the concept map generated for a need focused on obesity. In this example, the primary clusters are broken down by various mechanisms of action: (1) regulating food intake; (2) increasing energy expenditure; (3) reducing the motivation to take in energy; (3) reducing nutrient absorption; (4) pharmacologics; and (5) non-physiologic solutions. These clusters are further broken down into subgroupings as they are laid out in the concept map. For instance, the cluster focused on “ways to reduce the motivation to take in energy” is organized into a subgroup called “ways to reduce hunger.” This includes solutions that affect volume (space-filling, volume reduction) or reduce hunger through neural means (neural stimulation of the stomach, stimulating the vagus nerve). Using the chosen organizing principle, the actual solutions are then placed where they fit best within these clusters

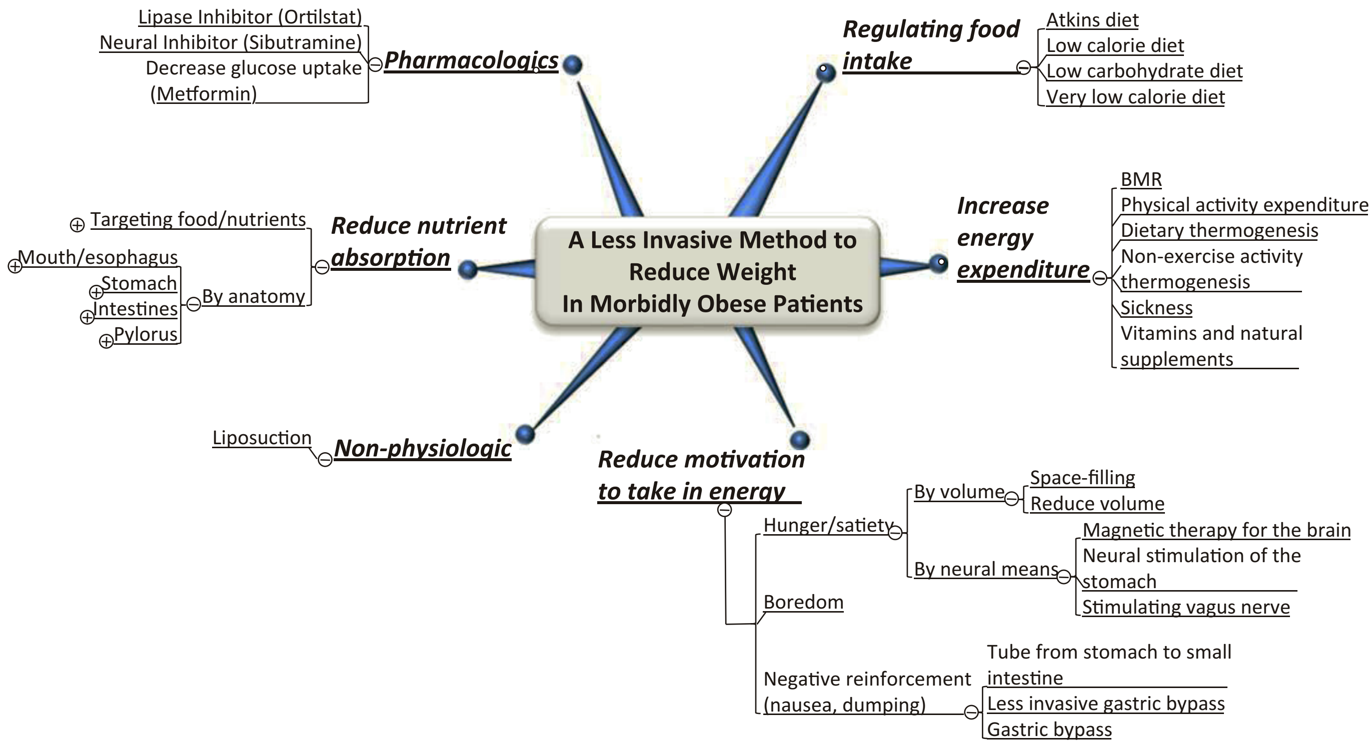



FIGURE 3.2.2
A sample concept map addressing the need for *a less invasive method to reduce weight in morbidly obese patients*, as developed by a team in Stanford University's Program in Biodesign (with permission from Darin Buxbaum; developed with Jennifer Blundo, Charles Hsu, MD, Ivan Tzvetanov, and Fan Zhang).

and subgroupings. In studying the ideas at the edges of the map, it is apparent that some are well-defined concepts while others are mostly general approaches. This could be the result of entering initial concept selection too early, without additional rounds of ideation to flesh out these areas. Alternatively, the innovators may have discovered through the process of creating the concept map that they had many more possible solutions to explore in these clusters. In this scenario, the innovators could choose to focus only on the clusters with well-defined solutions. Or, they could return to ideation to fill out the concept map with more concrete solutions before determining which ones to pursue. Regardless of the path chosen, the exercise of concept mapping plays an invaluable role in helping a team identify its next steps..

