2.4 Market Analysis

INTRODUCTION

Not all needs are created equal. For better or worse, innovators must recognize that even seemingly important needs cannot be addressed unless there is a compelling, accessible market to support the effort and expense required to bring forward a new solution. In today's healthcare environment, the size and growth rate of the target market, and the presence and nature of competition in the field all directly affect the attractiveness of the need. In addition, innovators must consider the opportunity to create value in the need area. There must be "room" within the market for the team to develop a solution that can deliver requisite improvements at or below a defined cost threshold in order to the capture the attention of the target market and drive adoption.

Market analysis enables innovators to understand which of their needs are associated with a commercially viable market. Key customers, prospective investors, and the team itself must all see value in addressing a need in order for it to be worth pursuing.

Market analysis begins with a landscaping exercise that is intended to provide a broad understanding of the need area in terms of its total size, range of existing solutions and competitors, and gaps that may exist and indicate opportunities for innovation. Next it focuses on a progressively detailed evaluation of different segments within the overall market to determine which one(s) the innovators should potentially target if they decide to pursue the need. An important part of this analysis is deriving a value estimate that articulates how much and what type of improvements a new solution must deliver, at or below a defined cost threshold, in order to have a reasonable likelihood of being adopted by the target market.

The information gathered through 2.4 Market Analysis is important throughout the biodesign innovation process. It provides essential input into 2.5 Needs Selection. As innovators make the transition from working with needs to solutions, market analysis is repeated and performed in greater depth in conjunction with 5.7 Marketing and Stakeholder Strategy. The output of that chapter then becomes essential input into 6.1 Operating Plan and Financial Model.

See ebiodesign.org for featured videos on market analysis.

OBJECTIVES

- Understand how to perform broad market landscaping to get a directional sense of a market when working with large numbers of needs.
- Learn to divide a market into segments of homogenous customers that share similar perceptions of and/or responses to medical need.
- Appreciate how to define the market size, growth, and competitive dynamics of each segment.
- Recognize how to determine the extent to which stakeholder needs are currently being addressed within each segment, assess stakeholder willingness to pay for alternate solutions, and bring this information together to create a value estimate for a market segment.
- Recognize key considerations in choosing a target market.

MARKET ANALYSIS FUNDAMENTALS

Market analysis is performed early in the biodesign innovation process to assess whether a potential need being evaluated is associated with a commercially viable market. Importantly, innovators must determine for themselves what constitutes an attractive market using input from potential customers, as well as feedback from possible investors (or other providers of capital). While the perspectives of these three constituencies will vary, customers, investors, and the innovators themselves must all see value in addressing a need in order to make pursuing a solution worthwhile. Fundamentally, the question that must be answered is: Will the gain be worth the pain?

As the cost and complexity associated with developing and commercializing medical devices continues to escalate, many innovators believe that having a large market is one key to success. As Richard Stack, who serves as the president of Synecor Inc., a Silicon Valley-based medical device **incubator**, summarized:[1]

> *The need has to have a very large market . . .. There's only so much time in the day, and it's really just as easy to develop a solution for a large market as it is for a small market.*

In contrast, other innovators prefer an alternate approach: starting with a smaller market and expanding over time. John Abele, co-founder of Boston Scientific, provided this perspective:[2]

> *I'm a big fan of niches – of not trying to take on an entire market at once – because there's less resistance to innovation when you do it on a smaller scale.*

While innovators may favor different market types, there is widespread agreement regarding the importance of performing market analysis before deciding on which **needs** to take forward into invention. Using market characteristics as factors for choosing which needs to pursue ensures that innovators understand the extent of the **value** that potentially can be generated and captured in a need area. The outcome of market analysis also enables innovators to appropriately refine the **need statement** and develop an expanded **need specification** (see 2.5 Needs Selection) that focuses on the unique needs and requirements of the chosen target market.

Market analysis is a multi-step process that leads the innovator through an increasingly specific investigation, as described in Table 2.4.1. The remainder of this chapter explores each of these important steps in more detail.

Step 1 – Landscape the market

With dozens or even hundreds of needs to evaluate, innovators cannot realistically perform an in-depth market analysis for each one. Often, it makes sense to start with a higher-level approach, focused on understanding the broad market landscape for each need, and then work toward increasing depth and detail as the list of needs is narrowed down through the iterative needs screening process.

A useful way to initiate a market landscape is to start by thinking about the total market for the need area. Innovators can go back to the research performed as part of 2.1 Disease State Fundamentals to refresh themselves on total spending for the disease state. For example, when Moshe Pinto, Dean Hu, and Kenton Fong were students in the Stanford Biodesign program, they began working on the need *to promote the healing of chronic wounds*. As part of the team's research, Pinto and his teammates discovered that the wound care market is immense, accounting for more than $20 billion in annual healthcare costs in the US alone and $566 million in wound care products.[3]

To begin thinking about how well needs are being addressed in the overall market, innovators can next revisit and build on the information they gathered in 2.2 Existing Solutions. Through this assessment, they should already have at least some data on which diagnostics, treatments, and therapies dominate the need area, as well as their approximate cost, utilization, and relative effectiveness. Use this information to create a map of the market from a solution point of view, conducting additional research as needed to fill in missing data. For example, in a simple version of a solution map, innovators place cost on one axis and effectiveness on the other and then plot the comparative position of the major treatment alternatives. In a slightly more advanced version, different sized "bubbles" can be used to convey

Table 2.4.1 The three key steps for performing a high-level market analysis.

Step	Topic	Questions to investigate
1	Market landscape	Thinking about all relevant stakeholders or the "total market," how well are customer needs generally addressed by existing solutions? If no solutions currently exist, then what is the magnitude or importance of the need when viewed from the customer's perspective? ***Gaps*** How closely aligned are available solutions with the need the innovators are seeking to address? What gap(s) exist where a new solution could potentially add value? How important is addressing this gap viewed from the customer's perspective? ***Size and growth*** What is the approximate size of the total market for all existing solutions? What is the size of the market by available solution? Is the market expanding or contracting? Where is the most predominant positive or negative growth occurring?
2	Market segmentation	What are the key factors that can be used to divide the total market of all potential customers into distinct segments, in which the population shares common needs and perceptions (e.g., patient characteristics, solution options, provider attributes, and **payer** mix)? Do meaningful differences exist? ***Size and growth*** What is the size of the market opportunity in each market segment and the potential for growth and expansion? ***Competitive dynamics*** What are the competitive dynamics in each market segment that a new entrant would face? How intense is the competition? Are new companies created and are they successful? What is the nature of their competitive relationship with existing companies? Are companies acquired in this space? ***Needs*** What are the unique customer needs of each market segment? ***Willingness to pay*** Which **stakeholder** could recognize the greatest value created by a new solution? What level and type of value would potentially cause the members of the market segment to change their behavior and embrace a new solution? How willing is each market segment to pay for a new solution and, if applicable, what do customers pay for existing solutions? How motivated is each segment to adopt a new solution?
3	Target market	Which market segment(s) stands to gain the most value from a new solution? Which market segment is likely to create the most value for the: • Customer (the decision maker that will pay for a solution) • Investor (the provider of capital) • Innovator (the provider of intellectual capital and labor)?

the approximate size of the market for each treatment. The rate at which treatment utilization is growing (or contracting) is another factor to consider adding to the landscape.

In some cases, innovators create multiple views of the high-level market landscape – for instance, developing one version that sizes the bubbles for each treatment based on the total number of patients using the

intervention and another version that sizes them based on total annual spending or the growth rate in each category. Innovators can also evaluate what treatments are available to patients (and at what cost) at different stages of the disease by replacing effectiveness with disease severity on one axis and creating a completely different map. Or they can evaluate the cost of treatment per patient versus total spending on treatment for patients at each stage of the disease.

After one or more views of the market landscape have been developed, innovators can begin thinking about what gaps exist in the overall market. Gaps often correspond to opportunities to create and deliver value. For instance, a landscape that looks at the cost of available treatments relative to their general effectiveness can help innovators estimate the *value* that any new solution would have to be able to deliver in order to displace available treatments. More information about constructing a **value estimate** is provided later in this chapter.

Figure 2.4.1 shows a market landscape diagram created as part of the wound care project referenced previously. This team, which eventually went on to found a company called Spiracur, identified that a sizable gap existed in the chronic wound care market for a solution with a moderate cost, along with effectiveness equivalent to leading solutions. They also perceived that the large treatment category of negative pressure dressings, which was the fastest-growing part of the market, was the "solution to beat." If they could provide a lower-cost solution that delivered comparable results, it would be feasible to make inroads into the market.

Figure 2.4.2 provides another example from a team focused on needs related to chronic obstructive pulmonary disease (COPD), a condition that costs $32 billion to treat each year in the United States. These innovators were drawn to the overall need for more effective and affordable solutions for diagnosis and treatment in the disease area. As team member Michael Winlo summarized, "COPD is one of the few chronic diseases that is *increasing* in prevalence globally, and the **morbidity** of the disease is really significant. But there aren't a lot of really great solutions to effectively treat this condition."[4] This group believed that a gap existed in the market for a solution that helped manage the disease that was less expensive yet more effective than basic telemonitoring.

Maps like the ones shown here are sufficient for providing an early, directional sense of where high-value opportunities may exist. However, as they are further developed and become more detailed, they also become more useful. For instance, by further quantifying each axis, innovators can better estimate what level of effectiveness a new solution would have to deliver, within

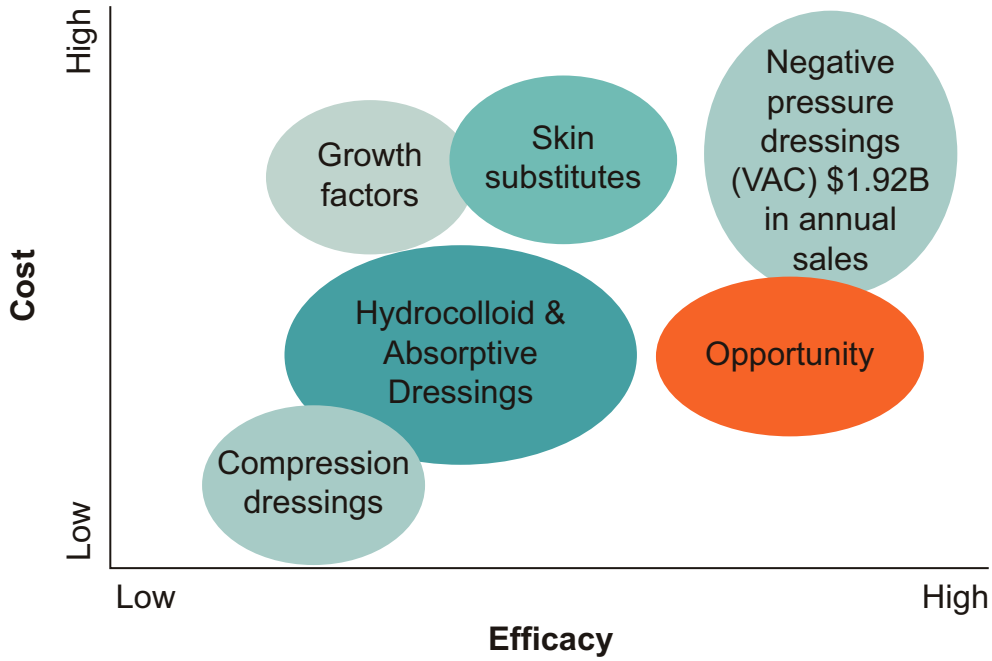

FIGURE 2.4.1
A high-level market landscape for wound care (courtesy of Spiracur, Inc.).

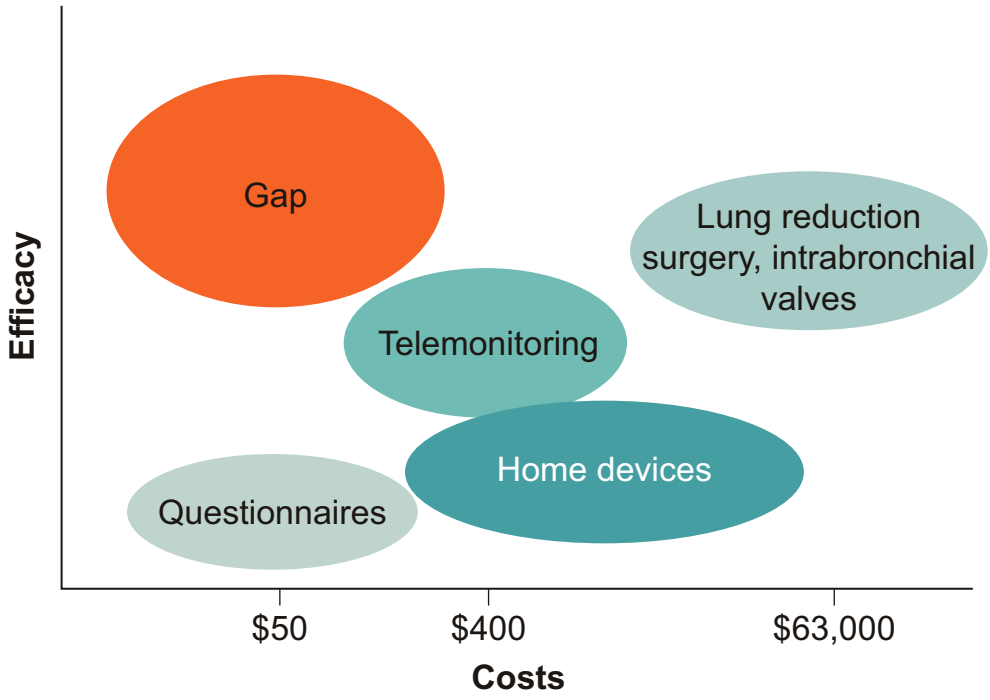

FIGURE 2.4.2
A market landscape for chronic obstructive pulmonary disease (courtesy of Mridusmita Choudhury, Jonathon Hofius, Raymond Hoi, Zubin Huang, Peter Livingston, and Michael Winlo).

what specific price range, in order to be perceived as compelling by the stakeholder(s) that will decide whether or not to adopt it. It is through the more detailed analysis that innovators can gain clearer perspective on exactly how well the need is served by competitive alternatives and how much room remains for an "improved" solution. The risk, as always, is that innovators will overestimate the extent to which an improvement will be significant from the perspective of the customer. As innovators begin narrowing their focus to a manageable set of needs and start thinking about segmenting the market, they can begin layering in this additional information to make their landscape maps more instructive.

