BioDesign
The Process of Innovating Medical Technologies
by
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IDENTIFY --> INVENT --> IMPLEMENT

THE 6 STAGES of MEDICAL DEVICE DEVELOPMENT
1) Identify -- Needs Finding
   strategic focus, need statement
2) Identify -- Needs Screening
   disease state, treatment options, stakeholder/market analysis, needs filtering
3) Invent -- Concept Generation
   ideation, brainstorming, concept screening
4) Invent -- Concept Selection
   intellectual property(IP), regulatory and reimbursement concerns, prototyping
5) Implement -- Development Strategy and Planning
   strategy for research/development, clinical use, IP, regulatory, quality, marketing
6) Implement -- Integration
   business plan, operating plan, financial model, funding sources, licensing

see website  www.ebiodesign.org

Quotes to inspire Needs Finding -->

If you want to have good ideas, you must have many ideas
   -- Linus Pauling, Nobel Prize, BioChemistry

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

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:

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.

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.

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**FROM THE FIELD | MEDTRONIC**

**Defining a meaningful mission statement**

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

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 be alive as a result of Medtronic's work (see Figure 1.1.2).  

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.

Medtronic's Mission is to:

- 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.”

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**FIGURE 1.1.2**

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

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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.

**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 biosdesign 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.
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. 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 biosign 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).

<table>
<thead>
<tr>
<th>Condition</th>
<th>Treated prevalence per 100,000</th>
<th>Spending (millions of dollars)</th>
<th>Approximate percentage change in total healthcare spending (1987-2000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart disease</td>
<td>6,189</td>
<td>30,450.1</td>
<td>56,678.6</td>
</tr>
<tr>
<td>Pulmonary conditions</td>
<td>10,389</td>
<td>11,684.5</td>
<td>36,476.5</td>
</tr>
<tr>
<td>Mental disorders</td>
<td>4,373</td>
<td>9,935.8</td>
<td>34,439.1</td>
</tr>
<tr>
<td>Cancer</td>
<td>2,862</td>
<td>21,167.5</td>
<td>38,901.8</td>
</tr>
<tr>
<td>Hypertension</td>
<td>9,734</td>
<td>8,008.6</td>
<td>23,394.5</td>
</tr>
<tr>
<td>Trauma</td>
<td>17,866</td>
<td>26,527.6</td>
<td>41,124.2</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>410</td>
<td>3,859.8</td>
<td>14,938.8</td>
</tr>
<tr>
<td>Arthritis</td>
<td>5,479</td>
<td>7,403.5</td>
<td>17,686.3</td>
</tr>
<tr>
<td>Diabetes</td>
<td>2,961</td>
<td>8,661.1</td>
<td>18,287.9</td>
</tr>
<tr>
<td>Back problems</td>
<td>3,400</td>
<td>7,964.6</td>
<td>17,451.0</td>
</tr>
<tr>
<td>Skin disorders</td>
<td>6,754</td>
<td>4,758.0</td>
<td>12,044.5</td>
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<tr>
<td>Pneumonia</td>
<td>1,537</td>
<td>5,437.6</td>
<td>12,641.3</td>
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<td>Infectious diseases</td>
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<td>Endocrine</td>
<td>5,515</td>
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<td>10,276.9</td>
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<tr>
<td>Kidney</td>
<td>675</td>
<td>4,938.1</td>
<td>8,169.5</td>
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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.
Applying acceptance criteria in evaluating a strategic focus

Making an explicit decision about the strategic focus to be pursued is an essential exercise for individual innovators, teams, companies, and company incubators alike. According to Josh Makower, founder and CEO of medical device incubator ExploraMed, “Choosing what is not a fit is as important as determining what is.” ExploraMed, which was started in 1995, has embedded this step in its process for identifying, creating, and developing new medical device businesses. When Makower initiates a new business, he and his team spend time assessing their relative strengths and weaknesses and articulating the acceptance criteria against which they will screen potential opportunities.