Another example focused on the need for *a better way for accessing the pulmonary veins* is shown in Figure 3.2.3.

Reviewing the figure shows that many solutions have been identified to support the cluster called "systems to aim at the PV" (pulmonary vein). However, when looking at the cluster "ablation systems," more brainstorming may be needed to flesh out the ideas since many of these solutions are much less well-defined in scope and are not closely linked to the central need. For their concept maps to be effective, innovators should ensure that all of the clusters have an obvious relationship to the need. They should also check to be sure that all solutions fit comfortably underneath the chosen headings. If an idea appears "forced" to fit within a group, this may indicate that the map is not based on the optimal organizing principle or that another heading is missing. This sometimes occurs if innovators have gone into the brainstorming session with a bias towards certain types of solutions (which places an artificial constraint on the brainstorming process). For example, if the need being

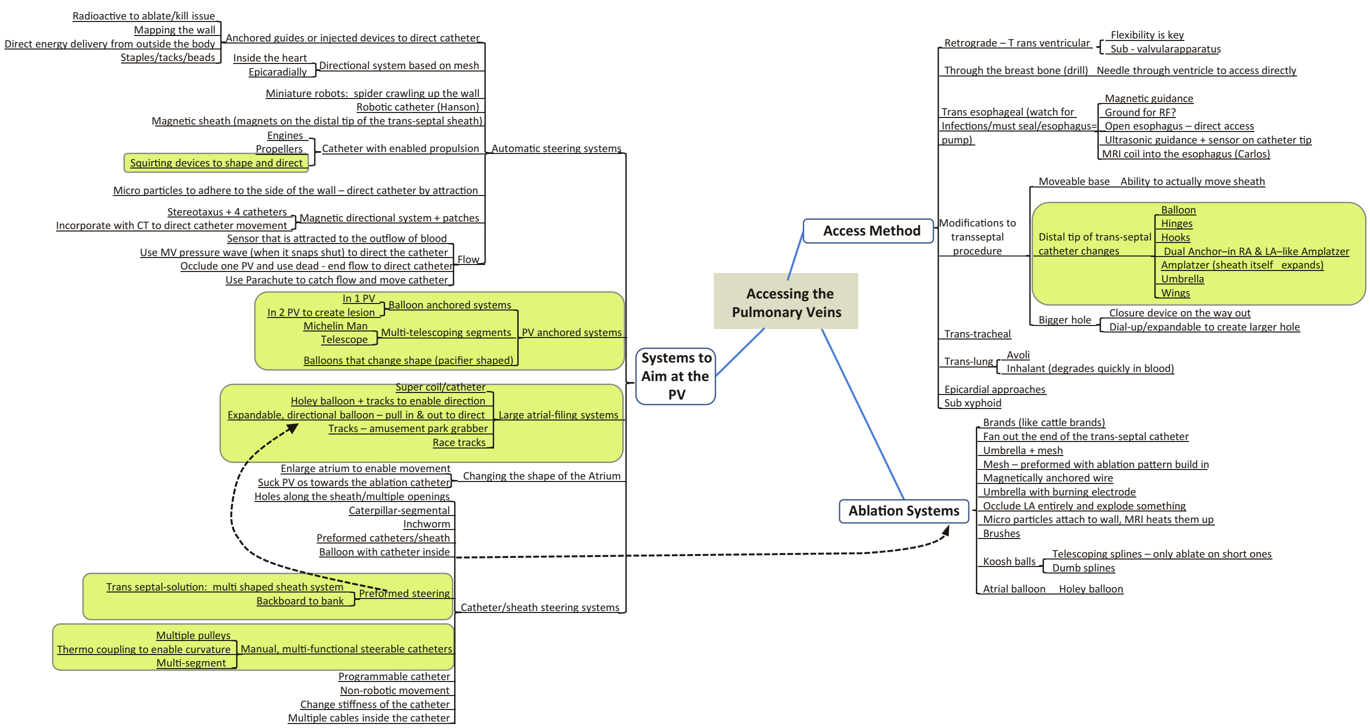



FIGURE 3.2.3

A sample concept map addressing the need for *a better way of accessing the pulmonary veins*, as developed by a team in Stanford University's Program in Biodesign (with permission from Uday N. Kumar; developed with John White, Kityee Au-Yeung, and Joseph Knight).

explored is for *a way to prevent bleeding from an artery*, a group with a mechanical engineering bias may subconsciously focus on mechanical solutions, completely forgetting about chemical or electrical ideas. When such biases are discovered, the team should complete more ideation. Involving people with different backgrounds, expertise, and experiences can help keep ideation balanced and potentially reduce the likelihood of generating significantly biased solutions sets (see chapter 3.1).