Depending on how a particular need has been scoped, it can sometimes be necessary to examine competitive positioning that may exist *within* an existing treatment area, as well. For example, in the COPD case, a closer evaluation of the approaches described as "Home Devices" would result in a map of the market positions occupied by current competitors in the space with devices to diagnose exacerbations (as shown in Figure 2.4.3). This type of competitive landscaping helps to determine how well a given need is currently being met by participants in a specific product category. Additionally, it can highlight gaps in competitive product offerings and guide the innovator toward more concrete opportunity areas that may be ripe for value creation. In the case of home devices, said Winlo, "What we realized was that none of these tools were very effective. That was clear from the published literature. There were very few alternatives, and the sensitivity and specificity of the portable solutions was very poor."

Like the need itself, the relevant competitive landscape can be scoped "up and down" by looking at different product categories. Innovators should recognize the strong relationship between needs scoping and competitive analysis and be particularly attentive where the solutions identified in this landscaping step are overlapped with respect to cost and efficacy to avoid overlooking a potentially competitive offering.

Step 2 – Segment the market

It is rare that any new solution to address a need will meet the requirements of *all* customers or stakeholders across a broad medical field (e.g., all patients with the heart rhythm disorder known as atrial fibrillation). It is far more likely for a solution to address the needs of a subset of the total population (e.g., patients with paroxysmal atrial fibrillation originating in the pulmonary veins, over the age of 65, treated by an electrophysiologist, and covered

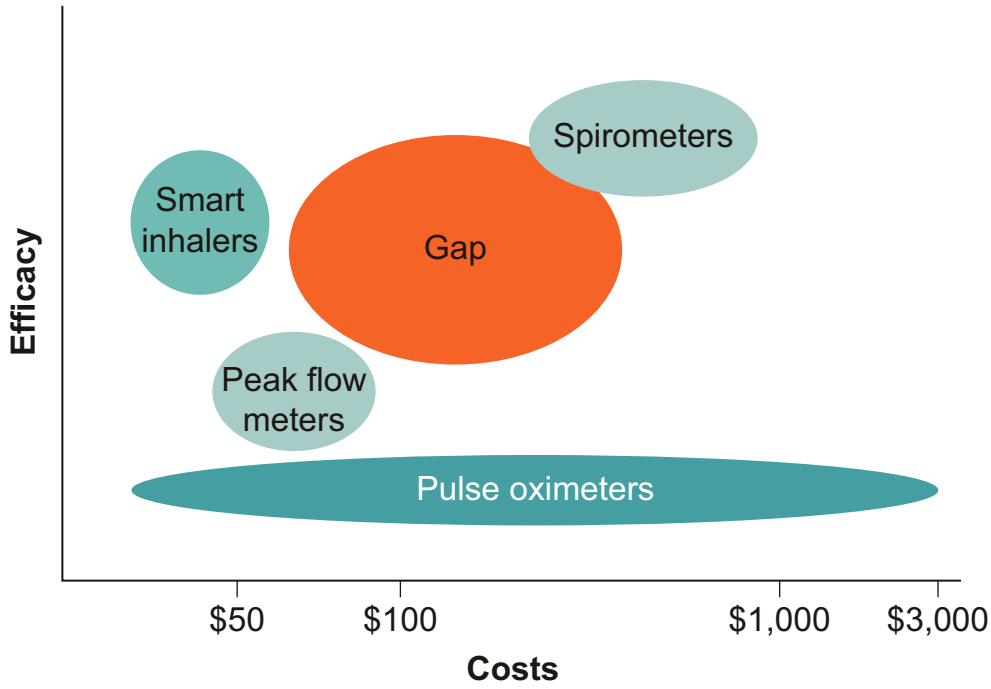

FIGURE 2.4.3
This treatment landscape for home devices used to diagnose an exacerbation provides a directional representation of the cost and relative effectiveness of these devices (courtesy of Mridusmita Choudhury, Jonathon Hofius, Raymond Hoi, Zubin Huang, Peter Livingston, and Michael Winlo).

by Medicare). Innovators can use **market segmentation** to divide patients, payers, and providers (in this context, physicians and facilities) into distinct groups that share similar perceptions about a need. The purpose of this exercise is to recognize and understand the subgroups that comprise a total market (even if those subgroups are somewhat over simplified at this stage of the process).

An effective market segmentation scheme identifies subsets of the population with the greatest similarity while maintaining maximum differences between the groups. Market segments should be measurable, accessible, durable (so as not to change too quickly), and substantial enough to be profitably and/or sustainably served.[5] Innovators will seek to understand the characteristics of customers in these different groupings in order to predict which one or two market segments are most likely to place the highest value on a solution to a given need. In turn, these segments will become the initial target market (read on for more information about target markets).

Because of the complex interactions among the multiple stakeholders that exist within medical markets, segmentation should be thought of as an iterative activity. With each iteration, innovators can use one or more attributes to divide larger groups into smaller ones. Figure 2.4.4 summarizes a sample of the dimensions that can be used to differentiate between market segments. When conducting a market analysis, recognize that important differences between market segments may not exist across all of these dimensions. However, they all should be considered to ensure that no important sources of distinction between subgroups are overlooked. Furthermore, keep in mind that there may be additional factors to consider based on the unique and distinguishing characteristics of the market being assessed.

One approach to segmentation is to begin with a relatively simple patient-based analysis and then layer in increasingly complex factors (e.g., payers, providers) to eventually account for the many different stakeholders and interactions that need to be considered in the assessment of the market. Four steps can be used to experiment with this method:

1. Segment patients based on symptoms and risk factors.
2. Segment patient subgroups based on treatment.
3. Segment patient/treatment subgroups based on providers.

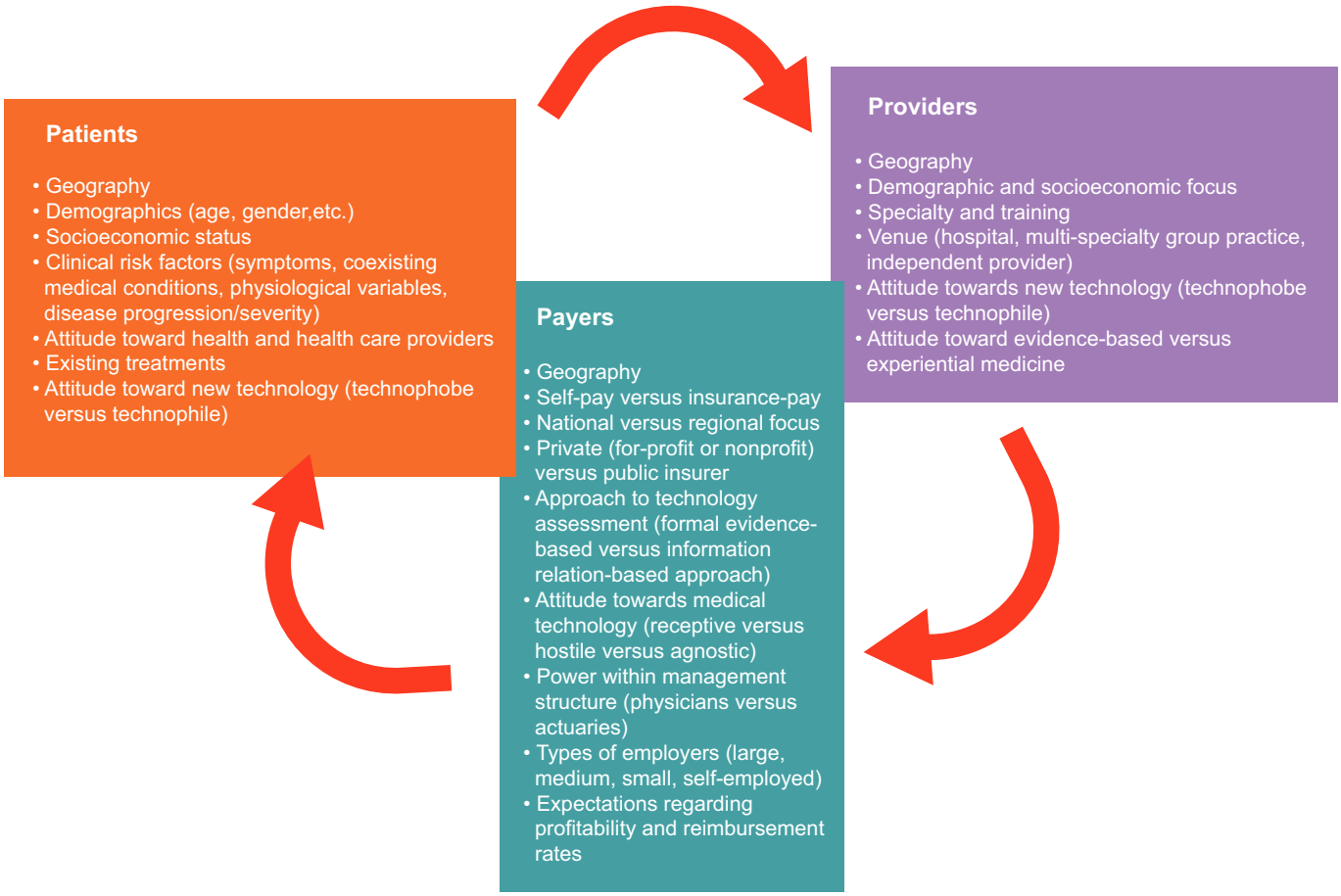

FIGURE 2.4.4

There are many attributes that can be used to differentiate between market segments. Innovators should consider a wide range of these factors in their efforts to come up with a meaningful segmentation scheme.

4. Segment patient/treatment/provider subgroups based on payers.

The high-level example that follows, which is focused on patients with chronic kidney disease (CKD), illustrates these four steps.

Segment patients based on symptoms and risk factors

First, to segment patients based on symptoms and risk factors, innovators can divide patients into diagnosed and undiagnosed categories, then further refine these groups based on the stage of their disease [stages 1–2 = mild, 3 = moderate, 4 = severe, and 5 = end-stage renal disease (ESRD)]. Most stage 1 patients are undiagnosed, while most stage 5 are diagnosed. Figure 2.4.5 provides a representation of the resulting segments. In this and the other segmentation figures that follow, the area of each subgroup reflects the size of the segment in terms of the number of patients it includes.

Segment patient subgroups based on treatment

The next step is to further subdivide patients based on the treatment they receive. Common treatment categories for CKD might include self-care management (e.g., dietary and fluid restrictions), drug treatment (glucose control medication for diabetics; blood pressure control therapy for those suffering from high blood pressure; or other treatments for patients with anemia or bone disease); hemodialysis (HD); peritoneal dialysis (PD); or transplantation (Tx). Figure 2.4.6 shows how patients in the diagnosed stage 5 (ESRD) group can be subdivided based on treatment type.

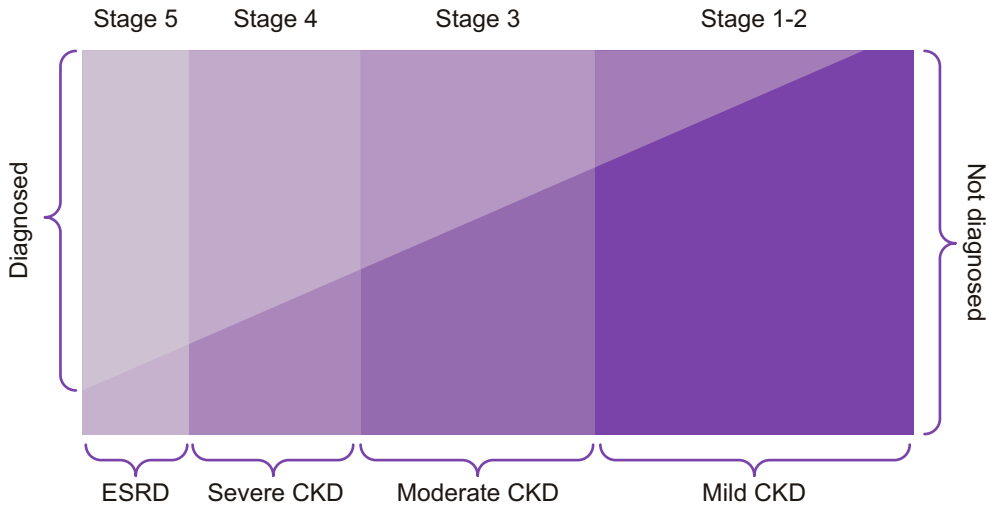

FIGURE 2.4.5
Segmentation of CKD patients based on diagnosis and disease stage.

Segment patient/treatment subgroups based on providers

These six treatment segments for stage 5 patients with ESRD can again be refined by overlaying the type of provider administering care to the patient. Typically, in the CKD market, there is a one-to-one correlation between providers and the treatments they deliver. For example, for PD and HD, treatment is delivered by a nephrologist in combination with a dialysis clinic. For transplantation, treatment is administered by a surgeon in collaboration with a transplant program, as shown in Figure 2.4.7.

Segment patient/treatment/provider subgroups based on payers

The final segmentation step is to evaluate payer type relative to the subgroups. To prevent the example from becoming too complex, Figure 2.4.8 seeks to differentiate only between patients covered by private insurance versus public insurance (Medicare in the US).

