IDENTIFY Needs Finding

IDENTIFY

STAGE 1 NEEDS FINDING
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Case Study: Stage 1

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INVENT

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IMPLEMENT

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If you want to have good ideas you must have many ideas.

Linus Pauling[1]

If I had asked my customers what they wanted, they would have said a faster horse.

Henry Ford[2]

Needs Finding

Both Pauling and Ford offer great insights into this *most important* starting point. Identifying a compelling clinical need may seem simple and obvious, but it is not. Get it right and you have a chance, get it wrong and all further effort is likely to be wasted. The process of identifying needs involves first a broad screening survey, which we call "Needs finding." The follow-on process, "Needs screening," is covered in Stage 2. By way of analogy, needs finding is akin to snorkeling; needs screening is more like a deep dive.

Needs finding is a simple and yet profound process. The diagnostic and therapeutic workings of the healthcare system offer fertile ground to search for unsolved problems. From the back of an ambulance, to the operating room (OR), or the outpatient clinic, real problems abound. The principle is to observe real people and real life situations in order to fully understand clinical procedures and techniques, *as they are currently practiced*. The observer should then look for difficulties that healthcare providers or patients encounter, and major obstacles or technical barriers that may be modified. Look for what might be missing (Henry Ford). The essential task is to identify the real clinical challenges and problems that impose a significant medical burden.

This is neither an armchair exercise nor an isolated epiphany. Rather, thoughtful observation of clinical encounters with "fresh eyes" is most likely to identify substantial unsolved problems. It may be a spoken need, such as a surgeon asking for a "third hand"; it may be the unspoken need, only appreciated when clinical troubles or complications are the expectation of the treating team. When an untoward clinical outcome or complication is met with the retort, "Oh, we see this . . ." – **pay attention**. This is a great stimulus to ask: "*Why* do you see this?" "Should you see this?" "Is this inevitable?"

This sequential and iterative process from *observation* to *problem* to *need* produces real clarity. For example, a chance observation – that an elderly woman was admitted to a nursing home because of urinary incontinence – sparked the interest of a team. Subsequent inquiries unearthed the fact that more money is spent on adult diapers than on infant diapers and that urinary incontinence is the leading cause of admission to a nursing home. Thus a compelling clinical need was identified.

Notes

1. As quoted by Francis Crick in his presentation "The Impact of Linus Pauling on Molecular Biology," 1995.
2. Unsourced quotation widely attributed to Henry Ford.

1.1 Strategic Focus

Introduction

An engineer with a needle-phobic mother decides to design an alternate method for administering the daily insulin she takes to control her diabetes. A spinal surgeon, frustrated with the limitations of the implants she uses to treat vertebral compression fractures, starts working on improvements to the device. A business student observing a birth at a hospital in Africa is struck by the need for a technology to prevent blood spray during the process to protect healthcare workers when the mother is infected with HIV. A resident studying oncology becomes passionate about understanding the disease and commits himself to cancer research and the pursuit of a cure. While all of these paths are worthwhile, they are not universally appealing. The course that excites one innovator may be uninteresting or overwhelming to another. But, the one thing that these paths have in common is that they are compelling to the people undertaking them. Their commitment to these unique focus areas will drive them forward through the many challenges that await them as they begin the innovation process.

OBJECTIVES

- Understand that innovators must explicitly choose their strategic focus.
- Appreciate the importance of achieving alignment between the strategic focus area that is chosen and the mission and strengths/weaknesses of the individual or team.
- Recognize the steps involved in choosing a strategic focus.

One of the first, most important steps in the biodesign innovation process is for innovators to discover and explicitly commit themselves to the strategic focus area that stimulates their personal enthusiasm. To make an effective, meaningful decision about a strategic focus area – which could be represented by a medical practice area, a specialty, or a specific need – innovators must ask themselves questions about why they want to pursue this path, what they hope to accomplish, and how their strengths and weaknesses may affect their efforts. Additionally, a high-level assessment of the characteristics of the medical area should be taken into account relative to these goals. Ultimately, the most rewarding and successful biodesign projects are those that achieve a high degree of alignment between the values and competencies of the innovators and the defining characteristics of the strategic focus area that is chosen.

Strategic focus fundamentals

As Mir Imran, CEO of InCube Labs and founder of more than 20 medical device companies, said:[1]

> I knew once I found a problem, I could solve it. The biggest challenge for me was which problem to solve.