These examples show that no two concept maps are exactly alike. The basic layout is similar, but innovators have a good deal of freedom to decide exactly how to visually present the concepts in the most meaningful and useful way. Again, it can be helpful to experiment with multiple concept maps based on various organizing principles before choosing the one that best presents the data from ideation. Additionally, it is important to remember that by creating maps, different gaps in the solution set can be more readily identified. Furthermore, well-defined solutions assigned to different clusters on differently arranged concept maps may help the innovator better define each concept along a variety of parameters. Both of these outcomes can lead to a more effective assessment of each solution against the need.

There are no specific guidelines for determining at what point a map has reached the optimal presentation of the data. Instead, innovators must rely on making an appropriate judgment call on a map that is logical, balanced, and comprehensive before moving to the next stage of concept screening.

## Comparing ideas using the need specification

With a solid understanding of the intent behind the various solutions and a concept map created, innovators are ready to compare the proposed solutions against the need. The goal of this process is to narrow the universe of ideas to a few concepts that seem to best address the need. To accomplish this, innovators first should revisit the **need specification** developed in chapter 2.5 and then evaluate each concept relative to the **need criteria** that have been defined. It is advisable to start by assessing the extent to which proposed solutions satisfy the **need**

**statement** itself and then the must-have need criteria. Concepts that fail to meet these essential requirements should be set aside. Those that perform well against the must-haves can then be evaluated against the nice-to-have criteria. Often the nice-to-have requirements can be used for "tie breakers" for choosing between multiple solutions that seem equally promising.

As this comparison is performed, it is essential for the innovator to apply the need criteria as originally defined. Modifying the need criteria or compromising in terms of how they are applied to different solutions can tarnish the integrity of the selection process and lead to poor choices, since they will no longer be driven by the pure requirements of the need. Importantly, while it can be tempting to let personal interest in a solution bias the process, this can ultimately be a costly mistake, leading to a solution that does not appropriately address the real need. This, in turn, can undermine the final success of any product emerging from the biodesign innovation process.

That said, the initial selection process is inherently subjective in that innovators are using their best judgment to determine which solution ideas demonstrate the greatest promise in addressing the need. While there is no fail-safe way to eliminate this subjectivity, the chance of successfully identifying the most promising solution concepts can be increased by considering each concept in a consistent manner. As mentioned above, the creation of different concept maps will naturally lead to greater understanding of different parameters along which each solution is aligned. This may also help in comparing these solutions with the need criteria. Involving more individuals in the selection process is another specific tactic that can be used to help minimize personal bias.

One way to perform this assessment is by holding a solution selection meeting. This is similar to a brainstorming session, in that a group of individuals with diverse backgrounds should be invited and a clearly defined protocol should be used. A facilitator should run the meeting with the goal of driving the group to identify the most promising solutions. The facilitator will be in charge of defining the process to select the ideas, as well as ensuring that the selection committee follows the process. However, unlike the facilitator's role in the brainstorming process, this individual should actively participate in the selection process.

Because initial concept selection requires a different skill set from what is required for brainstorming or other forms of ideation, it makes sense to involve different types of participants. For example, this is a stage where experts in the field can be invaluable. These experts might include physicians, nurses, and/or patients who can help evaluate the clinical usefulness of the various solutions. Also involving various types of engineers might help with understanding the technical feasibility of a solution and/or whether it seems realistic that it could solve the need. Participants with business backgrounds might also be able to help evaluate how needs might meet certain cost, marketing, or **value** criteria that may have been called out in the need specification. Having multiple perspectives can enhance the decision-making process. However, for practical purposes, innovators should seek to limit the number of people from which they solicit feedback. If too many people are involved, it can become impossible to rationalize each person's input, based on their individual preferences and biases.

In the meeting itself, participants can be asked to provide input and potentially even to vote to eliminate or to prioritize ideas. One approach is to give every person approximately five sticky notes and ask them to place one next to each of their top five ideas on the concept map (which can be drawn/copied on to a whiteboard or flip chart). After tallying the votes, the list of ideas can be reduced to roughly 10 leading concepts. Once the list of ideas is shortened to ten, the group can assess them in more detail relative to the need criteria, considering the must-haves and nice-to-haves, until a smaller set of concepts has been agreed upon. When experimenting with this approach, innovators should be sure to remind participants to make their choices based on which proposed solutions they believe will best address need statement and the must-have need criteria. If participants simply pick concepts that "sound cool," this can result in many varied concepts with little connection to those likely to deliver the best results.