ExploraMed’s defined mission is to “focus on clinical needs where there is an opportunity to dramatically improve outcomes and build freestanding businesses.” As Makower explained, “I get excited about working on things that are going to have a major impact on medicine. We want to work on projects that make a substantial contribution, can potentially change the direction of healthcare, and affect outcomes for thousands or millions of patients. If a large number of people are affected by a problem and currently have poor outcomes from the existing set of treatments, it could be a hot area for us to investigate.” Recognizing their own strengths and weaknesses, Makower and team further constrained their efforts to medical device opportunities, leaving drugs, diagnostics, and other healthcare technologies to a different set of innovators and entrepreneurs. Finally, they specifically decided that they liked the idea of being “contrarians.” “We like to go where others haven’t gone and where people believe there aren’t reasonable opportunities. You can create a competitive advantage for yourself by being the first to go in another direction. The other thing that we’re trying to do is create big enterprises. To do this, we almost always have to be willing to go into a space where there aren’t a lot of other players. A little fish can grow to be pretty big if he finds himself in a large pond all by himself. I like that a lot better than trying to establish a foothold in an already crowded market.”

These defined acceptance criteria are routinely used by ExploraMed to evaluate which opportunities to pursue, as the following example demonstrates. Early in the company’s history, when the team was actively investigating new projects, Makower’s elderly aunt fell and broke her hip. “Before the accident, she was energetic, vibrant, and active. After she fell, her life changed dramatically. She had trouble with her daily activities, as well as doing the things she loved like seeing her children and grandchildren. Suddenly, she was an old lady, when that wasn’t how she lived before.” With a new passion to address patient needs in this area, Makower and Ted Lamson, an ExploraMed project creator at the time (see Figure 1.1.4), began to investigate the space. What they quickly learned was that hip fractures represented a sizable problem. Some 350,000 elderly people broke a hip each year in the United States alone. Only 50 to 60 percent of those individuals recovered fully; 20 percent never walked again; and 40 percent ended up in a nursing home. Furthermore, within a year, 37 percent of Americans suffering a hip fracture were dead. “It’s a shocking mortality rate,” noted Makower. “We speculated that there was a need for a less invasive alternative to hip replacement, and that the size of the incision or morbidity from the operation itself was the key to the problem. Eventually, we discovered that this guess was wrong and that the real need was not in the surgery, but in post-surgery recovery. If we hadn’t been following a defined process for identifying and understanding needs, we easily could have become biased towards a solution early on that would have sent us in the wrong direction,” he emphasized.
ExploraMed’s acceptance criterion related to the size and severity of the problem was the first screen the team applied to the problem, and hip fractures appeared to be a promising market. Makower and Lamson conducted further preliminary research to understand what companies and innovations were active in the space. It turned out that numerous advancements had been made in hip surgery and the devices used to support it, but that few new technologies existed to improve post-operative care and recovery. “If you get the patient up immediately post-procedure, and you effectively manage their pain locally so they can walk around and never waste any of their muscles, then their outcomes are fantastic. But if they stay in bed more than they should because their pain is not managed well, they die terribly. What happens is that they lose muscle mass, they get sick or become depressed, and then they die of pneumonia or some other complicating condition.” With few individuals or companies working to address the non-surgical issues associated with hip fractures, the field appeared to be wide open to ExploraMed.

Unfortunately, when it came to ExploraMed’s desire to focus on medical devices, this is where the project took a different turn. “We discovered that the real need was for something to improve local pain management to help patients ambulate more quickly,” recalled Makower. “It was a big opportunity in an open market, but we realized it could probably be addressed best by a drug. We didn’t have the right technology, skills, or resources to take on a drug project. We really wanted to figure it out, but we realized that we weren’t the right guys to do it. Regardless of your passion for an area, you have to be honest with yourself about you and your team’s strengths and weaknesses.”