Choosing a strategic focus area is an essential decision that launches the biodesign innovation process. If innovators think of this process as a journey – from discovering medical needs to developing new medical technologies that solve those needs – then the selection of a strategic focus is analogous to charting a course. The myth that innovators spontaneously create new ideas and inventions in a sudden stroke of genius, and that the process of innovation has no structure or predictability, could not be further from the truth. For most medical technology (**medtech**) innovators, ideas do not just happen – they are the result of an intentional decision to go out and make observations in a specific area, study multiple aspects of the healthcare landscape, identify opportunities where poor (or no) solutions exist, and then generate new solutions that address the gaps that have been discovered.

By explicitly deciding in what areas to focus, innovators accept different risks, challenges, and potential rewards (e.g., working on heart problems is much different from working on knee problems). As the stories and case examples in this book reflect, the choices made by individual innovators early in their journey have a direct and meaningful effect on the obstacles and opportunities they encounter on their path. As a result, deciding on a strategic focus is one of the most significant and directionally important decisions that innovators will make, and one that can have a major impact on the ultimate outcome of their efforts.

Steps toward developing a strategic focus

As one of the first steps in choosing a strategic focus, it is helpful to conduct a personal inventory. Importantly, the inventory should be performed before the innovator begins thinking about any particular practice area, specialty, or specific need. The purpose of the inventory is to identify the mission of the individual or team, as well as their strengths and weaknesses. It should also result in the definition of project "acceptance criteria." These criteria will be used to evaluate and decide on an area of strategic focus later in the process when the innovators begin scanning the external environment for needs and opportunities. See Figure 1.1.1.

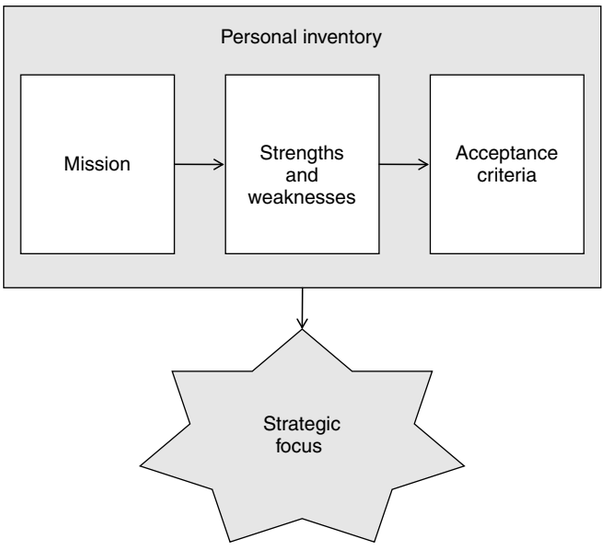

FIGURE 1.1.1
Taking the time to perform a comprehensive personal inventory can lead the innovator to the identification of an appropriate and exciting strategic focus.

Performing a personal inventory is equally important for individual innovators, academics/researchers, small teams, young companies, and large corporations, in that it helps ensure a good fit between the chosen strategic focus and the person (or people) undertaking the innovation process. The issues and priorities that emerge as a result of the inventory will be different based on the constituency performing it; however, the value of the exercise will be the same.

Determine a mission

Innovators need to be explicit about their mission. A mission is a broad, directional aspiration that defines what an individual or group wants to accomplish. Articulating a mission sets a desired destination for an innovation project and provides clarity about the ultimate goal the individual or group hopes to achieve.

To define a mission, individuals and groups should think about their priorities, beginning with questions about what is most important to them (or, conversely, what is not important to them). For example, a priority

for someone pursuing a career in research or academia might be to engage in an exceptionally compelling research project that, if successful, would have a dramatic impact on healthcare worldwide. While such a long-term mission might take an entire career to achieve, the magnitude of the potential outcome would be large enough to make that commitment worthwhile to someone with this goal. Getting involved in a project with a less significant outcome might take less time and effort to achieve, but would be less interesting to the individual due to the misalignment with his/her mission.

In companies and other established organizations, the mission sometimes takes the form of what is commonly known as a mission statement. The Medtronic example below illustrates how a corporate mission statement might look.

FROM THE FIELD MEDTRONIC

Defining a meaningful mission statement

Medtronic was founded in 1949 by Earl Bakken and his brother-in-law Palmer Hermundslieco as a medical equipment repair shop. The fledgling company quickly expanded into services and then into device design, development, and manufacturing.[2]

During the early years, Bakken was moved by the emotional response patients had to the company's products. Many were overjoyed to regain mobility, feel better, and sometimes even to be alive as a result of Medtronic's work (see Figure 1.1.2).[3] Inspired by their stories and the desire to make this type of human benefit the purpose of the organization's efforts, he and the board of directors created the Medtronic Mission, which remains an integral part of the company's culture and the driving force behind every project that it undertakes. This Mission guides the company's day-to-day work and keeps employees focused on the goal of changing the face of chronic disease for millions of people around the world.