At times, it may not be feasible to get all desired participants into a room at the same time and place to participate in the selection process. Another approach is to meet with targeted individuals one-on-one to seek their input. The feedback gathered from the experts can then be used as an input to the selection process that innovators and their teams employ. Regardless of how an innovator collects input from experts in the field, this feedback is essential to initial concept selection.

During this step of the process, it is possible that some proposed solutions will have to be eliminated even though they show potential to address the need statement and satisfy the must-have need criteria. In some cases, certain solution concepts are simply impractical or infeasible. This is often due to technology constraints, but other factors related to patient, provider, and payer concerns may make an idea unrealistic. Although additional primary and/or secondary research may shed light on whether or not an idea is truly impractical, an innovator must usually rely on a "gut check" regarding what can realistically be accomplished within a reasonable timeframe.

Innovators may also eliminate promising solution concepts based on their personal project **acceptance criteria** (as defined in 1.1 Strategic Focus). For example, if a team has conceptualized an electrical engineering solution that meets its need criteria, but the innovators are dedicated to working on mechanical solutions, they may choose to abandon the electrical idea. Another alternative would be to modify their acceptance criteria. While it is perfectly acceptable to make adjustments to acceptance criteria at this stage in the process, remember that the need criteria should remain intact.

As noted, innovators may also end up with different *approaches* to address the need, rather than specific solutions. Sometimes approaches may seem to meet the need criteria more effectively because of their lack of detail – concrete details are often the key factors in determining why a particular concept does not meet a need. For instance, revisiting the example shown in Figure 3.2.3, which focuses on the need of *a better way for accessing the pulmonary veins*, some of the need criteria were: (1) the ability to reach all configurations of the pulmonary veins; (2) easy to use; (3) faster than current methods; (4) low/no **morbidity**; and (5) must enable at least radiofrequency energy delivery. Other factors taken into account included the team's interest in pursuing solutions in line with current catheter-based procedures, the feasibility of the solution, and the expertise of the team. Based on these criteria, this team chose the subgroupings and associated solutions in the outlined and shaded areas on the concept map. Even after these initial choices, the team had to complete additional brainstorming and research to generate more specific concepts from these approaches, as there were still more than could realistically be taken forward. Performing more brainstorming after going through initial concept selection is certainly acceptable. However, it is usually more efficient for innovators to identify if they are working with approaches rather than true concepts before they initiate initial concept selection.

Although it is relatively rare, it is possible for initial concept selection to yield too many genuine concepts that meet the need criteria. In this scenario, the need criteria may be too broad. This can require innovators to revisit the need specification to generate more specific must-have and nice-to-have need criteria (see 2.5 Needs Selection). Importantly, innovators should not consider this a failure of the need specification step, but rather another example of the iterative nature of the biodesign innovation process.

As with so many other elements of the biodesign innovation process, there is no exact way to know when enough solution ideas have been generated and when they have been appropriately screened. Similarly, there is no right number with respect to the final number of concepts to take forward. In most cases, innovators will focus on three to five of the concepts that best meet their need criteria. Many of these may be chosen because they are practical, but it is also acceptable to include an idea that could represent a potential breakthrough and/or one that inherently excites the team. These are the concepts that will undergo more in-depth ideation, usually around their technical details, as well as research and prototyping in sequence or in parallel, in the next stage of the biodesign innovation process: concept screening.

The case example from the Singapore-Stanford Biodesign program illustrates how one team navigated initial concept selection.

## FROM THE FIELD — SINGAPORE-STANFORD BIODESIGN TEAM

### Organizing and assessing ideas to assist with concept selection

When Tze Kiat Ng, Luke Tay, Justin Phoon, and Pearline Teo were fellows in the Singapore-Stanford Biodesign program, they were focused on solving clinical needs in the ear, nose, and throat (ENT) specialty. After clinical immersion at the National University Hospital in Singapore, the team had about 300 needs, which it narrowed to a set of eight top opportunities. At this point, team members conducted a series of short, intense brainstorm sessions for the eight needs. "We wanted to see which needs we could get most creative with," said Phoon.[2] The innovators also used these initial brainstorms as a way to gauge team interest in the needs so they could use this factor in their final needs selection exercise.