The team confirmed its finding through additional research, observations, needs finding, and consultation with experts in the field (as described in 1.2 Observation and Problem Identification and 1.3 Need Statement Development). “Upon further research we actually discovered there already existed systems to do exactly what we wanted to do to address this need, but they were not being utilized because of healthcare management constraints or cost. This was very discouraging ... the answer was there and doctors were actually aware of it, but they were not using it for one reason or another,” Makower commented. Eventually, the team decided to reject the project, and continue their search elsewhere. “You have to be willing to accept a lot of failure,” he said, reflecting on the experience. “But you’ve got to keep on trying — and failing if necessary — in order to understand the parameters that will make you successful and ultimately enable you to choose the right path.” Later, Makower and Lamson redirected their focus to an entirely different clinical area and, after several months of investigation, found a compelling opportunity that met all their criteria and became a company called NeoTract, Inc. (see 5.2 R&D Strategy for more information about NeoTract).

Global considerations in choosing a strategic focus

In a 2008 article, worldwide medical device sales were estimated at $200 billion, of which the United States accounted for 45 percent, Europe 30 percent, and Japan 10 percent. The remaining 15 percent represented the rest of the world, including the large but still developing markets of China and India. While the vast majority of medtech innovation is presently centered in the West, this was expected to change dramatically over the next two decades. As a result, more and more innovators would begin choosing strategic focus areas outside the United States and Europe.

An important issue for innovators to recognize when seeking opportunities outside these well-developed markets is that their acceptance criteria will likely be markedly different. Particularly in the United States, there tends to be a heavy emphasis on practice areas with target populations that can support cutting-edge products with high profit margins. In emerging markets, such as China, India, and Africa, there are vast groups of patients that may only require a simple solution, but who have a limited ability to pay for new technologies. As the appetite for devices and the ability to pay for them develops in these countries, the innovators who focus on these markets will be drawn to them.
by their passion, commitment to helping others, and their desire to have a major impact on large numbers of prospective patients, rather than by an interest in optimizing their financial return. See Figure 1.1.6.

Beyond financial considerations, innovators exploring strategic focus areas in emerging markets also face an increased level of risk. For instance, in places like China, intellectual property (IP) enforcement and regulatory processes are still largely underdeveloped. This additional uncertainty prevents some companies and innovators from moving into these markets and creates additional challenges for those who do. Many of these types of risks will almost certainly be reduced or resolved over time, but the efforts of many motivated and committed innovators will be required to make this happen.

**Ethics in the biodesign innovation process**

Choosing a strategic focus is among the first of many steps in the biodesign innovation process where innovators may face ethical dilemmas. The potential for ethical conflicts exist at nearly every stage of an innovator’s journey. Ethics focus on the intentional choices that people make and the basic moral principles that are used to guide these decisions. Ethics do not provide a specific value system for making choices, but rather a set of basic principles that can be followed to guide decision making. Stated another way, ethics provide the rules or standards that guide (but do not determine) the conduct of a person or the members of a profession. In developing and bringing new medical technologies to market, the need to maintain the highest ethical standards extends to everyone involved in the process.

At the heart of most ethical issues are conflicts of interest, which arise when one person’s interests are at odds with another’s. For example, confidentiality, or the practice of discerning what is privileged information and rigorously protecting it, is an important principle in the medical field. If one party has an incentive to disclose confidential information about another party, a conflict of interest may arise. Because there are so many individuals and groups in the development and commercialization of any medical innovation, conflicts of interest are inevitable. Realistically, the objective of any innovator should not be to avoid such conflicts, but to ethically address and resolve them when they arise. In particular, in any scenario where conflicts of interests involve patients and the care they receive, innovators have a special obligation to act ethically.
A Jaipur artificial limb (as shown above) costs $35–40 to manufacture in India, while an artificial limb in the United States can cost anywhere from $6,000 to $35,000. Disparities such as these have sizable implications for the innovator in choosing a strategic focus. (Courtesy of the Stanford-Jaipur Knee Team from Professor Tom Andriacchi’s mechanical engineering course: L. Aye Roberts, Joel Sadler, Angelo Szychowski, and Eric Thorsett).

