1.2 Needs Exploration

INTRODUCTION

Two aspiring innovators are looking for ways to improve sternotomy[1] procedures, and they both contact a leading clinician. One simply asks the clinician for an interview. The other requests permission to follow patients through surgery and post-op care, and to talk with an administrator who can help identify the associated costs. Both innovators are likely to glean important insights from their investigations. But the one who actually sees the procedure performed, follows the patient into recovery, and digs into the actual costs associated with episode will learn dramatically more about the opportunities for improvement in care and where real value can be created.

Before the development of any new solutions can actually take place, innovators must first identify and understand the opportunities that are associated with their chosen strategic focus area. The process of identifying opportunities requires innovators to utilize a combination of background research, first-hand observations, and interviews to find new ways of looking at medical processes, procedures, events, costs, and resource allocation. The well-observed problems that emerge through these activities are at the heart of defining a need – the fundamental building block of the biodesign innovation process.

See ebiodesign.org for featured videos on needs exploration.

OBJECTIVES

- Learn how to perform effective background research, observations, and interviews.
- Identify the types of problems that are likely to result in significant opportunities.
- Appreciate the importance of value exploration and recognize the "signposts" that can point to high-value needs.
- Understand the relationship between problems, populations, and outcomes that, together, form the basis for need statements.

NEEDS EXPLORATION FUNDAMENTALS

Needs exploration is all about understanding various elements of a problem that a new technology or solution may be able to address. To understand a **need** fully, it is useful to consider it in three dimensions. First, there is the core *problem* – the basic issue that is somehow limiting the quality and/or affordability of care somewhere in the continuum of healthcare delivery. While some problems are obvious, others have not yet been recognized, even by those closest to them (see Figure 1.2.1). It may be that the same issue, or a version of it, will be observed in a variety of healthcare settings. The second dimension of the need is the *population* affected by the problem. The relevant population could be a subgroup of patients, a set of providers in a particular specialty, a type of hospital with a certain cost issue,

FIGURE 1.2.1
Direct observations help ensure that important clinical problems (and the associated needs) are not overlooked.[2]

or an entire healthcare system. The third dimension is the desired *outcome* – that is, the positive change or improved end result that would be experienced by the population if the problem is appropriately solved. Eventually, these three types of information come together in a **need statement**, as outlined in more detail in 1.3 Need Statement Development.

The three most common techniques for performing needs exploration are background research, observations, and interviews, with research typically completed first to help innovators prepare for observations and interviews. This chapter describes effective approaches for conducting this work.

Background research

At this early stage of the process, innovators perform background research to prepare for more detailed, first-hand data collection in their interest areas. In chapter 1.1, it was only necessary to look at high-level information to directionally understand the focus areas under consideration. For example, innovators investigated factors such as the size of the total population affected by a disease, the nature of the disease burden, annual expenditures on diagnosis and treatments, the general effectiveness of available technologies, and how crowded the space is with competitors. During needs exploration, it is time to go deeper to better understand the disease state (pathophysiology, patient demographics, and key terminology), existing solutions (companies linked to available technologies and how/where available diagnostics and treatments are delivered), **stakeholders** (the range of participants in core processes, procedures, and related interactions), and market factors (major expenditures in the space, what are the big ticket items) (see Figure 1.2.2). Primed with this background, innovators will better understand what is being said and done as they conduct observations and interviews. Chapters 2.1 through 2.4 can be used as a guide for deciding which factors to research at this stage in the biodesign innovation process. These chapters outline detailed approaches to conducting research in each of these areas. Innovators should begin their research at a relatively