FIGURE 1.1.2
Earl Bakken with a young Medtronic patient (courtesy of Medtronic).

Medtronic's Mission is to:[4]

- Contribute to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health, and extend life.
- Direct our growth in the areas of biomedical engineering where we display maximum strength and ability; to gather people and facilities that tend to augment these areas; to continuously build on these areas through education and knowledge assimilation; to avoid participation in areas where we cannot make unique and worthy contributions.
- Strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service.
- Make a fair profit on current operations to meet our obligations, sustain our growth, and reach our goals.
- Recognize the personal worth of employees by providing an employment framework that allows personal satisfaction in work accomplished, security, advancement opportunity, and means to share in the company's success.
- Maintain good citizenship as a company.

As William Hawkins, CEO of Medtronic, explained, "The Mission is our moral compass. It is the glue that binds all of our businesses together. It underpins everything we do. In good times and tough times, the one constant in our business model is our core values. We use the Mission to ensure that we work on the right things *and* that we strive to do things right." [5]

Large corporations may also choose to define specific missions for their divisions or groups. At this level, other priorities may surface as they approach the innovation process. With established portfolios of products to leverage (and protect), a division might not always be interested in finding the biggest near-term innovation. Instead, it may focus on driving incremental improvements in existing product lines that enable it to stay ahead of the competition. Or, with more extensive resources at its disposal, a company might be willing to make slightly larger, longer term investments with the intent of leapfrogging competitors over time.

The missions of aspiring entrepreneurs or young start-up companies may be different still. First and foremost, these individuals and teams do not necessarily need to create mission statements that are as formal or expansive as those of a large company. As long as the mission is clearly articulated, it can be significantly more informal (although it is still advisable to put it in writing). Second, the mission might be somewhat more practical or applied. For example, without the resources to support a vast, long-term research program, two innovators working together on a shoestring budget might decide that one important aspect of their mission is to identify a solution that is readily achievable (within one to two years) and compelling enough from a business perspective to raise financial support. Unlike the researcher or aspiring academic, these innovators would be more focused on near-term opportunities that are sizable, but not too expensive to pursue.

Identify strengths and weaknesses

In addition to thinking about a mission, individual innovators, academics/researchers, small teams, young companies, and large corporations will all benefit from assessing their strengths and weaknesses. Specifically, they should evaluate what they do well, and how they can capitalize on these strengths. They should also consider in what areas they are less experienced, competent, or confident, and how they can compensate for these relative weaknesses.

Some people can be successful in leading the innovation process (especially in its early stages) on their own. However, many individuals *and* groups recognize after they assess their strengths and weaknesses that they will benefit by collaborating with others who offer different, complementary skill sets. For example, if an innovator is a strong clinician, but not an engineer, it might be a helpful to partner with an engineer if the mission is to develop a device technology. Or, if that same innovator is interested in developing a business plan to pursue a concept, s/he might want to consider collaborating with someone with business training or experience to help construct and execute that plan. Wildly creative types are best paired with grounded, detail-oriented types, and so on. Fundamentally, the most important objective of this step is to identify where certain competency gaps and opportunities exist so that the innovator can address them when the time is right. It is rare for one person to embody all the talents necessary to identify, invent, develop, and commercialize a technology all on his/her own. However, if the innovator is aware of areas where help may be necessary, s/he can begin building a team with the strengths that complement known weaknesses, and can make sure that team expands as the need for more diverse skills increases.

Define acceptance criteria

The identification of a mission and the evaluation of strengths and weaknesses are direct inputs to the definition of project "acceptance criteria." At their most basic, acceptance criteria are parameters that must be met to make an innovation project attractive to the innovator. These criteria are used to choose an area of strategic focus, as well as to evaluate the specific opportunities that are discovered in the early stages of the biodesign innovation process. Common examples of factors to consider in defining acceptance criteria are found in Figure 1.1.3.

For example, suppose that a large corporation has a mission to develop a product that expands its portfolio into a new clinical area within the next two to three years to drive increased growth within the company. Before defining its acceptance criteria, the company would have to think about what strengths and weaknesses it has that would enable it to achieve this goal.