This simplified CKD example demonstrates steps for performing progressively detailed patient, provider, and payer segmentation using a sequence of Venn-like diagrams. Although the method may seem complex (and the figures difficult to replicate for another disease area), the basic approach provides a structured way for aspiring innovators to begin thinking about market segmentation in the early stages of the biodesign innovation process. More experienced innovators also perform these steps, although they often do so in a less structured, more instinctive fashion.

Another way to illustrate market segments is by using simple tables alone or in combination with diagrams that resemble decision trees. For example, when the team working on needs related to COPD was thinking about how to segment the total market of 12 million US patients, it experimented with many different approaches, taking into account patient gender, age, risk factors, treatment type, and other factors. The innovators also considered patients based on the severity of their disease, ranging from mild to very severe. Seeking to further differentiate patients in these disease subgroups, they evaluated exacerbation rates associated with each stage of COPD and learned that they steadily increase as the condition worsens. Additional research revealed that exacerbations are major drivers of treatment costs. Across all disease subgroups, 1.2 million patients seek treatment in the emergency department (ED) during a COPD incident, and more than 900,000 are admitted to the hospital. Intrigued by the fact that hospitalizations for COPD account for more than 43 percent of all spending on the disease, the team dove deeper into characterizing the segment of patients hospitalized from COPD. In doing so, they learned that 20 percent of this population is readmitted within 30 days, and 38 percent is readmitted within 18 months.

Key data relevant to this aspect of the team's segmentation analysis are shown in Table 2.4.2 and depicted in Figure 2.4.9.

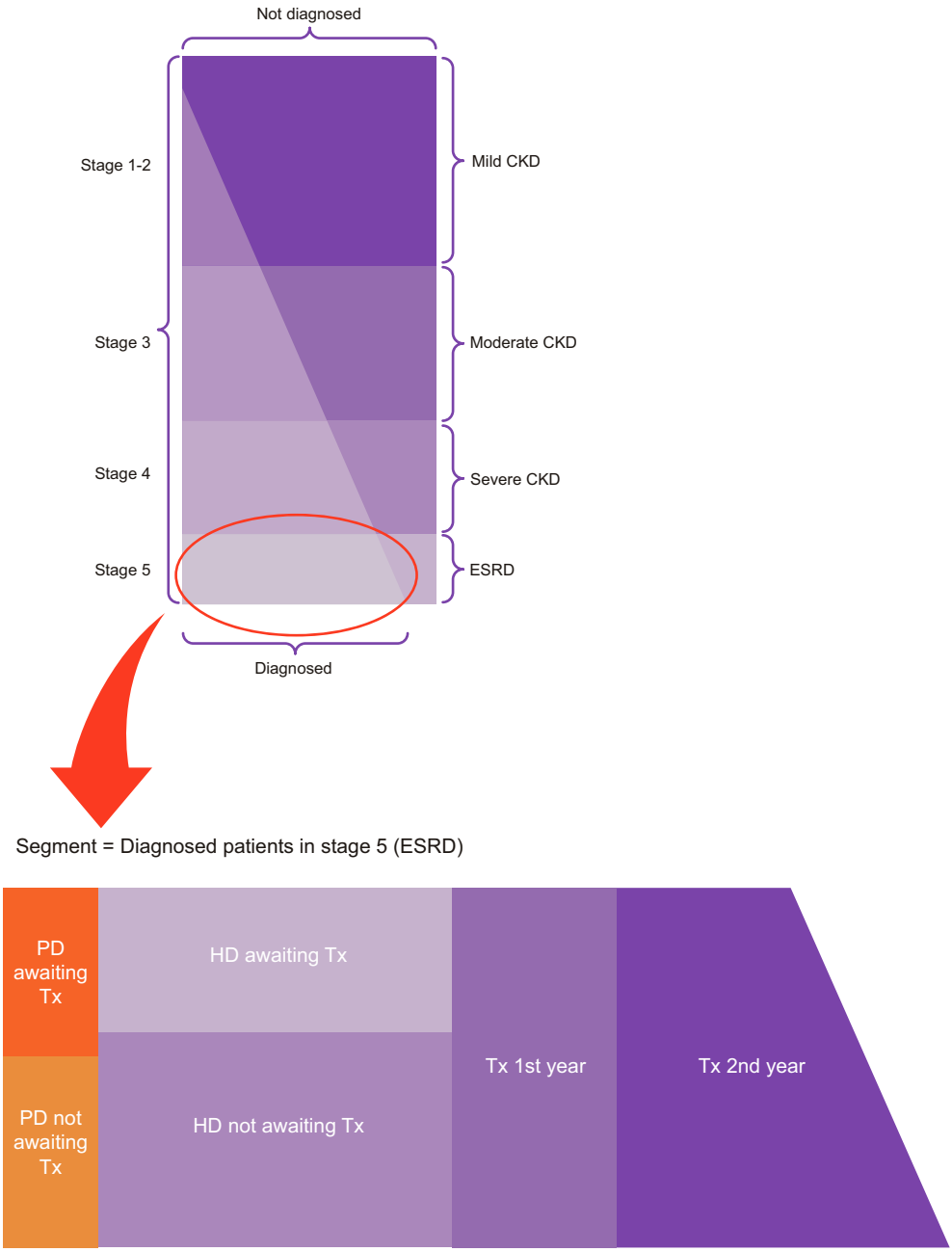

FIGURE 2.4.6
Further segmentation of diagnosed patients in stage 5 (ESRD) based on type of treatment.

Assess segment size and growth

After defining meaningful market segments, innovators can size the market opportunity associated with each one. This involves addressing a series of important questions that are not always easy to answer (as Figure 2.4.10 illustrates):

1. How many patients are there in each market segment (if not calculated as part of the segmentation exercise), and how can they be reached?
2. What diagnostics, treatments, and/or therapies are currently being used within each segment? What companies provide these solutions? What is their relative market share?
3. What is the total dollar value of each market segment (i.e., total cost of treatment or total medical expenditures)?
4. What is the epidemiologic growth pattern in the segment? Is the segment contracting or expanding?

Table 2.4.2 Exacerbation and hospitalization rates for diagnosed COPD patients by severity of disease (courtesy of Mridusmita Choudhury, Jonathon Hofius, Raymond Hoi, Zubin Huang, Peter Livingston, and Michael Winlo).

Severity of disease	Percentage of all COPD patients	Exacerbation rate/year	% Requiring hospitalization/ year	# of hospitalizations/ year
Mild	40%	0.82	2%	64,800
Moderate	55%	1.17	7%	462,000
Severe	4%	1.67	18%	324,000
Very severe	1%	2.1	33%	118,000
Total				**968,800**

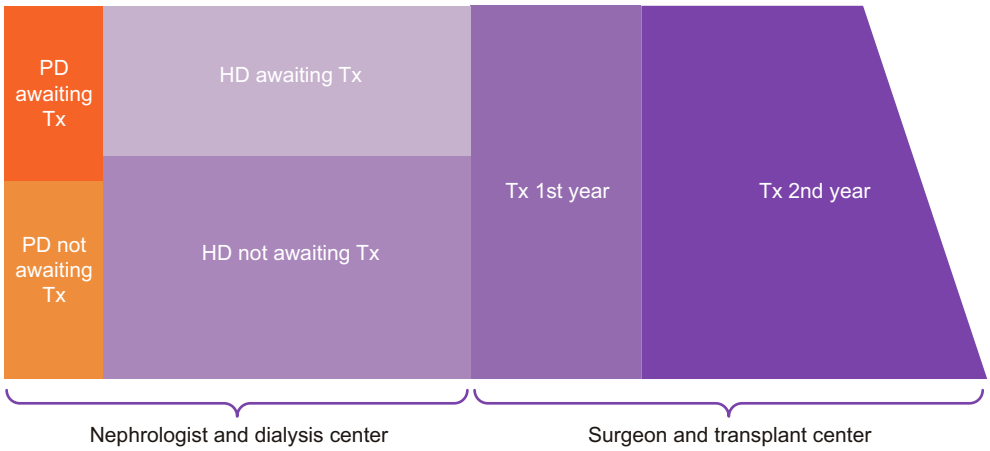

FIGURE 2.4.7
Additional segmentation of diagnosed patients in stage 5 (ESRD) based on the provider administering care.

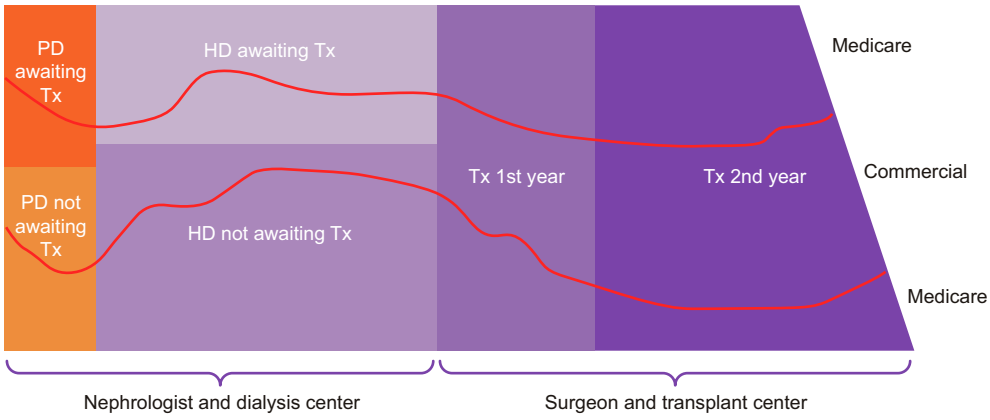

FIGURE 2.4.8
One more layer of segmentation of diagnosed patients in stage 5 (ESRD) based on payer type. The center section, bounded by the lines, indicates the portion of private or commercially insured patients, while the remaining areas, top and bottom, represent those covered by Medicare.

What do growth projections look like in the near, medium, and long term?

Keep in mind that the size of the market segment should not be considered in a vacuum, with bigger always presumed to be better. In some cases, a smaller market that is easier to access may be more attractive than a larger market in which the potential purchasers of an offering are difficult to reach.

Innovators can take either a "**top-down**" or a "**bottom-up**" approach to calculating the dollar value of each

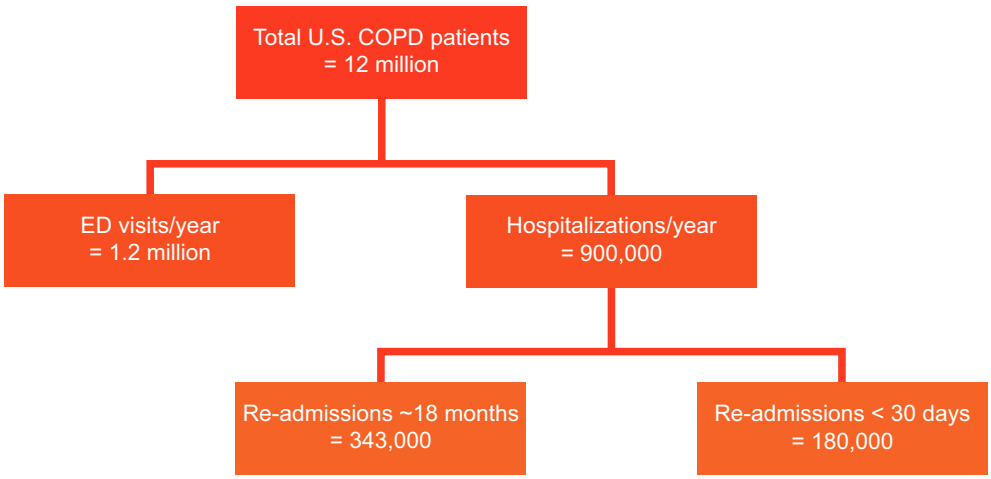

FIGURE 2.4.9
High-level patient segmentation for US COPD patients hospitalized due to exacerbations (courtesy of Mridusmita Choudhury, Jonathon Hofius, Raymond Hoi, Zubin Huang, Peter Livingston, and Michael Winlo).

FIGURE 2.4.10
Market analysis can provide innovators with confusing or conflicting answers to important questions. But a rigorous assessment approach will help generate less ambiguous information.[6]

segment. A top-down approach begins with the overall spending on the disease state, and then divides total spending into categories based on the percentage of customers in each segment. The problem with the top-down approach is that it essentially assumes the same spending per patient across the various segments. However, its advantage is that it does not demand as much data, which can be helpful when innovators are still evaluating multiple needs. A bottom-up approach derives the total market size by multiplying the number of customers within each market segment by the associated costs of their treatment. It is more precise than the top-down approach but may require data that are not readily available at this point in the biodesign innovation process. Initially, either of these approaches can be used to determine a high-level estimate of market size. However, it may be useful to perform both types of analysis and compare/validate the results. (An example of a bottom-up analysis is provided later in this chapter in the section entitled "Bringing it all together: **patient towers**." More information about top-down and bottom-up market estimates can also be found in 6.1 Operating Plan and Financial Model.)

The Spiracur team used top-down market sizing when performing its early assessment of the chronic wound care market. One of the simple market segments that the innovators looked at was patients suffering from venous ulcers. They were intrigued by this particular segment because they felt that the gap between existing solutions and desired outcomes was so great – most ulcers remained open after 12 weeks of treatment (an unacceptably long period). To size the subgroup, the team estimated that between 0.5 and 1.5 percent of the US population suffers from venous ulcers based on extrapolations of available epidemiologic statistics.