"After the mini-brainstorms, it became quite obvious which needs triggered a lot of interest and creativity within the members of the team, and which ones seemed to be more limited in terms of possible solutions. We went from eight to four needs based on this input," Teo recalled. They then evaluated the remaining needs against a variety of other factors, to get from four needs to the two that they would officially take forward into concept generation. They also created need specifications and defined clear need criteria to help guide more in-depth ideation.

According to Teo, "When we began brainstorming in earnest, we averaged about two sessions per need." The first meeting usually resulted in several broad approaches and general concepts for solving the problem. For instance, for their need for *a safer way to prevent cerumen impaction at home*, the team came up with ideas such as a soft expandable cleaning tip, a suction device, an ear "stent," and an endoscopic curette. The team relied primarily on whiteboards to capture the results of their brainstorms in real time.

Before the second brainstorming session, the team organized these broad approaches and general concepts into different categories (see Figure 3.2.4). Going back to the cerumen impaction need, the team grouped its ideas into the categories of preventing wax from sticking in the ear canal, improving drainage in the ear, "eating" or dissolving the wax, and safe cleaning instruments. This helped the team members identify

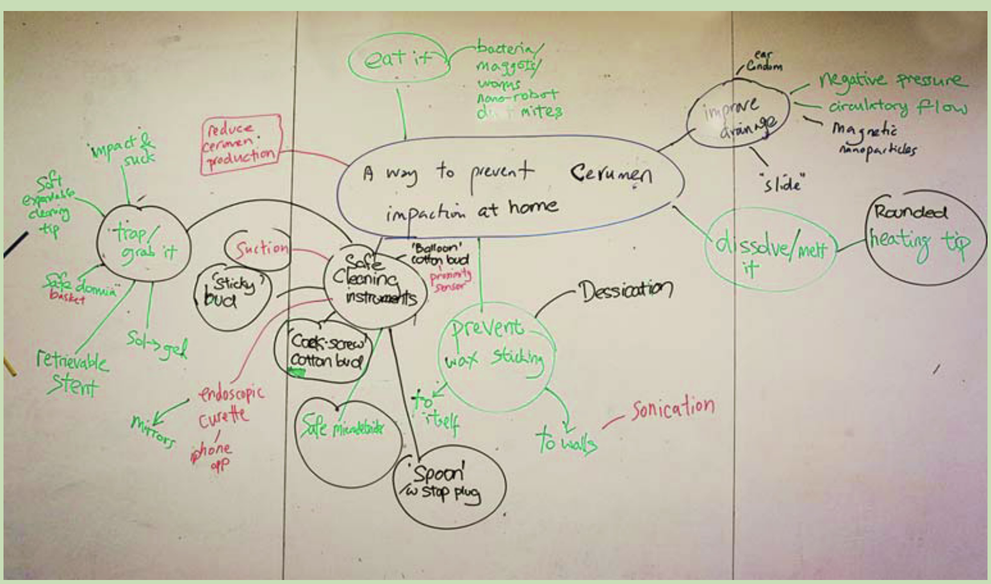



FIGURE 3.2.4
One of the team's early concept maps (courtesy of Tze Kiat Ng, Justin Phoon, Luke Tay, and Pearline Teo).

gaps in their ideas, with areas that they missed serving as a starting point for the second brainstorm meeting. For example, with the cerumen need, they realized that they had not touched upon ways to reduce cerumen production in the ear. As Phoon described, "Our strategy to organize our ideas into categories paid off because it helped us identify gaps which, in turn, drove more focused, productive brainstorms." Teo added, "This approach also made it clear when most of the concepts generated were basically variations of the same approach to solving the problem. This pushed us to expand our thinking into other areas."

Another important objective of the second brainstorming session was to help the team get more specific about their most compelling ideas. According to Teo, "In the case of the more interesting approaches, we challenged ourselves to come up with more detailed and actionable concepts – how exactly would we create something that tangibly embodies the approach." The team used some if its need criteria to help its members stay focused on generating actionable concepts. For example, Teo explained, "We mostly wanted to work on relatively simple mechanical concepts that we could develop in roughly a six-month time frame." With these criteria top of mind, they encouraged one another to come up with increasingly concrete solutions.

The series of second brainstorming sessions resulted in detailed concepts for several of the most interesting approaches. For example, with the cerumen need, the team members generated eight to 10 actionable concepts on which they could potentially work.