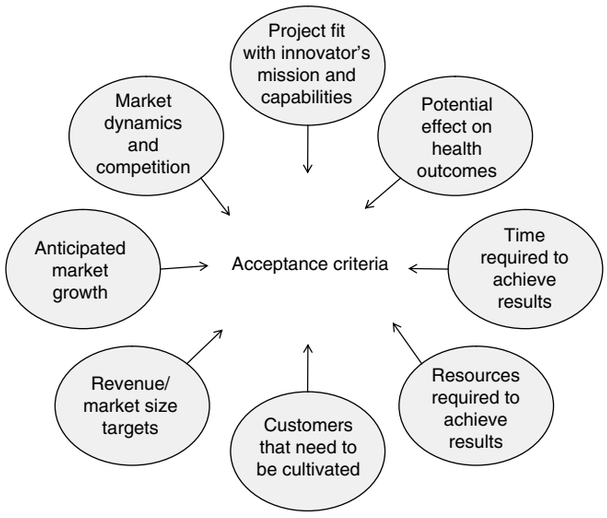

FIGURE 1.1.3
These and many other factors help shape an innovator's acceptance criteria, which can then be used to help define a strategic focus.

The availability of resources (staff, funding, and time) could certainly be a strength. However, the way in which the company's existing sales force is deployed (i.e., which types of doctors it already calls on) could be a strength or a weakness, depending on the specific area of focus that is chosen. After performing an assessment, the corporation might decide to engage in a project only if it meets the following acceptance criteria.

- The clinical practice area is new to the company and is growing at a minimum of ten percent per year and/or can generate a minimum of $100 million in revenue per year.
- Technologies in this space have a relatively simple regulatory pathway and straightforward **clinical trials** requirements so they can be brought to market quickly.
- The company's established sales force already calls on these same customers, so the commercial fit is very good.

For example, in the mid-1990s, American Medical Systems (AMS) had two primary products: an implantable urinary sphincter and a penile prosthetic line. The company had a mission of becoming a well-rounded urology company by broadening its focus to include other urological products. As it began to think about its acceptance criteria for new opportunities, the list included the following: (1) technologies that could be sold to the same customer or at the same "call point," (2) technologies that were more mechanical in function than biological, and (3) opportunities/areas that could grow at greater than 20 percent per year to add to the company's revenue growth.[6] Under different circumstances (for instance, if the company had saturated its existing customer base), the corporation might have eliminated the criterion to stay within the same customer group. While this would have made a wider cross-section of potential projects attractive to the company, it might not have allowed the company to achieve certain economies of scale by offering the same customers a wider line of products through the existing sales force. In this respect, the acceptance criteria defined by the company appropriately reflected the priorities of AMS at the time and capitalized on the perceived strength of its established sales arm.

Without any limitations imposed by a pre-existing business, an innovator or young company might define acceptance criteria around the magnitude of the impact its innovations can have on peoples' lives. In this scenario, with a mission to improve important outcomes for patients on a major scale, the acceptance criteria might require a project that:

- Has a total potential market of $1 billion or more.
- Will be attractive to investors (so it gets adequate financial support).
- Results in an innovation that has a significant impact on patients' **quality of life** (as opposed to an innovation that makes a device cheaper, faster, or easier to use).
- Has platform potential so that the benefits from one medical specialty can be rapidly leveraged to affect patients in other practice areas.
- Is focused on a patient segment where head-to-head competition can be avoided, especially if the company is concerned about its ability to compete with entrenched firms.

The acceptance criteria above are similar to those used by medtech **incubators** such as ExploraMed, The

Foundry, or The Innovation Factory. Such criteria enable these organizations continually to deliver powerful innovations in a number of diverse fields.

Fundamentally, acceptance criteria are the mechanism through which a mission, priorities, strengths, and weaknesses are woven together into a list of requirements that an innovation project must meet. There is no single set of acceptance criteria that works for every individual or team. However, whether they are driven by charitable motives, purely academic or scientific interest, or entrepreneurial drive, setting these criteria early will help ensure that their goals are ultimately achieved.

Articulating a strategic focus

Once specific acceptance criteria have been defined, the innovator can start exploring different medical specialties and practice areas for a good fit. Innovators are encouraged to look at a broad range of areas, keeping in mind that deep expertise in a field is not necessarily required. All too often, people who are deeply immersed in a field fail to see the opportunities and needs that surround them because they have been indoctrinated into a certain way of doing things. Individuals and teams that bring diverse experiences and different backgrounds to a field can sometimes be more successful in identifying needs and opportunities because they are more willing to question the status quo.

While a sweeping investigation of opportunities across the healthcare landscape is useful for some innovators, others have defined acceptance criteria that point them to a specific field based purely on a personal interest or passion for a practice area. For instance, someone might be committed to addressing needs in the breast cancer field after losing a loved one to the disease. While this is certainly a valid approach, such individuals are encouraged to get even more specific about their strategic focus. For instance, would it be a better fit to embark on a long-term research-based path to cure the disease, or to pioneer near-term improvements in the effectiveness of breast cancer treatment? The innovator can use his/her other acceptance criteria to define a focus within the desired field that is most likely to lead to a fulfilling experience and outcome.