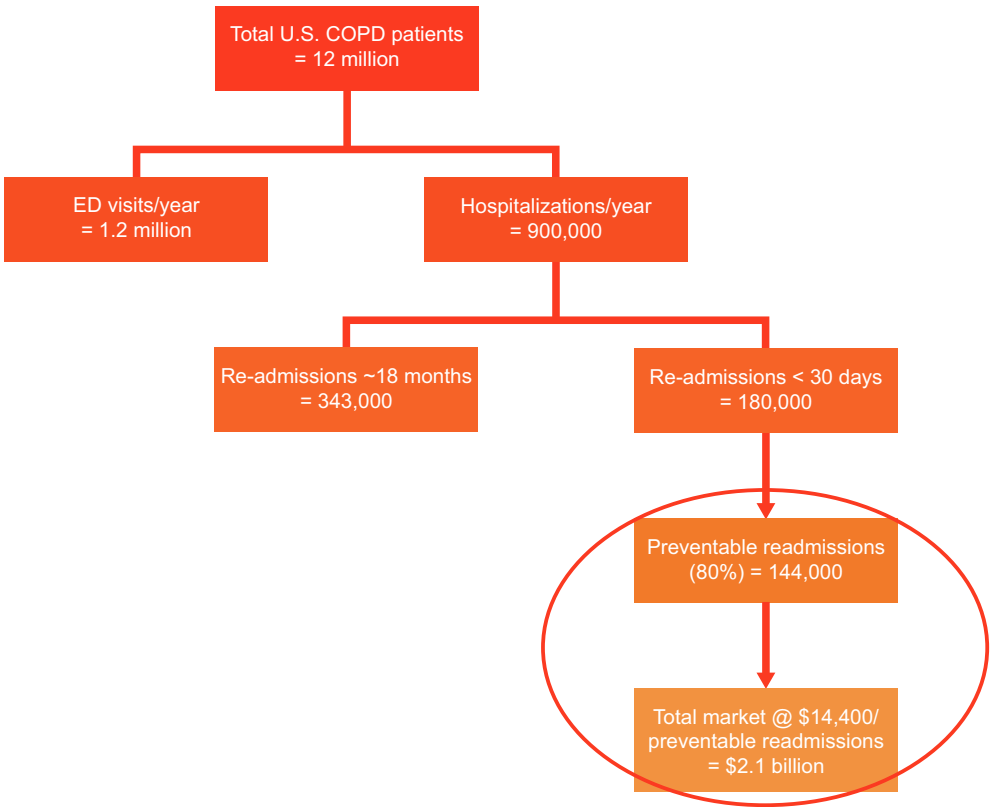

FIGURE 2.4.11
Estimated total market opportunity for the segment of US patients with mild to very severe COPD who are hospitalized (courtesy of Mridusmita Choudhury, Jonathon Hofius, Raymond Hoi, Zubin Huang, Peter Livingston, and Michael Winlo).

Competitive analysis revealed that the aggregate daily cost of the leading product for venous ulcers was $150.[7] To obtain the potential segment value, the team multiplied this amount by the duration of the therapy and by the prevalence of venous ulcers, and then incorporated growth estimates into the calculations to reach a total potential market size of $12 billion by 2009[8] (the total market size included all patients with venous ulcers). At the time of the analysis, that market segment had a penetration rate of approximately 30 percent (i.e., less than one-third of patients with a venous ulcer received some form of treatment). Even without any increased penetration in the market, the team believed that a new solution would have a total potential market opportunity worth $3.6 billion.[9] This top-down approach sizes the market using data from a comparable solution as a benchmark. It assumes full penetration with an alternative solution whose cost to the customer would be equal to (for the purposes of this estimate) the full avoided cost of the prevailing best-in-class solution ($150 per day).

The COPD team derived an early, top-down market size estimate in a slightly different way. For the segment of the US market comprising patients with mild to very severe COPD who are hospitalized, they believed that the total market opportunity could be estimated based on cost savings associated with preventing unnecessary readmissions. In particular, they believed that there was a sizable opportunity linked to preventing readmissions that occur within 30 days of discharge because research revealed that physicians believe as many of 80 percent of these repeat hospitalizations for COPD are avoidable.[10] Cost per admission ranged from $1,500 to $40,000, but they decided to use the average of $14,400 for their preliminary top-down calculations. This data led them to calculate the market opportunity estimate shown in Figure 2.4.11.

In contrast to the comparables approach taken by the Spiracur team, this approach to sizing the market considers the total "solution value" viewed from the purchaser or payer's perspective. Specifically, the team assumed the substitution of an unknown solution that would prevent the total cost of readmission. Stated another way, this top-down market estimate indicates that the solution could be worth up to a maximum of

$14,400 per prevented readmissions to its target customer. Importantly, crude top-down market sizing models often overestimate the size of the opportunity.

Innovators should expect to share potential savings (or other economic benefits) with the stakeholder(s) that will purchase or pay for a solution to give them an incentive to change their behavior and adopt a new offering. This idea is best illustrated by the COPD example. In this case, payers (as a group) most directly stand to benefit from a solution by avoiding up to $2.1 billion in readmission-related costs. But if an innovator or company tries to capture the full $2.1 billion in potential savings through a product that ends up costing payers $2.1 billion to purchase, then the payers arguably could be indifferent to the offering on purely financial terms. In this case, to encourage a change in practice, the innovators would need to leave a portion of the total potential savings with the payers to create a meaningful economic incentive for adoption to occur. To understand the "threshold" at which a behavior change would occur, innovators must assess how important a new solution is likely to be to the buyers and what magnitude of savings would potentially motivate them to adopt it. Although it varies with the size of the market being addressed, a rule of thumb is that innovators will need to consider sharing from 30–50 percent of the savings with purchasers in order for a new solution to be compelling. Note that sometimes, if the savings opportunity allows a facility to redeploy assets (e.g., beds) on more profitable services, then this guideline may be somewhat more flexible.

Evaluate market dynamics

After sizing each market segment, it is important to spend more time understanding the market dynamics within them. For many markets that are characterized by the presence of active competitors, this means figuring who they are, how they compete with one another, and what are their strengths and weaknesses. Innovators sometimes assume that the current market situation will remain static during the many years required to develop and introduce a new solution. Focusing specifically on market dynamics helps innovators anticipate how key market opportunities may change over time, identify possible hurdles, and project the likely responses of competitors in the space. For example, with the COPD example, it would seem that a new solution focused on preventing readmissions would be attractive to payers but controversial to hospitals operating under a fee-for-service **reimbursement** model in that it would potentially reduce their revenue. However, if these hospitals were facing a reimbursement penalty for patients rehospitalized within 30 days, they would be dramatically more receptivite to the new offering. Such factors can only be uncovered and understood through a thorough assessment of the current and expected market landscape. As Winlo of the COPD team described, impending changes made the needs to prevent COPD-related rehospitalization significantly more attractive. "Readmissions for COPD exacerbations were set to be penalized, so that gave hospitals a large incentive to do something proactive," he said. "Another important trend was the shifting of medical care reimbursement towards value-based **payment** models such as accountable care organizations (**ACOs**) that were just beginning to emerge at the time. These organizations would be 100 percent on-the-line for caring and for treating high-risk COPD patients and so they are more motivated to pay for solutions helping prevent unnecessary hospitalizations."

By assessing market and competitive dynamics, innovators can also strengthen their understanding of: (1) how much value (in terms of improved performance and cost) may be necessary to differentiate a new solution; and (2) how much market share they may realistically capture in the early years following a product's launch. These aspects of market analysis are the source of the two most common and costly mistakes that innovators make. It is critical that innovators distinguish between opportunities to create simple, incremental *improvements* and those necessary to create *value sufficient to change customer behavior*. Virtually any product or service can be improved by addressing its specific shortcomings. Incremental improvement opportunities are plentiful. Yet once a stakeholder's basic needs are met, they tend to be resistant to upgrading or accepting new features that incrementally enhance the performance of an offering until those improvements achieve a threshold of innovation meaningful enough to motivate a behavior change. Most solutions fail because the innovators underestimate

this threshold within their target market. Innovators can gain insight into what magnitude of improvement may be needed to capture the attention of prospective customers by examining the history of innovation within the segment of interest. Direct customer feedback can also be used to help validate the importance of the need and magnitude of the desire for new solutions. However, as always, innovators should remain as objective as possible and be alert to the **biases** that this feedback can contain.

Innovators may find at least two well-established frameworks helpful for assessing competitors and other dynamics in a market. The first is **Porter's Five Forces**, which can be used to evaluate the overall competitive landscape in a field. The second is **SWOT analysis**, which is focused on understanding the dynamics surrounding individual competitors. This section briefly describes how both of these approaches can be used to evaluate market dynamics. It also includes a Working Example that revisits the InnerPulse story (introduced in 2.3 Stakeholder Analysis) to demonstrate the importance of considering market dynamics.

Porter's Five Forces Porter's Five Forces framework, developed by Michael Porter of Harvard Business School, identifies the five primary forces that drive competition within an industry:[11]

- The **threat of new competitors** to the market (and the barriers that prevent them from entering).
- The **bargaining power of suppliers** (as measured by the number of suppliers in a market and the costs of switching from one to another).
- The **bargaining power of buyers** (in terms of the extent to which buyers can directly affect profitable sales).
- Pressure from **substitute products or services** (which necessitates differentiation).
- The **intensity of rivalry** among existing competitors.

These five forces interact with one another to shape the profit potential of an industry (and the primary firms within it).[12] By investigating each factor, and how they are interrelated, innovators can objectively characterize the market, the potential for profitability and/or sustainability, and the critical issues that must be managed. The most common mistakes innovators make when doing this analysis include underestimating competitive R&D pipelines, failing to account for all substitute solutions (including the customer's option to do nothing), and ignoring the extent to which **switching cost** can influence buyer behaviors.

For optimal results, the Five Forces framework should be applied within a single specialty or therapeutic field. An overview of the framework and a **medtech**-specific example is available in online Appendix 2.4.1

SWOT analysis SWOT analysis, which is credited to Albert Humphrey of Stanford University, focuses on the internal and external factors affecting a project or company (including strengths, weaknesses, opportunities, and threats).[13] Using SWOT analysis to understand what is occurring within the competitive environment requires an innovator to identify the primary competitors in a market and assess each one individually. In doing so, the first step is to identify each competitor's primary objective. Then, the following factors can be considered to determine the relative power of their competitive position:[14]

- **Strengths** – *Internal* attributes of the organization that are helpful in achieving the objective. Identify the company's competitive advantage and what differentiates its products/services.
- **Weaknesses** – *Internal* attributes of the organization that are harmful in achieving the objective. Consider what barriers or hurdles the company is facing.
- **Opportunities** – *External* conditions that are helpful in achieving the objective. In the medtech field, these might include intellectual property (IP) and regulatory issues, partnerships, stakeholder satisfaction, and other economic, social, and technological factors.
- **Threats** – *External* conditions that are harmful in achieving the objective. Explore the same factors listed above, in addition to the activities of the company's direct and indirect competitors.

An assessment of competitors' strengths and weaknesses helps an innovator understand the capabilities and limitations of other players in the market. Strengths represent capabilities that must be overcome (e.g., barriers to entry

and/or attributes against which a company must differentiate itself). Weaknesses represent limitations that have the potential to derail a competitor's success. Innovators must be careful to avoid or mitigate the same risks within their own projects (and may be able to exploit the weaknesses of competitors by turning them into opportunities). More information and a sample medtech SWOT analysis can be found in online Appendix 2.4.2.

After performing these types of analyses for the most important competitors within each market segment, innovators can summarize the resulting data and look for trends and issues across products and the organizations that market them. At a minimum, such a summary should include the following information:

- Number of established and/or emerging companies working within the market segment.
- Specific products or services offered.
- Maturity of products or services offered.
- Actual or projected pricing.
- Market penetration.
- Estimated market share.
- Revenue.
- Actual or projected profitability.

Another important factor to consider as part of market dynamics is investor interest in the space. Because almost all medtech innovations require significant funding to reach commercialization, it is essential to understand how compelling a need might be to the providers of capital, whether these "investors" are traditional venture capitalists, the executives responsible for funding projects within large, existing organizations, or foundations that back technologies targeted at addressing the needs of underserved **user** populations. Unless these providers of capital can be convinced that they will realize value from investing in a solution, then the project will go unfunded and the customer need will go unaddressed. In the simplest case, a target market will already have sufficient investor interest that the innovators can feel optimistic about raising the money necessary to fund future development. If so, the challenge for the innovator will not be to persuade the investors that the market has commercially attractive needs (which can sometimes be a difficult challenge if, for example, the team is the first to identify a need). Instead, it will be convincing them that the need identified and the **concept** that is eventually chosen to address it are unique and can be differentiated from existing and future competitive offerings. Ultimately, an investor's question is similar to the customer's: "If I invest in this, how likely am I to get more out of it than I'm required to put in?" Signs that investor funding is available include the creation of investor-funded new businesses in the space, as well as merger and acquisition activity (which can provide a path to profitable liquidity for investors and drive new investments – see 6.3 Funding Approaches).

Understand segment needs

The next challenge is for innovators to understand how the needs of stakeholders from segment to segment may vary and how well those needs are currently addressed by existing solutions. This assessment is closely linked to evaluating segment willingness to pay (as described in the next section). Ultimately, the extent to which the stakeholders in a segment are potentially motivated to adopt a new solution and how much they are presumably willing to pay come together to provide a "*value estimate*" associated with a need. A value estimate helps innovators continued to expand their understanding of how much and what type of improvements a new solution must deliver, at or below a defined cost threshold, in order to have a reasonable likelihood of being adopted. Quantifying value in this stage of the process is difficult since no specific solutions have yet been defined to address the need. However, innovators can develop a directional value estimate for a need area by considering who the real decision makers are with respect to adopting any new solution, how significant they perceive the need to be, to what degree available solutions are effectively addressing their needs, and therefore how much margin there is to offer a new technology with a different improvement/cost equation.