FIGURE 1.1.6

because of the potential to both improve and harm human lives.

Ethics in the medical field have a difficult past, with trials, such as the Tuskegee syphilis experiment, creating issues of fear and distrust between medical providers and the patients they are meant to serve. In this particular case, the US Public Health Service ran an experiment on 399 black men from 1932 to 1972. These patients, who were mostly poor and illiterate, had late-stage syphilis but were not informed from what disease they were suffering. The doctors involved in the experiment had no intention of curing the men—instead, their objective was to collect scientific data from their autopsies. Over years, the patients experienced tumors, heart disease, paralysis, blindness, insanity, and, eventually, death. Since then, significant strides have been made in enforcing a strong code of ethics across the medical community. Moreover, every member of the medical community, medtech innovators included, has an important role to play in promoting and adhering to ethical behavior.

Early in the biodesign innovation process, for instance when choosing a strategic focus, innovators often struggle with the tension between altruistically addressing important medical needs and the imperative to do so in such a way that the solution has a viable chance of reaching the market for which it is intended. An inspirational new therapy cannot, in most cases, reach patients without the necessary capital to develop it; yet capital will only be provided by commercial investors if they feel that a reasonable profit can be obtained. It can be frustrating to innovators to identify important medical needs only to discover that the market or profit potential for a solution is too small or risky to attract funding. Although capital can be obtained from government grants, non-governmental organizations (NGOs), or beneficent donors, there are inherent limitations associated with this type of funding that can prevent an innovation from achieving its full potential.

To develop a truly sustainable solution, most innovators have to strike a balance between satisfying the needs of the target audience and satisfying the interests of investors. Protecting investors is known as a fiduciary duty. A fiduciary is any individual or group that has the legal responsibility for managing somebody else’s money. As a fiduciary, the innovator has an obligation to carry out the responsibility of managing others’ funds with the utmost degree of “good faith, honesty, integrity, loyalty, and undivided service of the beneficiary’s interest.” At the most basic level, this means that the innovator has a duty not to favor anyone else’s interests (including his/her own) over those of the beneficiary. If the fiduciary violates this responsibility, s/he may be subject to legal liability, which is another reason why ethical behavior is so important throughout the innovation process.
Table 1. An example of a medical ethics (from the American Medical Association’s "Principles of Medical Ethics" reprinted with permission).

<table>
<thead>
<tr>
<th>American Medical Association’s principles of medical ethics</th>
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<tbody>
<tr>
<td>A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.</td>
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<tr>
<td>A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.</td>
</tr>
<tr>
<td>A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.</td>
</tr>
<tr>
<td>A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.</td>
</tr>
<tr>
<td>A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.</td>
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<tr>
<td>A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.</td>
</tr>
<tr>
<td>A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.</td>
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<tr>
<td>A physician shall, while caring for a patient, regard responsibility to the patient as paramount.</td>
</tr>
<tr>
<td>A physician shall support access to medical care for all people.</td>
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Striking an appropriate balance can be difficult when conflicting interests arise. The important thing to remember is that the right solution may vary for each individual innovator based on his/her ethical compass. By openly acknowledging the fact that “gray areas” exist and taking time for self-reflection, innovators can more readily determine the approach that is most closely aligned with their values.

Regarding other ethical conflicts in the innovation process, innovators are generally advised to maintain a primary focus on the needs of patients in resolving issues. Seeking input and advice from objective third parties can be an invaluable resource for resolving conflicts. However, more often than not, innovators must rely on their own codes of personal and professional ethics. The following four principles are widely accepted as ethical standards in the medical field.15

Respect for autonomy
Respect for autonomy refers to others’ rights to make their own choices. This means, for example, that all parties with an interest in a new innovation need to be informed about its risks and benefits, any potential conflicts of interests among those involved in its development and delivery, and about any other factors that could conceivably affect their choice.