As exploration of the healthcare landscape begins, certain choices can be immediately eliminated. For example, an innovator who is determined to have a major impact on treating or curing chronic illness can quickly set aside the investigation of any acute conditions. One who has defined acceptance criteria around the treatment of heart disease has no need to evaluate opportunities in other practice areas. If speed to market is a priority, areas that would require long regulatory or clinical processes are best avoided. All of these decisions, if identified early, can shape the strategic focus and have a powerful impact on the outcome.

One way an innovator can begin the process of screening focus areas against his/her acceptance criteria is to examine high-level data related to a practice area (note that more in-depth research will be performed in subsequent steps of the biodesign innovation process). Statistics to consider include the number of people affected by a disease state, the clinical impact of the disease or the outcomes of existing treatments, the profitability of existing treatments, and the rate at which spending is growing. See Table 1.1.1. Innovators can also glean insights from the total revenue realized each year in a particular medical field. See Figure 1.1.5.

The more rigorous this evaluation process, the better. However, even a cursory evaluation of different treatment areas (and their sub-specialties) will potentially help to narrow one's focus. For example, an innovator or company seeking a large business opportunity might review certain statistics and other data and immediately become interested in the cardiovascular field. Yet, the fact that this is a relatively well-established, mature field may conflict with some of the other acceptance criteria that the innovator has defined. If s/he is committed to new opportunities and needs that have not yet been defined or where innovation has not occurred for quite some time, another field outside of cardiology might be a better fit (e.g., respiratory medicine or urology). In an area with a well-defined market opportunity, there may be intense competition and a great deal of pressure to be first to market with technology that could set the new **standard of care**. In less popular

Table 1.1.1. *Data such as the percentage of total change in healthcare spending accounted for by the 15 most costly medical conditions, as shown in the table, can be an interesting source of ideas regarding areas that meet an innovator's acceptance criteria (copyrighted and published by Project HOPE/Health Affairs as Kenneth E. Thorpe, Curtis S. Florence, and Peter Joski, "Which Medical Conditions Account for the Rise in Health Care Spending?" Health Affairs, web exclusive, August 25, 2004; the published article is archived and available online at www.healthaffairs.org).*

	Treated prevalence per 100,000		Spending (millions of dollars)		Approximate percentage change in total healthcare spending
Condition	1987	2000	1987	2000	(1987–2000)
Heart disease	6,189	6,226	30,450.1	56,678.6	8.06
Pulmonary conditions	10,389	15,526	11,684.5	36,476.5	5.63
Mental disorders	4,373	8,575	9,935.8	34,439.1	7.40
Cancer	2,862	3,348	21,167.5	38,901.8	5.36
Hypertension	9,734	11,382	8,008.6	23,394.5	4.24
Trauma	17,866	12,338	26,527.6	41,124.2	4.64
Cerebrovascular disease	410	854	3,859.8	14,938.8	3.52
Arthritis	5,479	6,966	7,403.5	17,686.3	3.27
Diabetes	2,961	4,260	8,661.1	18,287.9	2.37
Back problems	3,400	5,092	7,964.6	17,451.0	2.99
Skin disorders	6,754	7,990	4,758.0	12,044.5	2.26
Pneumonia	1,537	1,370	5,437.6	12,641.3	2.29
Infectious diseases	6,588	5,841	3,658.0	9,849.5	1.35
Endocrine	5,515	7,322	5,247.8	10,276.9	1.18
Kidney	675	908	4,938.1	8,169.5	1.03

areas, the advantages of weaker competition are balanced by greater uncertainties. Both issues impact the ability to attract investment and motivate behavior change among physicians who are entrenched in the old ways of treating patients. This is where the innovator's acceptance criteria (and prioritization) can help to resolve inherent conflicts and facilitate effective trade-offs, which become clearer when evaluating these different risks and rewards.

Once preliminary data about the defining characteristics of various practice areas have been considered against the acceptance criteria, a strategic focus or a few acceptable focus areas should begin to emerge. While the focus area will be different for every individual or group, the key is to ensure that it is aligned with the innovator's mission, strengths, weaknesses, and acceptance criteria. For example, one innovator might choose to pursue opportunities related to chronic obstructive pulmonary disease, while another decides to go after opportunities associated with retinal detachment in the eye. In either scenario, a strong sense of "the right fit" is essential to anyone embarking on the biodesign innovation journey.

The following story from ExploraMed describes how one innovator worked through the process of choosing a strategic focus.