As described in 2.3 Stakeholder Analysis, identifying the decision maker(s) involved in a need area is imperative. Within each market segment, innovators should be sure they understand who makes adoption decisions and how they are typically made. In light of this information, the team can then carefully consider what it has learned about each market segment to discern in what ways the

Working Example
InnerPulse revisited

Porter's Five Forces can be used to examine the decision made by InnerPulse (introduced in 2.3 Stakeholder Analysis) to develop a less invasive implantable cardioverter defibrillator (ICD) for patients at risk of experiencing sudden cardiac death (SCD). In 2007, when InnerPulse was getting started, the existing competitors in the ICD space were Boston Scientific, Medtronic, and St. Jude Medical (Boston Scientific entered the ICD market after its **acquisition** of Guidant in 2006, following a bidding war with Johnson & Johnson). These firms traditionally enjoyed a comfortable oligopoly because of significant barriers to entry, which include the high capital requirements to develop and get approval for new ICD devices, as well as their strong IP positions. Suppliers of components for the industry used to have some power, but it was diminishing as certain manufacturers were independently developing components that they previously would have had to purchase from suppliers. Buyers (payers, such as private insurance companies and Medicare) had significant power, but it had been weakened through clinical and patient advocacy efforts supporting the need for ICDs. There was also some evidence of competitive rivalry (e.g., litigation around IP and the bidding war between Boston Scientific and Johnson & Johnson for the acquisition of Guidant). However, this rivalry could primarily be observed among new entrants, rather than between established firms. Further, alternative or substitute solutions were not available to treat patients who had suffered from secondary prevention or were at risk of primary prevention (i.e., no drugs had been shown to be as effective at reducing the risk of SCD as an ICD). Importantly for InnerPulse, unlike the smaller secondary market, which was well penetrated, significant growth opportunities existed in the larger primary prevention market since the overall market penetration was low (approximately 20 percent). Stated another way, only one in five patients at risk for secondary prevention received an ICD. This was primarily due to the inability of primary prevention patients to be seen by the physicians who implanted ICDs.

This quick analysis suggests that the incumbents are highly profitable (in fact, gross profit margins for ICDs are in excess of 80 percent) and that they will protect their market aggressively. InnerPulse's strategy to focus on the under-penetrated primary prevention market (in which it could fill the major void in the total ICD market as opposed to trying to "steal" market share from incumbents) showed that it recognized the challenges of direct head-to-head competition with the incumbents. By taking this approach, InnerPulse could maximize its likelihood of differentiating its own product from products of the established companies as it entered the market. Because the incumbents were undoubtedly looking into the primary prevention market as a growth opportunity, InnerPulse could eventually become an acquisition target (see 6.3 Funding Approaches).

When possible, innovators who envision building a start-up company may want to initially avoid segments where they will face direct, head-to-head competition with strong entrenched players. If they can focus instead on untapped or under-penetrated market segments with a reasonable market size and need, they can potentially differentiate their solutions more effectively from the products of the incumbents. However, this guidance is never absolute. Recalling Stack's comments in the InnerPulse example in chapter 2.3, sometimes, by examining industry structure in this way and identifying specific gaps in the product offerings of the entrenched competitors, innovators can position themselves for early acquisition. This scenario was played out multiple times in the evolution of the markets for balloon angioplasty and stents, and at the time of this writing was proving to be the case in the early days of renal denervation.

needs or improvements being sought by the decision makers within each subgroup are distinct. Remember, the goal is not necessarily to find the largest segment with at least some interest in the need, but rather the (usually smaller) segment with a strongest possible interest in the need. Refer back to notes from observations and other forms of research gathered through the biodesign innovation process to date to see if they shed light on unique problems, preferences, or other requirements that exist within the segments and how they affect

the need. In some cases, it may be necessary to perform additional observations or interviews.

Next, seek to understand how well the needs of key decision makers within each subgroup are currently being met. As part of the broad market landscape, innovators performed this type of gap analysis for the total market. Now they can get more detailed and specific by looking at each market segment. To accomplish this, they can begin by evaluating outcomes for patients within each segment. For example, what is the prognosis for patients over the age of 65 with paroxysmal atrial fibrillation originating in the pulmonary veins? What outcomes should they expect if their condition goes untreated?

Once this information is understood, evaluate how expected outcomes change as a result of the existing solutions that represent the **standard of care** within the market segment. Using the same example, to what extent does the prognosis change when patients over the age of 65 with paroxysmal atrial fibrillation originating in the pulmonary veins are treated by a cardiologist using a minimally invasive procedure such as pulmonary vein ablation (or another relevant treatment)? Be sure to take note of the improvement in outcome, as well as any complications or new risk factors introduced by the treatment, as these can have a significant effect on the overall level of patient satisfaction with the intervention, as well as the satisfaction of the physicians delivering it.

Determining how well existing solutions meet patient needs, along with the needs of physicians, requires some qualitative analysis. There are no "rules" that define how great an improvement in outcome a treatment must provide to satisfy their needs. Ideally, each treatment would provide a long-term "cure" or prevent the consequences of the condition it was developed to address. However, in the absence of a complete cure, innovators must apply their judgment to evaluate how effective existing treatments are in improving patient outcomes *and* the extent to which new complications and risks associated with each treatment are considered an acceptable trade-off by patients and physicians alike.

These factors, in combination, determine how receptive decision makers are likely to be to available solutions. By extension, their level of satisfaction with existing treatments typically corresponds to the level of perceived need for new treatment alternatives within a market segment. If the level of satisfaction is relatively high, it does not necessarily mean that a new treatment is not needed. It does, however, mean that any new treatment option introduced into the market will have to perform significantly better than available treatments (in terms of improved outcomes and diminished risks/complications) in order to be adopted, or it will have to deliver comparable results at a significantly lower cost.

Of course, the needs of other stakeholders, such as facility purchasing managers and public and private payers, must also be taken into account. The needs of these individuals and groups are often cost-related, but they are also interested in other outcomes such as improving quality and increasing efficiencies. The important thing to keep in mind is that if a representative from a payer or purchasing organization is the primary decision maker for adopting a new solution, then the new solution must offer strong economic benefit along with its other advantages.

In addition to looking at individual treatment alternatives, innovators should review the competitive analysis that they performed when exploring the dynamics within each market segment. The results of this analysis can help innovators identify broad unmet market needs and gaps in competitor offerings that should be taken into account when evaluating overall market needs.

Competitive analysis can also provide innovators with examples of new solutions that were perceived as attractive enough by the key stakeholders in a market segment to cause them to change their behavior and adopt a new approach. Benchmark these examples and evaluate them for insights regarding the extent of the improvements offered by new solutions that achieved significant market penetration.

Importantly, not every segment will be equally receptive to new solutions. In some medical areas, new treatments are introduced and embraced frequently; in others, the same treatment paradigms have been in use for decades. Similarly, certain patient, provider, and payer groups have characteristics that make them more or less willing to adopt new solutions. Do not underestimate the importance of this receptivity and keep in mind that the benefits will have to be significant to get certain segments to change behavior.

Table 2.4.3 Patients, providers, facilities, payers can all affect willingness to pay for a new medical innovation.

Decision makers	Common issues affecting their willingness to pay

Payers	• Is the need being addressed sufficiently important when viewed from the perspective of the payer?
	  ○ Measured against other opportunities, what is the magnitude of the benefit that a new solution to the need must create?
	  ○ What is the total cost of care for patients in each segment with existing solutions, and how might a new solution affect the total cost of care?
	  ○ To what extent must a new solution reduce related expenditures for a defined population (e.g., through prevention and/or eliminating complications)?
	• Is a new solution likely to be covered by existing reimbursement codes or will it require a new code?

Patients	• Is there a precedent for patients paying **out-of-pocket** for solutions to the need? • If so, how much have patients been willing to pay for relevant solutions?

Physicians	• Will the physician be impacted economically by a new solution?
	  ○ Does a new solution have the potential to increase their productivity?
	  ○ What would make physicians potentially willing to cover the cost of a new solution from the reimbursement they receive for the procedure?
	• What clinical benefits would a new solution have to offer relative to existing solutions to get physicians interested? How much have physicians paid for solutions in the past that have provided similar benefits?

Facilities	• How is adoption of a new solution likely to positively or negatively impact overall facility economics?
	  ○ To what extent might a new solution reduce costs for the facility?
	  ○ Could a new solution provide other market benefits for the facility, such as the opportunity to grow its market penetration?
	  ○ Is the profitability of the procedure more or less than a new procedure that might replace it?
	• To what extent could a new solution enable the facility to achieve key quality goals?

Assess willingness to pay

Once market needs are understood, innovators can consider how much the members of a market segment are potentially willing to pay for a new solution, and then bring these two factors together into a value estimate. Note that understanding willingness to pay is not the same as asking how much the segment is currently paying for an existing solution since new solutions may be held to a different standard. In today's value-oriented environment, new solutions are increasingly required to offer substantially better performance or a meaningfully lower cost – or sometimes both – to drive significant adoption.

Like market needs, willingness to pay depends to a large degree on which stakeholders are the decision makers for adopting a new solution – who will be making the payments and how will the new innovation affect them? Remember that some decision makers will be attracted to the improvements offered by a new solution but lack the budget to act on their interest. This scenario is becoming more common as facility purchasing managers become more powerful in making buying decisions at the same time the spending authority of individual physicians wanes. Table 2.4.3 outlines some of the main stakeholders who may act as decision makers and the issues to consider when anticipating their response to a new device technology.

To evaluate and understand the answers to these questions, innovators can use one of the following approaches. Whenever possible, experiment with multiple methods to triangulate the information collected. Remember that this willingness to pay analysis will be

"directional" (and, admittedly, somewhat speculative) since a specific solution has not yet been defined to address the need.

1. **Interviews and/or surveys** – Gathering information directly from the decision makers who would purchase a new solution can be extremely helpful. Surveys can be issued in a written format, but similar information is often gathered via interviews or other one-on-one interactions. The idea is to determine the maximum payment a decision maker would be willing to make for different degrees of innovation. A survey should provide a description of the improvement a potential solution might provide and a range of prices. Users can then be asked whether or not they would be willing to use a solution offering those specific improvements for each of the prices presented. Take care to be specific about the advantages a new solution will enable. Sometimes a useful question to ask is, "At what price would you stop being interested in purchasing the product's described benefits?" Customers should be strongly enthusiastic about the prospect of a new solution and offer limited resistance to the possible changes the innovators describe for a new solution to have reasonable chance of adoption. Some stakeholders will not indicate much price sensitivity – especially if they do not actively participate in the purchasing decision. Be aware of the potential for this kind of positive bias and try hard to reach stakeholders that play active roles in relevant purchasing decisions.
2. **Comparables** – Evaluate the prices for technologies across medical fields that deliver benefits similar to those desired by the market segment, could potentially be adapted to address the need, or that are roughly aligned with the solution gap in the segment. Learn as much as possible about pricing for existing solutions within the same medical field, too. These comparables provide a rough benchmark for how high a price the market segment is likely to bear, although (again) new solutions may be held to a different standard. Remember, pricing can be dynamic – be sure to factor in any information that may show evidence of a negative overall trend, keeping in mind that a new solution may take several years to get to market.

Once innovators have a reasonable sense of a segment's willingness to pay, they can consider this information in combination with the improvements a new solution must deliver to create a value estimate for the need. Remember, the value estimate is intended to provide guidance on how much and what type of improvements a new solution must deliver, at or below a defined cost threshold, in order to have a reasonable likelihood of being adopted. In 2.5 Needs Selection, these data will be translated into **need criteria** that become part of the need specification and guide the development of solutions. Typically, requirements defined by the value estimate translate into "must-have" need criteria – meaning that they must be satisfied by any solution that the team decides to bring forward into invention.

The COPD team did not go deep into creating a value estimate, but background research gave the members a directional sense of the improvement they would need to deliver, and at what cost, in devising a new solution. As Winlo explained, "One of our mentors at the time, who was COO of a major healthcare organization, was very motivated to do something about COPD. His organization had seen some early success in home outreach – hiring nurses to make outbound calls to COPD patients who had recently been discharged to see how they were doing. But these nurses could only reach so many patients in any given day." This care management team would semi-randomly contact patients and ask them a series of questions about their condition. Periodically, they would catch a patient as s/he was experiencing an exacerbation. By swiftly intervening to manage the symptoms before they worsened and get the patient into see a doctor, the nurses were able to prevent some hospital readmissions. "They were literally catching exacerbations by luck," Winlo said. "We figured there had to be a better way." On the other hand, the team was encouraged by the fact that early intervention was effectively preventing exacerbations from progressing to the need for rehospitalization. They also saw the potential for a new solution to improve upon this model. "There's an infrastructure that's already in place that has shown some positive results," he noted,

"How can we make it more effective?" Analysis revealed that it cost healthcare payers approximately $400 per patient for a care management team to follow up periodically during the 30-day post-discharge period. Limited information was available, but a couple of studies indicated that follow up from care management teams could reduce hospital readmissions by up to 50 percent within the 30-day post-discharge period. Based on these directional inputs, the team estimated that it would either have to come up with a solution that more systematically intercepted a substantially greater number of exacerbations during the 30-day follow up (i.e., reduce readmissions by 75 percent) or make the care management team members significantly more productive (i.e., enable them to manage a greater number of patients while achieving comparable results) to drive down the per-patient cost of follow up. In a third scenario, the team could seek to devise a solution that would prevent more readmissions *and* make the care management teams more productive to reduce the per-patient cost of the program. This approach would, of course, be most compelling to the purchasers of the new solution.

Step 3 – Choose the target market

Choosing a target market takes into account all of the information uncovered throughout the market analysis process to focus on the segment with the most promising combination of size, dynamics, needs, and willingness to pay. The ideal target market is the market segment that offers the innovators the greatest opportunity to create value – first, for potential customers, then for prospective investors, and finally for themselves. Clearly the emphasis should be placed on assessing how favorably customers – or purchasers – respond to the possibility of a new solution in the need area. However, unless the innovators are motivated to pursue the opportunity, and the providers of capital are motivated to fund it, then the market will not be commercially viable (see Figure 2.4.12).