To help them move into the next stage of the biodesign innovation process, concept screening, with a reasonable number of ideas, the team decided to use a voting system to eliminate some ideas from consideration. For each need, individual team members were given three votes and asked to assign the first to the concept they thought was most revolutionary, the second to the concept they thought was technically most likely to succeed, and the third to the concept that they were personally most excited to pursue. When the scores were tallied, the most promising three or four concepts emerged. "The concepts with the highest scores were the ones we chose to spend our time on," Teo stated. At that point, the team evaluated each of the top concepts against the need specification, creating matrices to help compare each solution to the must-have and nice-to-have need criteria. The solutions that were best aligned with these important criteria were the first to move into prototyping to assess their technical feasibility. Concurrently, the team conducted more detailed research and evaluation of those ideas.

## Online Resources

Visit www.ebiodesign.org/3.2 for more content, including:

Activities and links for "Getting Started"

- Review and document raw data
- Cluster ideas
- Develop a concept map
- Assess the concept map
- Compare concepts against the need to complete concept screening

Videos on initial concept selection

## CREDITS

The editors would like to acknowledge Joy Goor and Ritu Kamal for their help in developing the chapter. Many thanks also go to Justin Phoon and Pearline Teo for contributing to the case example.

## NOTES

1 “Leap of Faith,” Dictionary.com, http://dictionary.reference.com/browse/leap%20of%20faith (November 19, 2013).

2 All quotations are from interviews conducted by the authors, unless otherwise cited. Reprinted with permission.

# Acclarent Case Study

## STAGE 3: CONCEPT GENERATION

With a well-validated 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*, as well as a firm commitment to finding a less invasive way to treat chronic sinusitis, Makower and Chang began aggressively exploring potential solution concepts. In doing so, they finally returned to some of Makower's preliminary ideas before launching the biodesign innovation process, including the concept of developing "interventional devices" for sinusitis. This approach made even more sense in the context of the team's recent disease state and solution research. "Seeing the three-dimensional anatomy in cadavers and reviewing so many CT scans caused us to appreciate how tortuous the bones and mucosa were in the sinuses. It reinforced the observation that those drainage pathways resembled blood vessels," Makower commented.[1] "So we started to imagine how we could implement cutting, dilating, stenting, energy delivery, and drug delivery across this bony network, utilizing whatever we had learned from our experiences in the cardiovascular space."

### 3.1 Ideation

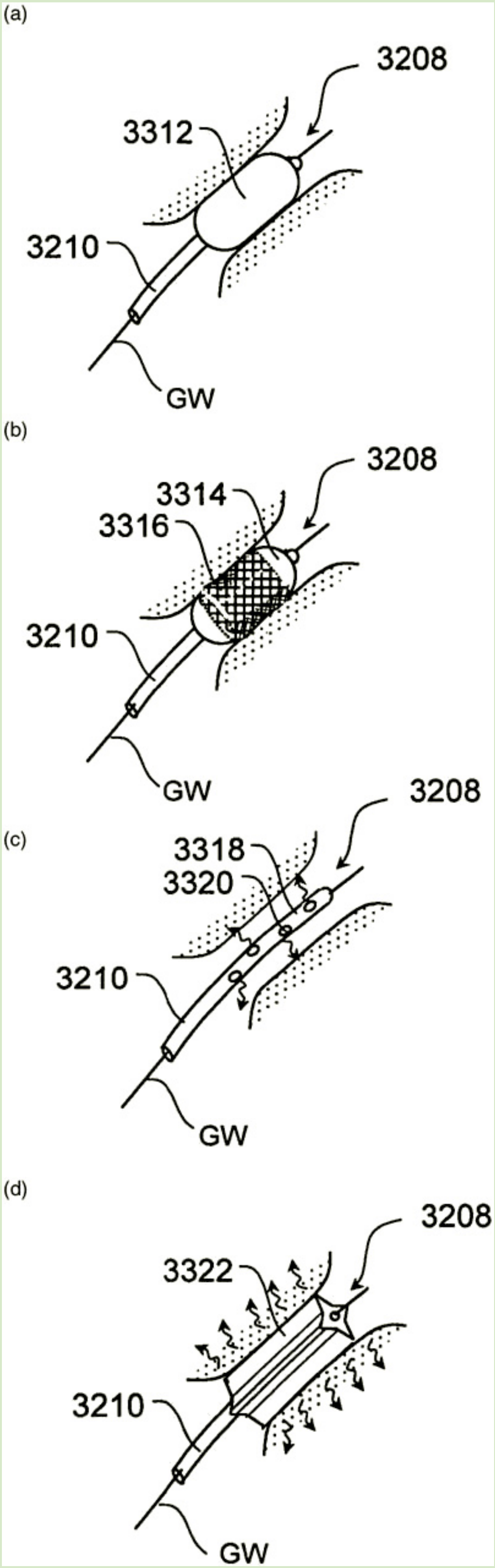
To develop a more specific set of potential solution concepts, Makower and Chang began exploring different possibilities in earnest. Makower, who had a bias against disclosing his ideas with a wider audience too early, advocated for a scaled-down, hands-on version of the ideation process. While they did not assemble a cross-functional group of participants to hold formal brainstorming sessions, Chang noted, they still benefitted from multidisciplinary input: "In a way, we did get multiple perspectives, because Josh is an engineer, a doctor, a scientist, and a business person, and I'm an engineer." He went on to describe their ideation approach:

> *Josh and I spent a lot of time brainstorming around what we had learned about the disease and anatomy and from our cadaver work. We dug into how we could use flexible instruments to get around and preserve anatomical structures while gaining access to the sinuses. And we considered what we could do to make access easier. For example, one way we developed this understanding was to section a cadaver head at one of the labs. By sectioning the specimen, we had an unobstructed view of the anatomy with our own eyes, instead of using an endoscope. We laid down malleable wire and got an appreciation for the dimensions of the anatomy, relative locations of the structures, openings, and where instruments would need to travel. It was hands-on brainstorming while we were assessing the anatomy.*

Through this process, they developed multiple types of potential solutions. First they thought about ways to dilate the anatomy to gain access to the sinuses, using tools such as lasers, balloons, stents, and what Chang described as a "chomper." They also generated ideas to address a blockage area once it was reached. "We thought about a catheter that cuts, a spinning burr, different kinds of lasers, and balloons. Maybe we could freeze it, or maybe we could use microwave energy. We considered anything that would ablate or cut, that we could deliver on a flexible platform," Chang said (see Figure C3.1).

### 3.2 Initial Concept Selection

After the team felt that they had more or less exhausted the possibilities for ways to address the need, they started to narrow down the list of concepts. Makower



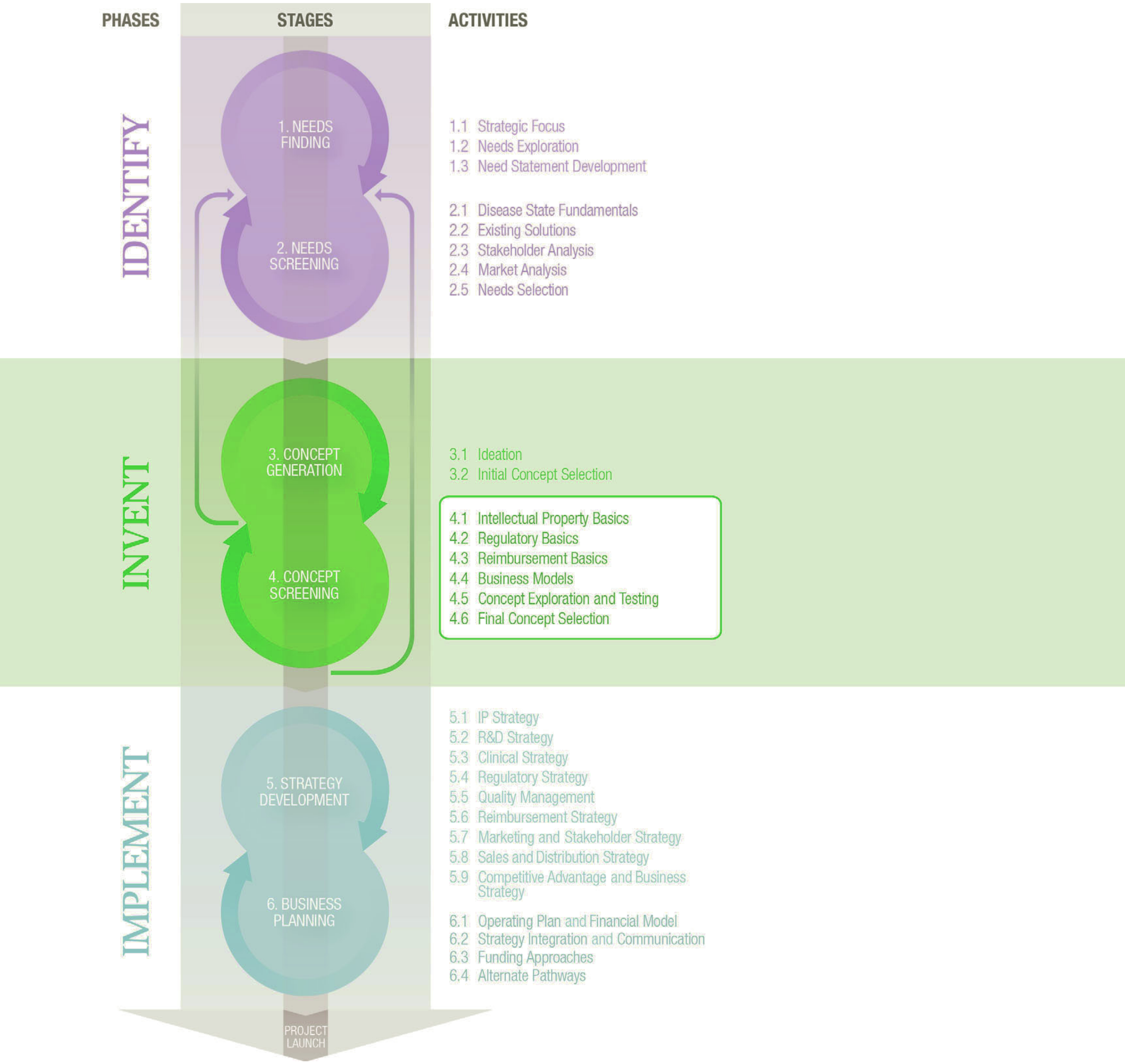

and Chang both had a desire to do something fast and had a preference to try one idea at a time. For these reasons, they saw some logic in starting with one of the concepts that was quickest to prototype. If it worked, they would press forward. If not, they would go back to the drawing board and choose another solution to explore. When they rationalized their list, they decided that the quickest idea to investigate was related to the use of balloons. "We said, 'Look, if we can make it work with a balloon, that'd be great,' " Makower remembered. "It doesn't involve complicated instruments. It doesn't involve bleeding. There's no cutting, no energy, and no hardware. Given our backgrounds, we could also make or obtain balloons to test easily." He continued, "If the balloon works, we're in great shape. If not, we can try energy next, or blades, or maybe even stenting. We knew our mission was to open the sinus drainage pathways in a flexible, less invasive way, but which technology was going to be required was really not clear yet."

## NOTES

1 All quotations are from interviews conducted by the authors, unless otherwise cited. Reprinted with permission.

FIGURE C3.1
The team considered many methods of opening sinus pathways, including the use of balloons (a), stents (b), drug delivery (c), and energy-based devices (d) (excerpted from US utility patent 7,462,175 with permission from Acclarent).