Beneficence
Beneficence is the practice of doing good. In the medical field, this mandate extends to maximizing benefits while seeking to minimize potential harm.

Non-maleficence
The mandate of non-maleficence is also captured by the phrase “First do no harm.” Often beneficence and non-maleficence cannot be separated. In the process of providing a medical benefit, healthcare providers may also expose patients to risk. For instance, in clinical trials, patients are exposed to risks for the sake of others, by making it possible for life-saving devices to reach the market. The Hippocratic oath taken by each physician essentially combines the principles of beneficence with non-maleficence, by stating that the obligations of healthcare professionals is to provide the greatest net medical benefit at minimal risk.16
1. Take inventory

Getting Started

1.1 What to cover - Before thinking about a specific practice area to pursue, perform a personal inventory. Define a mission that reflects the defined purpose, priorities, and specific goals in launching the biodesign innovation process. Next, assess key strengths and weaknesses, and begin thinking about how to complement the innovator's skills with those of team members.

1.2 Where to look

Personal reflection - Spend time alone reflecting on the fundamentals section of the chapter. Complete an honest assessment of opportunities, reflecting on strengths and weaknesses, and identifying key acceptance criteria.

2. Articulate a strategic focus

What to cover - Begin by performing research to identify areas of potential opportunity. Some of the key questions to ask include:

- Is the project feasible?
- Are there any existing technologies that could be leveraged?
- Will the project be scalable?

Facilitated sessions - If working in a group, consider holding one or more facilitated sessions to build consensus regarding the team's mission, strengths/weaknesses, and ongoing issues.

Acceptance criteria - Advice from respected advisors - Sometimes, other members of the team can help an innovator identify his/her strengths or weaknesses. Through the process of getting to know the innovator, advisors can offer important insights that can help one develop a vision.

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2.2 Where to look

- **PubMed** - PubMed is a database of the US National Library of Medicine that includes more than 16 million citations from MEDLINE and other life science journals dating back to the 1950s.
- **Agency for Healthcare Research and Quality (AHRQ)** - Sponsors and conducts research that provides evidence-based information on healthcare outcomes, quality, cost, use, and access. From its website, one can gain access to longitudinal data regarding patient interactions with the healthcare system, including all transactions and their codes (indicating procedures and diagnosis), as well as location of service, which can be used to help develop market segments. Important databases accessible via the site include:
  - **HCUPnet** - A free, online query system based on data from the Healthcare Cost and Utilization Project (HCUPnet). It provides access to health statistics and information on hospital stays (inpatient encounters) at the national, regional, and state levels.
  - **MEPS Data** - The Agency for Healthcare Research and Quality provides longitudinal data on the health expenditures of 30,000 US households via the Medical Expenditures Panel Survey (MEPS).

Data is publicly available for primary analysis. It is useful for more detailed analyses of market segments (and sizing), but working with the data can be labor-intensive. This source is probably most helpful if the innovator or company needs to support a need specification with actual publications as part of a marketing strategy. Data is available for conditions with a 1 percent prevalence rate or greater.

- **US Census Bureau** - Provides online access to the latest US census data
- **World Health Organization** - WHO is the directing and coordinating authority for health within the United Nations system. Information on global health trends, research, policies, and standards can be found through this group.
- **Professional societies** - These associations can provide a wealth of information to help innovators understand issues and opportunities within a potential focus area. See Appendix 1.1.1 for a table that includes a sample of the professional societies that exist within fields associated with the 15 most costly medical conditions.
- **Industry-specific news resources** - Online and offline publications in the medtech field, such as Medtech Insight, InVivo, and Start-Up Magazine are also useful sources of relevant information.

Credits

The editors would like to thank William Hawkins and Richard L. Popp for their contributions to this chapter.
## Professional associations for select medical conditions

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