Innovators should be especially careful not to mistake the enthusiasm of their potential customers for the

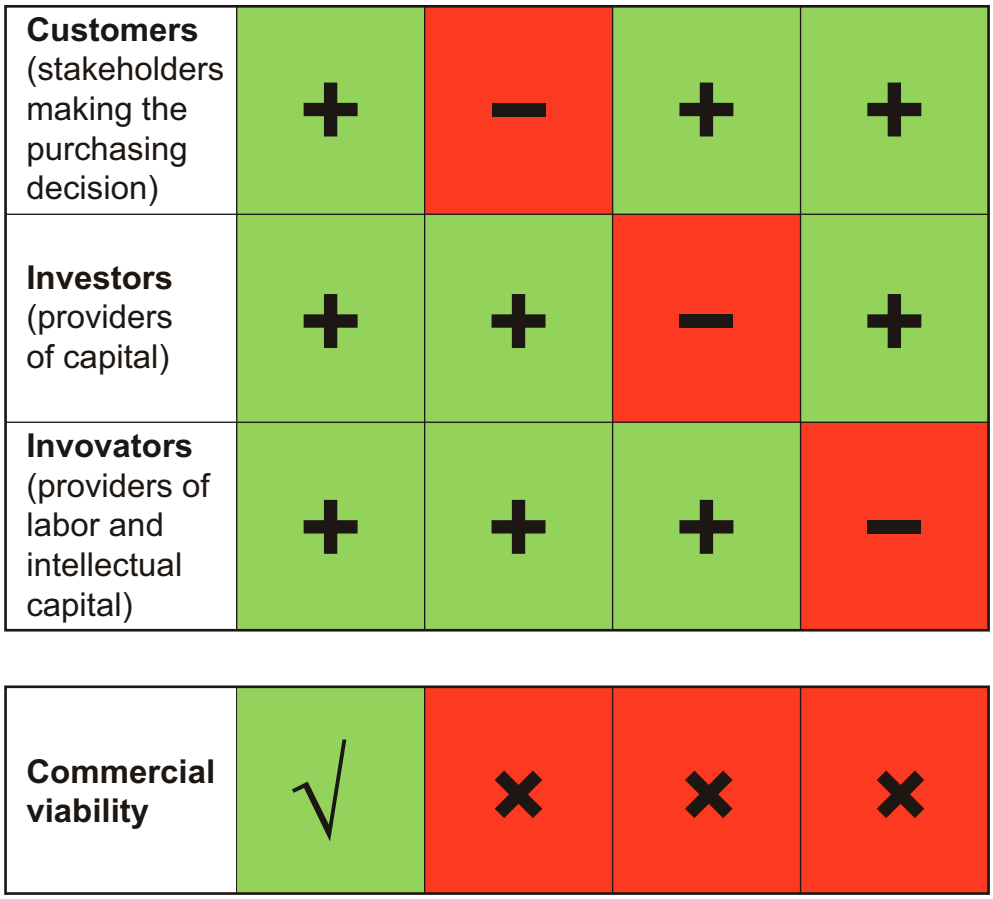

FIGURE 2.4.12
If addressing a need for a specific market segment does not have the potential to create value for any one of these key participants – customers, investors, and the innovators – then it is not likely to be commercially viable. Note that some ideas that address an important need may not support the development of a commercial business, but instead may have value in a non-profit context.

Table 2.4.4 Choosing a target market can be challenging, but the following guidelines can help.

	Risks to consider	Questions to answer	Common innovator errors
Customers (stakeholder making the purchasing decision)	• Value of a solution is too small to change behavior	• Is the need sufficiently important to the customer? • Is gain sufficient to motivate change in behavior?	• Assume improvement is sufficient to change behavior • Assume that a "need" equates to an "opportunity" • Overestimate the role price plays in purchase decision • Underestimate impact of switching costs Unrealistic timeline for adoption
Investors (providers of capital)	• Market is too small to justify effort and investment • Takes too long to develop and commercialize • Competitors may improve their products	• Is the potential market at least 3–4 times the cost of developing a solution? • Are there ways to mitigate risk during development by shortening timelines? • Will a new solution still be competitive when it reaches the market?	• Underestimate competitors ability to improve product offerings over time • Project unrealistic market share
Innovators (providers of labor and intellectual capital)	• Need is too weak to justify time necessary to develop, fund, and introduce a new solution	• How long will a solution take to develop? • What is the **opportunity cost**? • When and how do innovators tell when they have succeeded or failed in the space?	• Losing objectivity • Misreading customer encouragement to mean market validation • Giving up too early • Giving up too late

viability of the market segment. Other risks and pitfalls are outlined in Table 2.4.4. At this stage of the biodesign innovation process, it is difficult to know with certainty the extent of the value that can be created for these participants within any particular market segment. The idea is to objectively consider how the segments compare and then choose the one as a target that seems to hold the greatest overall promise.

Keep in mind that sometimes the greatest opportunities can be asymmetrical – that is, they may be exceptionally strong in one particular dimension while significantly weaker in others. Some innovators create quantitative ratings systems to help them score and prioritize segments when the choice of a target market is not clear; others rely purely on a qualitative assessment. With either approach, they must exercise judgment in making the final determination. Deciding on the best available target market requires innovators to make a series of assumption about decision maker and stakeholder behavior based on limited information. Benchmarking, proxy analysis, and engaging experts are all tools that can be helpful in developing credible assumptions. Make a best effort to gather information and then make an educated choice to avoid becoming paralyzed by uncertainty. Innovators should keep in mind that they are using estimates as an input to screening and, at this early stage, there is still time for doing significant validation work to confirm their assumptions as the biodesign innovation process moves forward.

The rapid development of mobile health (**mHealth**) applications targeted at healthcare consumers provides a good example of how innovators can validate their

assumptions. Because the development cost for these technologies is low and the time to market can be rapid compared to traditional medical devices, many innovators are motivated to work in this space. In doing so, they can make use of this ready access to the market to validate their product's features focusing on a concept called the Minimum Viable Product (MVP).[15] The idea is that getting traction with an initial set of customers – at the lowest possible cost to investors and the entrepreneurs – is the best way to prove a need and iterate a product offering, while also refining the target market segment. However, innovators should note that these exceptionally low barriers to entry come with their disadvantages in other aspects of market selection. The competitive landscape in these markets is exceedingly complex and rapidly changing, with roughly 100,000 healthcare apps competing for the attention of the consumer in 2013,[16] and that number expected to increase by 25 percent per year for the foreseeable future.[17] As a result, marketing and promotion have become more important at the same time that competition has made funding difficult to obtain. Whether innovators undertake rapid development of a mobile app or the longer-term creation of a new implant therapy, the key is to fully understand the characteristics of the market they are targeting through ongoing information gathering and then the validation of specific assumptions.

Admittedly, the process of performing detailed market analysis and identifying a target market involves collecting an immense amount of information and synthesizing it into a coherent story that supports the chosen target market, as shown in the Working Example for chronic kidney disease. The results of a preliminary market analysis also enable innovators to refine their need statements (and ultimately develop a need specification) to appropriately address the needs of the target market. Eventually, this output is also used as the foundation for the development of detailed marketing and sales plans (see chapters 5.7 and 5.8), as well as to support the company's **financial model** and funding strategy (see chapters 6.1 and 6.3).

Working Example
Market analysis for chronic kidney disease

Patients with CKD are often diagnosed late in the disease's progression and are frequently hospitalized. However, early and effective diagnosis of CKD reduces the incidence of hospitalization and also diminishes the rate of disease progression. As a result, there is a need for a device, method, or system that would successfully diagnose patients with CKD earlier in the **cycle of care** to help prevent disease progression.

After landscaping the market, innovators can dive into a patient-based market segmentation, using markers of disease progression to identify basic similarities and differences among patient populations. Recall that, for CKD, the marker is a measure of kidney function which can be used to divide patients into five CKD stages: 1–2 = mild, 3 = moderate, 4 = severe, and 5 = ESRD (end-stage renal disease). (Note that provider and payer considerations will be taken into account later in this example.)

Once these basic segments are defined, primary and secondary research can be conducted to identify the size of each segment (number of patients), the extent of the medical need in each segment (mortality and morbidity rates, expenses per patient), and segment growth rates. Literature searches can be used as a starting point, but beyond that, public databases can provide relevant information. Two such databases that are widely used are the National Health and Nutrition Examination Survey (NHANES)[18] and the Medical Expenditure Panel Survey (MEPS).[19] These surveys provide **longitudinal data** for large samples of patients regarding medical condition(s) and medical expenditures for families and individuals, and they provide a wealth of information that can be used for any preliminary market analysis. Using data from sources such as these, a bottom-up analysis of the market size for the various segments can be performed.

The NHANES database provides information that innovators can use to calculate the prevalence of each stage of CKD, as well as mortality rates, morbidity rates, and hospitalization expenditures. Figure 2.4.13 presents the number of patients in four segments and the corresponding rates of hospitalization.

These data are presented in a "patient tower" format in which the total patient population is divided in segments

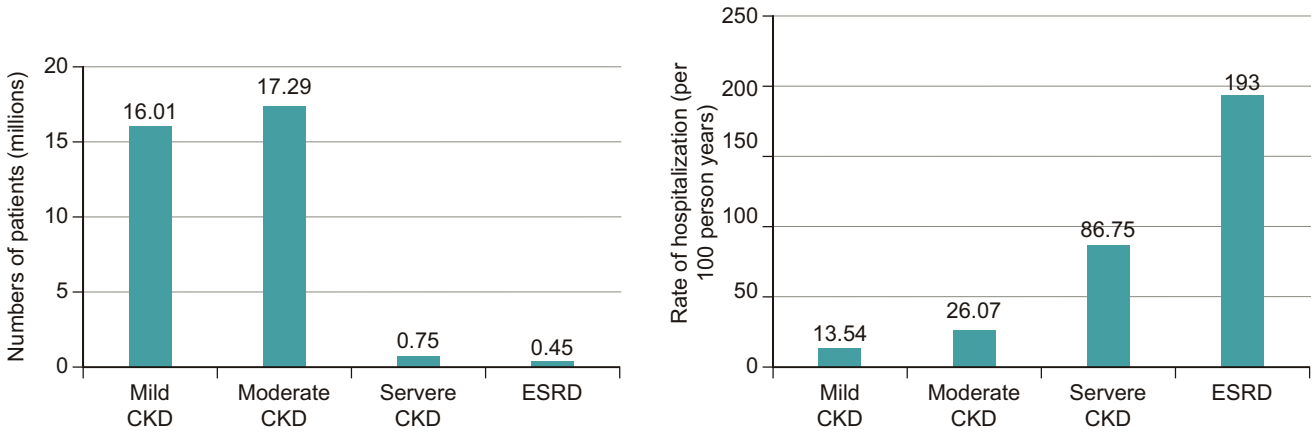

FIGURE 2.4.13
Patient towers for CKD: (a) number of patients by segment and (b) hospitalization rate by segment.

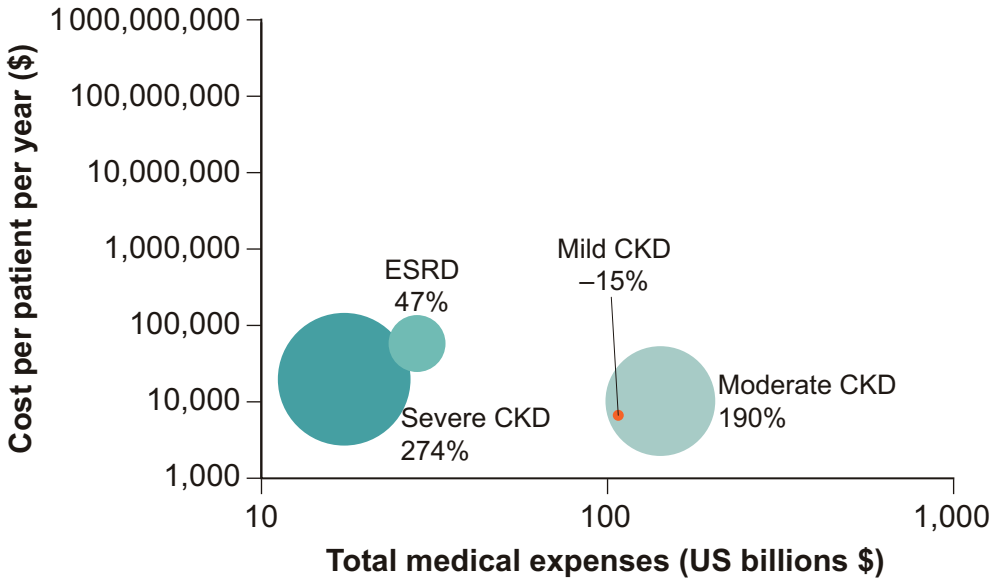

FIGURE 2.4.14
Market size and growth analysis for CKD.

of diminishing size, but increasing medical needs. Reading from the left of the diagrams (mild CKD) to the right (ESRD), the number of patients typically decreases but the severity of the condition increases. While other visual methods can be used to present these data, the patient tower approach has the advantage of visually contrasting the trade-off between the number of patients in each segment and the severity of the medical issues affecting each segment.

To identify a target market, the innovator also needs to get a sense for the cost associated with each stage of the disease. Sources such as NHANES do not provide cost information (even though they provide information on the utilization of medical services). Therefore, some data extrapolation using numbers obtained from a literature search may be required. Another potential strategy is to use data from MEPS, which typically includes expenditure information or data from disease-specific data sources. Figure 2.4.14 summarizes the data (the horizontal axis gives the total medical expenses for each segment, the vertical axis gives the cost per patient in each segment, and the size of the bubble indicates the expected growth rate).

The data in the figure were based on expenditure data provided in the US Renal Data System report (the annual medical cost per prevalent case of severe CKD was

$20,784 and for ESRD patients it was $59,412).[20] To obtain cost estimates for the other two segments (where no data were reported), an assumption can be made. In this case, the CKD cost for earlier stages was scaled by taking the cost for stage 4 and multiplying the ratio of the hospitalization rate in each stage, divided by the hospitalization rate for beyond stage 4 [cost for stage 1 (or 2) = cost of stage 4 × hospitalization rate in stage 1 (or 2)/ hospitalization in stage 4]. Using this approach, the total annual medical cost for each stage was estimated; then the growth in the prevalent population (estimated from NHANES) was used to obtain the growth in total costs for each stage.