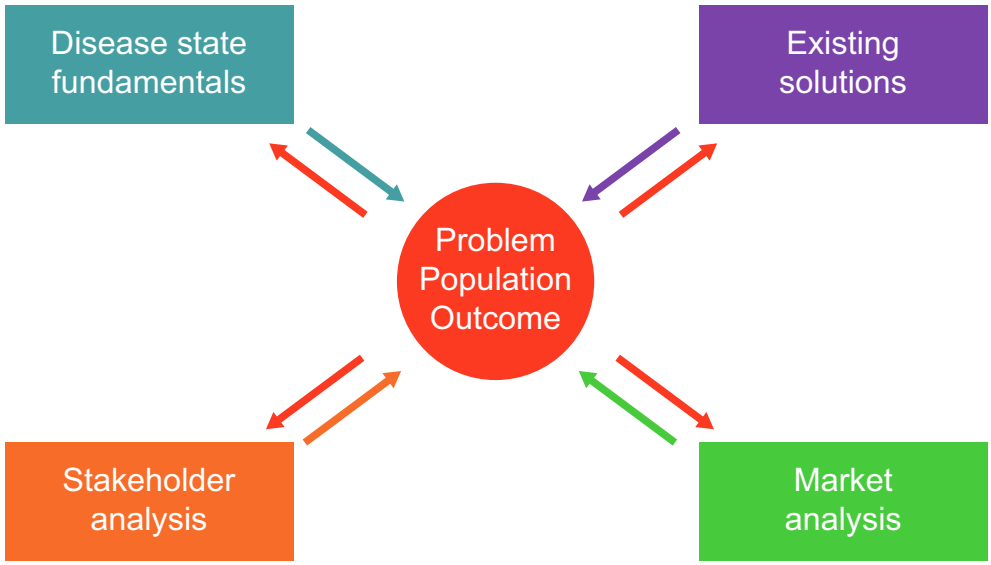

FIGURE 1.2.2
Maximizing the value of needs exploration requires a fundamental understanding of disease, existing solutions, stakeholder, and market factors.

high level with the expectation that it will become more detailed and in-depth as they become more focused on specific needs.

As innovators become more knowledgeable about their focus areas through their research, they can use the acquired information to plan for observations and craft questions to direct their interviews. In doing so, it is essential to explicitly recognize the different perspectives of all involved stakeholders throughout the **cycle of care**, including patients, physicians, nurses, and the many other representatives of the healthcare system. Problems often are uncovered when the inadequacies or limitations of current approaches are identified. But something that is problematic to one stakeholder may be viewed as perfectly acceptable and routine to another. To be sure that nothing is missed, it is essential to research and then explore how processes work from the point of view of every participant. By outlining questions or inquiries from multiple points of view, innovators ensure a broad understanding of potential issues and opportunities across a focus area. As a guide, the questions in Figures 1.2.3–1.2.5 can be used to frame observations from multiple perspectives for a patient undergoing a hospital-based surgical procedure.

Consider colonoscopy screening for colon cancer as an example. Background research in this area should highlight at least two primary stakeholders to consider when preparing for observations and interviews – physicians and patients – and should reveal that their points of view may differ substantially across the cycle of care. If innovators plan only to observe the procedure and interact with the physician, important patient-related insights will be lost. For instance, when physicians comment on the most difficult aspects of the procedure, they often refer to the technical challenges of reaching the furthest regions of the bowel with the colonoscope. In contrast, most colonoscopy patients report that, by far, the biggest problem with the procedure is the "bowel preparation" the day prior to treatment. Patients are asked to drink large quantities of a special preparation that causes severe diarrhea, often accompanied by bloating, flatulence, and other forms of discomfort. Yet this problem is not observable during the procedure. Even when asked directly about patient discomfort, physicians often describe colonoscopy as relatively easy to tolerate. Their point of view is based on the fact that they see only limited patient discomfort when the scope is in the bowel and tend to forget about or minimize the discomfort that many patients experience when preparing at home.