# INVENT Concept Screening



Opportunity is missed by most people because it is dressed in overalls and looks like work.

*Thomas Edison*[1]

Junk can dance.

*David Kelley*[2]

# 4. CONCEPT SCREENING

After careful screening of many needs, you have a clear statement of a focused problem worth solving. Ideation has generated hundreds of ideas, many whimsical or even outlandish. In the Identify phase, many needs were winnowed down to a focused, clinical needs specification. In this second stage of the Invent phase it's time again to make choices. Some innovators have a tendency to perseverate, to delay because of uncertainty. The plain reality is that no decision is a failure. It is impossible to pursue a dozen concepts simultaneously.

The United States Marine Corps knows something about decision making in the middle of uncertainty. In the classic book *War Fighting*,[3] the message is clear – perfect certainty doesn't exist. It is far better to move expeditiously with the best information available at the moment and to react flexibly as the situation changes and as you learn on the fly.

So, too, choosing a concept that is directionally correct, and acting upon it, will frequently provide new insights and refine your direction. There is no shame in meeting a blind alley and even reversing if necessary. Strong teams know how to backtrack to success.

Concept screening requires an understanding of the rules of the road for medtech innovation. The complex and frequently conflicting interplay between intellectual property, reimbursement, regulatory, and business model options requires sophisticated judgment. There is seldom a single "right" way.

Experienced, serial entrepreneurs will emphasize that time is money . . . and more. A balance between thorough deliberation and the opportunity cost of time lost to paralytic analysis is needed.

Just as concept screening is an iterative process, so too is concept exploration and testing. Prototyping, which is at the core of this activity, involves several steps, the first of which is closely linked to ideation. We build to learn. Early on, crude mock-ups are constructed to serve as a "looks like" or "feels like" version of a device made of easily shaped and assembled materials. Access to junk makes this easy and fun. Foam core, plastic, cardboard, outdated surgical instruments, catheters, and endoscopes can be "cannibalized" for early prototyping. (Duct tape rules!) The goal is to fail early, fail cheaply, and ultimately to fail better. Crude can become more refined and the rules of the road revisited.

## NOTES

[1] As quoted in John L. Mason, *An Enemy Called Average* (Insight Publishing Group, 1990).
[2] As quoted in Tom Kelley, *The Ten Faces of Innovation* (Doubleday Business, 2005).
[3] U.S. Marine Corps Staff, *War Fighting* (Create Space Independent Publishing Platform, 2012).