With this information, innovators can define the characteristics of the ideal market segment: large total medical expense (all segments satisfy this), high expenses per patient (which makes the total number of patients relatively small and easier to access), and a high growth rate. Using these characteristics as a filter, the ESRD and severe CKD segments emerge as most attractive.

However, before the analysis is complete, the innovator needs to study whether all patients who have the condition are actually aware of it (if not, they are unlikely to seek treatment, which will negatively affect the total potential market size). In the example, data provided via NHANES included a response to a survey question that asked patients whether or not they were aware of diminished kidney function. This survey showed that only 25 percent of the patients with serious CKD were aware of it, and all those who were aware of it had other symptoms that helped make the diagnosis (e.g., elevated albumin to creatinine ratio, ACR). This information suggests that patients who are correctly diagnosed are often patients with high ACR. As a result, the target market could be defined in even more specific terms: patients with severe CKD and high ACR.

To some, this definition of the target market may appear to be surprising (after all, these are the patients who are already diagnosed). However, what makes this patient segment attractive is that their disease is already recognized by the healthcare system and, therefore, this segment can be accessed by the innovator. For this reason, addressing the need for better diagnosis and/or control of complications for these patients is more likely to be clinically feasible than targeting patients who are not currently diagnosed. The latter segment (of undiagnosed patients) could potentially provide an innovator with an opportunity for expansion, once the preliminary target market has been addressed, but may not be as easy to target.

A word of caution

The most common mistake in market analysis is to make assumptions that lead to overly optimistic market estimates. Overestimating a market opportunity can give innovators unrealistic expectations and result in a business plan that is unachievable and/or unsustainable. It can also hurt their credibility with investors and other stakeholders if they present an idea that is based on overly aggressive estimates and/or impractical assumptions.

To avoid this common pitfall, watch out for these four sources of error:

1. Calculating market size based on the total market, not the market segment(s) most likely to adopt an innovation. This error can be driven by failure to understand the needs of specific segments and their different adoption patterns.
2. Underestimating how much of an improvement is necessary for early adopters to change behavior. A strong value estimate is needed to understand how much benefit must be delivered, at what cost, to drive adoption.
3. Failing to recognize that not all people with a need will take steps to address it (e.g., seek treatment). This could be the consequence of relying on "sanitized" data obtained from well-controlled studies. When obtaining estimates for number of patients in a treatment area, it is important to confirm that the estimates reflect community practices and not well-controlled academic environments.
4. Overestimating the amount of market share that a new entrant can capture in an established market or the rate at which a new innovation will be adopted in

an emerging market. This error is often driven by the tendency to underestimate: (1) the effect of competition; (2) the capital requirements needed to sell a product; and (3) the time required to establish a sales or distribution capability. In most cases, innovators should not expect to gain more than 1 percent market share in the first year, increasing to a maximum of 15–30 percent based on market conditions.

Remember that market analysis can be complicated and difficult, potentially requiring a certain amount of trial and error. An iterative, increasingly detailed approach to market analysis is recommended. Innovators should be sure to revisit and adjust their preliminary market analysis as more becomes known about the need, as well as potential solutions. The story of Genomic Health demonstrates how one company tackled the challenge of market analysis.

FROM THE FIELD GENOMIC HEALTH INC.

Market analysis for a revolutionary product

Identifying the target market segment and sizing the overall market can be especially challenging for innovators considering a need with ground-breaking potential, but no proven market. Genomic Health Inc., founded by Randy Scott, Joffre Baker, and Steve Shak, is one company that faced this challenge.

In his previous role as the co-founder of Incyte Corporation, Scott and his team had made massive databases of genomic information available to major pharmaceutical companies to aid their research and development efforts in identifying targeted therapies at the molecular level. However, as the cost of genomic information came down (due to what Scott called a "Moore's Law effect" in biotechnology), he recognized that it would become possible to analyze genomic information on a patient-by-patient basis and develop truly personalized regimes to treat disease. Passionate about helping make this happen, he set out to pursue *the need for high-value, information-rich diagnostics based on patient-level (gene expression) genomic testing to enable more personalized treatment decisions*.

Scott initially pitched the idea to Incyte, but the need was met with mixed reviews. "One of my more controversial views with Incyte at the time," recalled Scott, "was that drugs would ultimately be commodities, and that greater value would come from genomic information about disease. I believed that there was more power in the information than in the solution because what's more important than understanding exactly, precisely what the molecular cause of a disease is? Once you have that information, there will be 10 potential therapies developed to treat it. These drugs will ultimately become generic, but the value in the diagnosis of that information will hold." Scott positioned this as a paradigm shift in the healthcare industry that would occur gradually over the next 30 years. When Incyte decided it was not interested in taking this direction, Scott decided to pursue the idea himself, recruiting Baker and Shak to work with him.

In terms of analyzing the market opportunity related to the need, Scott remembered that they had an initial interest in focusing on cancer patients. However, with so many other life-threatening conditions affecting relatively sophisticated patients who would understand the benefits of personalized, genomic-based medicine, more in-depth research of the potential market segments was required. To narrow the scope of their segmentation analysis, they identified several fields (such as oncology, inflammation, cardiovascular, infertility) that would potentially benefit from personalized medicine and ranked them according to several clinical and market criteria, including market size; potential for genomic information to predict disease progression; drug development pipelines (and whether the percentage of responders for the new drug would be high); patient involvement in treatment choices; and physician

willingness to adopt new treatment paradigms. After performing this analysis, "The bottom line," said Scott "was that we just kept coming back to cancer." Unlike other diseases, such as cardiovascular, where lifestyle factors played a big role in disease progression, cancer is mostly a genome-based disease. Further, response to existing drugs (or drugs under development) was considered to be variable and uncertain, and a strong history of patient advocacy showed that patients would drive the adoption of new technologies. Beyond that, the total market for oncology drugs was in the multibillions of dollars, with most drug manufacturers developing several new therapeutics.

While identifying cancer as a focus area was a good first step, it was only the beginning of their segmentation analysis. The next challenge was to determine which type of cancer to target. Ultimately, they decided to focus on breast cancer for five primary reasons: (1) *prior experience*: Shack led Genentech's clinical development program for Herceptin® (a novel, genomic-based cancer therapeutic[21]) and had a vast network of contacts, as well as a strong reputation in that clinical area; (2) *top four*: breast cancer is one of four most prevalent cancers (the others being colon, prostate, and lung cancer) and the team wanted to "do something big"; (3) *market accessibility*: breast cancer is characterized by a large system of patient advocacy groups, readily accessible education channels that make it easy for a new company to reach the market segment, and patients that tend to be highly involved in their treatment decisions; (4) *likelihood of adopting new technology*: both physicians and patients are likely to embrace new treatments in this clinical area; (5) *clinical knowledge*: there is a deep and broad body of knowledge on the genetic basis of breast cancer and a vast library of breast cancer tissue samples that make it technically feasible to develop and clinically validate any new test.

Within breast cancer, the founders focused on further refining the target market segment. The team examined the various drugs available to breast cancer patients, and their effectiveness or ineffectiveness at various stages of the disease. What they learned is that for late-stage cancer patients, treatment choices are unambiguous and highly aggressive. Patients and physicians do not want to "give up hope" and they will try everything to stop or slow the disease. In contrast, decisions about what treatments to pursue (beyond surgery) for early-stage patients were relatively subjective and varied significantly from physician to physician, making it difficult for patients to determine the appropriate course of treatment to prevent recurrence. Most early-stage patients do well with only surgery and hormone therapy. However, chemotherapy is commonly prescribed to minimize a woman's chance of repeat tumors even though only a small fraction of early-stage breast cancer patients benefit from it (approximately 4 percent). This led to an "a-ha" moment for the team: predicting distant recurrence of breast cancer for early-stage patients would likely help them make better decisions about what treatment to pursue. For example, patients with a low risk of distant recurrence could potentially be counseled to forego chemotherapy, a physically stressful and disruptive therapy, since their cancer was unlikely to return. Taking the process one step further, based on what was known about the disease, the team defined its preliminary target market segment as patients with early stage, node-negative (N–), estrogen receptor positive (ER+) breast cancer. They also further refined their need statement based on the result of their market analysis to address requirements for *high-value, information-rich diagnostics based on patient-level (gene expression) genomic testing to predict the recurrence of early stage, N–, ER+ breast cancer and enable personalized treatment decisions*.

With the market segment identified and need refined, the next challenge was to determine the size of the segment in order to determine if the market potential would justify the high anticipated cost of clinical development and the anticipated risk to prospective investors. According to the company's estimates at the time, there were approximately 200,000 new breast cancer cases diagnosed in the US each year, of which roughly 50 percent were early-stage, N–, ER+ cases. Quantifying the total market size (in dollars) was

challenging, though, because of the lack of comparable products available in any clinical field. Any solution that would address Genomic Health's defined need would be classified as a diagnostic test. However, Scott and team determined that diagnostic companies traditionally charge between $25 and $50 for their tests, commanding margins of just 5 to 10 percent. Using a $50 price for the new test, the total potential market size (assuming full penetration) would be just $5 million per year. The results of this analysis clearly illustrated that the success of the venture would necessitate a completely different pricing paradigm to support the heavy investment in research and development required to make genomic testing practical.

Two types of analysis suggested that a price in the range of $1,000 to $7,000 per test could be viable. The first was comparables analysis. Kim Popovits, COO of Genomic Health, recalled, "There was another diagnostic in the marketplace at that time, a genetic test that looked at the mutation of the BRAC-1 and -2 genes to assess a woman's hereditary risk of breast cancer." This test was priced around $3,000 and was on its way to being reimbursed on a relatively broad scale. The second was based on the value estimate for the need. Over time, Genomic Health's test had the potential to save money for the overall healthcare system and could, thus, shift the pricing power from therapeutics to diagnostics. Specifically, the total cost of chemotherapy for early-stage breast cancer patients was conservatively $15,000. If the test cut the number of patients undergoing chemotherapy by 50 percent (by predicting low recurrence risk), then the total savings to the healthcare system would be roughly $7,000 per patient. This meant that Genomic Health could command a price of up to $7,000 per test, making the total potential market for kits sold to the healthcare system $700 million.

In fact, this estimate brought Scott and team back to an earlier market estimate they developed when they raised their preliminary funding. Back then, Genomic Health's business plan was not as precise about the market segment and size (highlighting the iterative nature of market analysis as part of the biodesign innovation process). The original vision was that consumers would pay for genomic test results out-of-pocket. As a result, the team felt that a reasonable price would be somewhere in the four figures range (primarily because consumers pay analogous amounts for cosmetic surgery and other elective medical procedures funded out-of-pocket). Using similar projections regarding the total number of consumers willing to pay for the test, the founders reached a total market estimate in the billion dollar range and raised more than $30 million in investments. About a year later, they focused their market segment and further developed the company's value forecast.

FIGURE 2.4.15
The Oncotype DX specimen collection and transportation kit, along with a results report (courtesy of Genomic Health).

The Genomic Health team went on to develop the Oncotype DX® test to predict the risk of distant recurrence for early-stage breast cancer patients (see Figure 2.4.15). Multiple clinical studies established that the test is not only effective in predicting the likelihood of recurrence, but also a patient's response to chemotherapy. Priced at $3,650, in line with the team's initial value forecast, the test is now included in the treatment guidelines set forth by the American Society of Clinical Oncology and the National Comprehensive Cancer Network.

Market analysis in emerging economies

The approach to market analysis described in this chapter can be effectively utilized in any geographic setting. However, innovators working in emerging economies are likely to face a much greater challenge in implementing it. This is particularly true when innovators seek to work in a location where they do not yet have a deep, personal knowledge of cultural, business, and healthcare customs. In these cases, fundamental differences in healthcare stakeholders, how healthcare is financed and delivered, and important variations in standards of care must be understood as a precursor to assessing the market. Similarly, significant attention should be paid to understanding the unique aspects of local competition, which can vary dramatically from what innovators may be used to seeing in the US or Europe.

Another important distinction about working in less developed markets is that reliable market data can be much less widely available. Research reports and formal data sets rarely exist, which can make learning about the market difficult, especially from afar. Even in areas where market research exists, the information can be inaccurate, dated, or misleading. Understanding how data has been collected can help innovators assess its relevancy and reliability. (For more information about taking the lack of available secondary data into account during needs screening, see 2.5 Needs Selection.)

More often than not, innovators have to perform their own market research in the space where their need exists. However, there are certain challenges to relying solely on primary data collection when assessing a market. Intentionally or not, stakeholders have a tendency to apply their own lens to a situation, especially when they have a vested interest in either maintaining the status quo or altering it. Innovators must consider the source for all information gathered and to remember that not everyone will necessarily want to be helpful.

Additionally, stakeholders may be tempted to provide innovators with the answer that they believe they want to hear, instead of what they really think or feel (although this can happen in any geography). This is especially true if a perceived power differential exists between the person being interviewed and the person conducting the interview. According to one innovator working on health solutions in Kenya, "You have to be really careful how you frame your questions and sometimes take people's answers with a grain of salt." One way to validate the information provided in interviews is to observe actual user behavior whenever possible. Even if no product or service exists to address a particular need, find a proxy offering against which to benchmark stakeholder actions. For example, when trying to understand willingness to pay, this innovator continued, "I find it far more valuable to see what people are actually buying. Look at what's really going on as opposed to what people report they would hypothetically spend their money on." John Anner, President of the East Meets West Foundation, elaborated on that point in an article: "Listening is tricky. Without multiple ways to verify what people really want, it can be hard to cross the barriers of language and culture to truly understand what people need and want (good or bad). This is why the best way to figure it out is to provide a range of options and let people vote with their own money."[22]

Another issue is that primary research takes time and often cannot effectively be conducted from a remote location. This can be a challenge for US-based innovators with an interest addressing global health needs in that it requires them to spend significant time in the field. As Krista Donaldson, CEO of the non-profit product design company D-Rev described:

> *You can spend a lot of time just getting to the people you want to talk to. That might mean a lengthy car trip on rural roads or several hours sitting in traffic. Then there's navigating the hospital to find the right person. And sometimes that means tea with the medical superintendent first. Not infrequently, you could spend all day waiting to talk to one person, particularly in busy hospitals where, rightly, we are a relatively low priority. Innovators often want to get in and get out – that's very Western treatment. But you just can't do that. This type of work takes a lot of patience and relationship building. And it also takes the ability to go with the flow and recognize that you may spend a week trying to visit hospitals and get nowhere, but you're still learning a lot. You just*

might not appreciate that until you're able to step back and think about it.

Donaldson also noted that it can be a challenge for innovators to know when they have enough information to stop and move on. While the answer varies from case to case, she offered this advice: "Once you start hearing the same thing over and over again, you know that you've done good research."

The following story, from a team that ultimately became Consure Medical, highlights some of the challenges involved in conducting market analysis in an emerging economy.

FROM THE FIELD CONSURE MEDICAL PVT. LTD.

Redefining a need statement through market analysis

Nish Chasmawala and Amit Sharma, both participants in the Stanford-India Biodesign Program, spent six months in California learning and applying the biodesign innovation process. Early in their Fellowship, one of their classmates went back to India to help care for his mother, who had become very ill. When that colleague returned to Stanford, Chasmawala and Sharma tried to distract him from his worries by asking if he had identified any needs while he was away. "And the need that he threw out on the table that day was fecal incontinence," Chasmawala recalled. "It's pretty embarrassing and nobody talks about it. But it's also a genuine need, and there didn't seem to be any good solutions for it."

The second half of the yearlong Fellowship took place in India, where Chasmawala and Sharma decided to further investigate opportunities and problems related to fecal incontinence (FI). Patients with FI are unable to control their bowel movements, which can result in the involuntary excretion of liquid, mucous, or solid stool from the rectum. Ranging in severity from minor soiling to a complete loss of bowel control, FI is a psychologically distressing condition that significantly affects **quality of life** both within and outside institutional settings.

For six weeks, the team conducted observations in a variety of medical settings, including a large tertiary care hospital, a new, state-of-the-art trauma center, and rural and community public health centers. While both men were born and raised in India, they were still surprised by what they saw when observing the cycle of care for FI. Absorbent pads (or adult diapers) were the standard of care for most FI patient. Within home settings, Sharma described a typical situation: "Imagine a 65–70 year old bed-bound male with fecal incontinence. In India, generally speaking, a female family member will provide the home care. So, you might have a daughter-in-law who has to change her father-in-law's diaper, clean the area, and so on, which is undignifying for both of them." In addition, he pointed out, "The diaper is not even a good solution." Diapers delivered mixed results. They prevented bed soiling, but caused skin breakdown. They also were uncomfortable to wear, and unpleasant and time-consuming to change. "If you look at the current gold standard, you realize that it is not at all 'gold'," Sharma noted.

In the hospital setting, the situation was equally as troubling. Overworked nurses often relied on family members to address the problem of FI, even when patients were under the hospital's care. Chasmawala explained, "In rural community hospitals in India, there are usually eight beds in a room with limited ventilation and inadequate waste disposal systems [see Figure 2.4.16]. Family members usually try to form a human shield to do an absorbent pad change and clean the patient." Summing up the observation experience, he said, "Spending time in these settings created a sense of pathos is us, but also motivated us to develop a solution for this unaddressed problem."[23] Based on what they saw, one of the need statements they defined was *for a better way to manage FI in resource-constrained environments*.

FIGURE 2.4.16
A typical rural community hospital in India, where patients experiencing fecal incontinence would be treated (courtesy of Consure Medical Pvt. Ltd.).

In parallel with disease research, an assessment of existing solutions, and stakeholder analysis, Chasmawala and Sharma dedicated themselves to understanding the market for FI. However, their search for information confirmed that conducting market research in India could be difficult, with reliable numbers hard to find. Sizing the market for FI was particularly challenging because, in most cases, it is a secondary condition or comorbidity to a primary disease state, such as stroke or other condition that damages the nervous system. This makes it somewhat more problematic to study. Prevalence studies of fecal incontinence in the general population are rare, and the results can differ significantly. As one literature review revealed, the estimated prevalence of fecal incontinence in selected studies varied from 0.4 to 18 percent.[24]

In terms of spending and competitive activity in the FI space, the team thought about the per-day treatment burden rather than the cost of competitive solutions themselves. Diapers were the most widely used product, and also the least expensive at roughly US$10 per day. Collection devices, which were slightly more effective in containing feces, caused more clinical complications and were available at a higher cost of roughly US$15 per day. In-dwelling catheters were significantly more expensive at US$60 per day. These devices could only be placed by a trained care provider and were typically used only in the intensive care unit (ICU) setting. According to Sharma, they were also not widely adopted because they were suboptimal in many ways: “Products that existed to address other needs have been scaled in their size and used for FI. For instance, most in-dwelling catheters are essentially a larger version of Foley’s catheter [used for urinary incontinence]. Nobody has looked at the physiology of the rectum and designed an appropriate solution for fecal incontinence.” For chronic fecal incontinence due to neuromuscular degradation, surgery was also an alternative. However, this treatment was exceedingly expensive for the majority of patients in India. In fact, the team believed that cost was a critical factor in each treatment category since most patients in India covered their medical expenses out of pocket. Taking all of this information into account, Chasmawala and Sharma determined that there was a significant gap in the market landscape and they had significant room to add value (see Figure 2.4.17). Their primary focus would be on seeking to displace the adult diaper, FI collection devices, and in-dwelling catheters with a new solution.

To segment the market, they started by evaluating a variety of different subgroups within the total FI patient population. Specifically, they explored patient characteristics across five different dimensions: (1) acute versus chronic condition; (2) pediatric versus adult; (3) ambulatory versus non-ambulatory; (4) major versus minor incontinence; and (5) hospital versus home setting. This assessment revealed important insights about the need. For instance, in patients with acute FI (e.g., linked to a stroke), the function of the bowels is temporarily compromised. In contrast, patients with chronic FI have experienced neuromuscular degradation or other changes to the apparatus of the bowels from which they will not recover. Patients with acute FI, who receive care in a hospital setting, have access to skilled healthcare providers capable of assisting with treatment (beyond

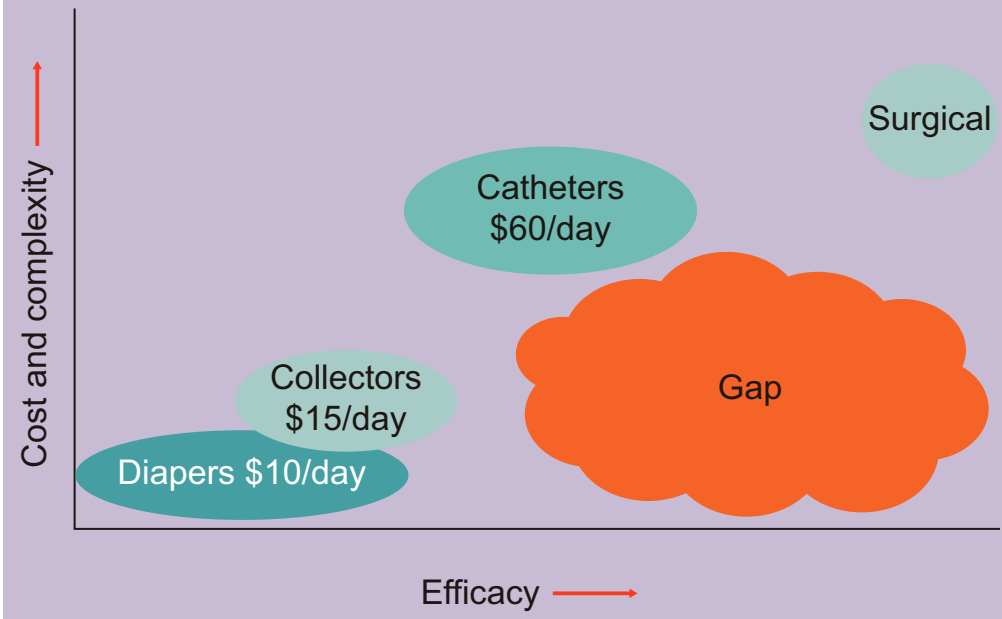

FIGURE 2.4.17
A high-level version of the comparative landscape prepared by the team during its early market assessment (courtesy of Consure Medical Pvt. Ltd.).

absorbent pads). However, patients with chronic FI are forced to manage this condition over the long term at home and must rely on family members without any medical training to assist them.

From this analysis, the team defined two primary market segments that seemed attractive as potential targets. The first segment included ambulatory patients who suffer from chronic minor incontinence outside the hospital, often linked to old age, diabetes, traumatic childbirth in women, and other such conditions. "These patients experience some leakage of feces when they cough, sneeze, or laugh loudly. This is not a major clinical problem, but it is extremely embarrassing for patients and can become a traumatic issue that isolates and depresses them," Sharma explained. The second market segment focused on non-ambulatory acute patients suffering from major incontinence, who start in the hospital setting but then move to the home setting for long-term care.

Thinking further about their two potential market segments, Chasmawala and Sharma believed the basic market needs were similar across both groups. For example, a new solution should be easy to use to meet the needs of both segments. For the home, the solution would have to be so simple that unskilled, untrained, possibly illiterate family members could administer it. In low-resource hospital settings, a solution that could be delivered by a nurse or an assistant would be preferred. Both segments also required a more effective and more dignified solution.

One important difference that emerged between the two segments was how the team would potentially access them. The minor incontinence, home-setting segment of the market would primarily be accessed by selling products over the counter to patients via medical product shops, whereas the major incontinence, hospital segment would be reached through hospital procurement departments and doctor recommendations. Further, Sharma mentioned, "The need in the hospital setting was bigger. From the clinical point of view, the under-management of fecal incontinence can lead to a higher rate of comorbidities in the patient. Thus, the hospital setting had a great 'pull' factor associated with it, as opposed to the home setting where we would have to push the device." In combination, these factors drove the team to pursue the hospital market segment as its first priority.

To develop a more specific understanding of the size of this segment, they conducted additional literature

searches and also performed primary research to gather anecdotal market estimates from doctors in the field. Eventually, due to the paucity of available information, they investigated the number of the non-ambulatory patients suffering from major FI as a secondary condition within institutional settings in the US. Acknowledging that it was an imperfect approach, they determined that they could use US data as a rough proxy for market size with the assumption that the US population is roughly one-third the size of the Indian population, but in India only one-third of people can afford regular clinical care. After validating a series of rough estimates with in-country clinical and medical technology experts, they felt comfortable that they were directionally on target. This research suggested that their target segment included approximately 16 million patients in India each year. They sized the total worldwide market at 100 million patients.

In terms of willingness to pay, Chasmawala and Sharma thought more deeply about the value that any new solution would have to deliver to get physicians and other stakeholders to adopt it. In terms of effectiveness, the bar was set relatively low and they felt that patients and care providers would be unanimously receptive to an alternative to diapers and clumsy collection devices if it was affordable. Using diapers as a comparable benchmark, they determined that if they could create a considerably better approach that costs approximately US$10 per day, their solution would be compelling enough to get patients and providers to change their behavior.

Based on the outcome of their market research, Chasmawala and Sharma were able to refine their need statement. As Sharma stated, "The new need is for *a better way to manage fecal incontinence in order to improve clinical outcomes and reduce costs to hospitals by minimizing hospital-acquired infections and decreasing nursing time*." Over a number of months, the team, which founded a company called Consure Medical, developed a device similar to a short-term implant to address this need. The Consure solution diverted all fecal material from the rectum to an external collection device without interfering in peristaltic movements and other physiological functioning of the anorectal apparatus. It also had a slick insertion mechanism that allowed it to be placed in a clean and hygienic manner and was explicitly designed to be simple enough for a nurse or family member to use without physician involvement. Additionally, it would be priced to be competitive with adult diapers. As of 2013, Consure had completed a 10-patient safety study and another 10-patient efficacy study in India, which produced promising results and no adverse events. The company had also raised a Series A round of funding and was on its way to achieving regulatory clearance for the device. Although India remained the company's preliminary geographic focus, the team was already working with sites in the United States and the United Kingdom that were enthusiastic about the device.

Online Resources

Visit www.ebiodesign.org/2.4 for more content, including:

Activities and links for "Getting Started"
- Landscape the market
- Segment the market
- Size the segments
- Understand the dynamics of each segment
- Assess market needs
- Evaluate willingness to pay
- Choose a target market
- Bring it all together

Videos on market analysis

Sample appendices that demonstrate
- Porter's Five Forces analysis for drug eluting stents
- SWOT analysis for drug eluting stents

CREDITS

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NOTES

1 From remarks made by Richard Stack as part of the "From the Innovator's Workbench" speaker series hosted by Stanford's Program in Biodesign, March 6, 2006, http://biodesign.stanford.edu/bdn/networking/pastinnovators.jsp. Reprinted with permission.

2 From remarks made by John Abele as part of the "From the Innovator's Workbench" speaker series hosted by Stanford's Program in Biodesign, February 2, 2004, http://biodesign.stanford.edu/bdn/networking/pastinnovators.jsp. Reprinted with permission.

3 "U.S. Medical Device Market Outlook," Frost & Sullivan, 2008, http://www.frost.com/prod/servlet/frost-home.pag (July 16, 2014).

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

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8 It should be noted that ulcers larger than 5 cm^2 take longer to heal (68 days) but, to be conservative, it was assumed that the average healing time is 52 days, as it is for smaller venous ulcers.

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