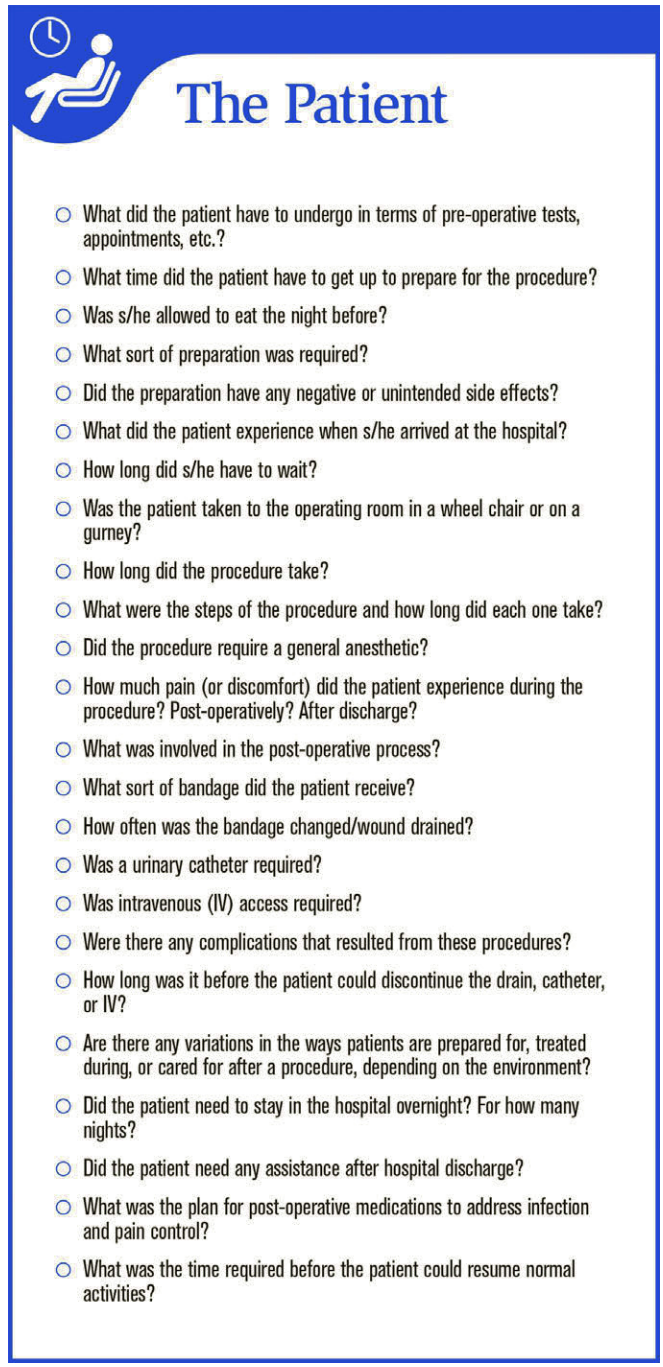

FIGURE 1.2.3
A checklist of illustrative questions for exploring the patient's perspective across all aspects of their care.

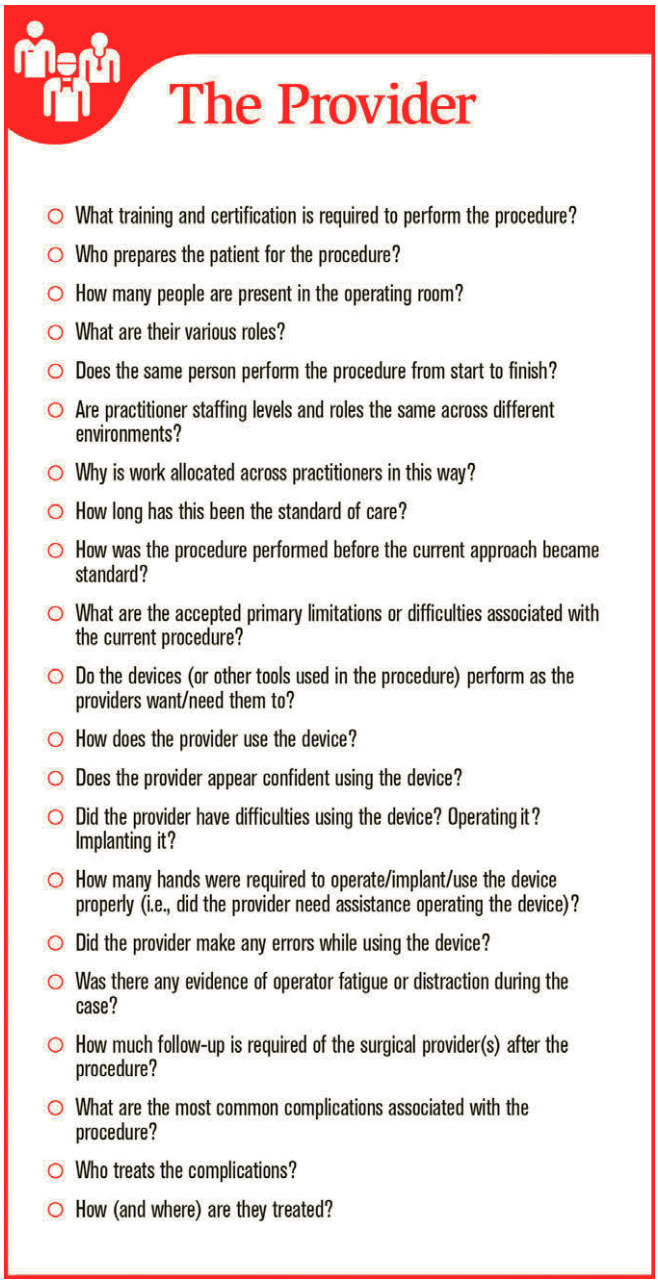

FIGURE 1.2.4
A checklist of illustrative questions for understanding the provider's perspective across all aspects of patient care.

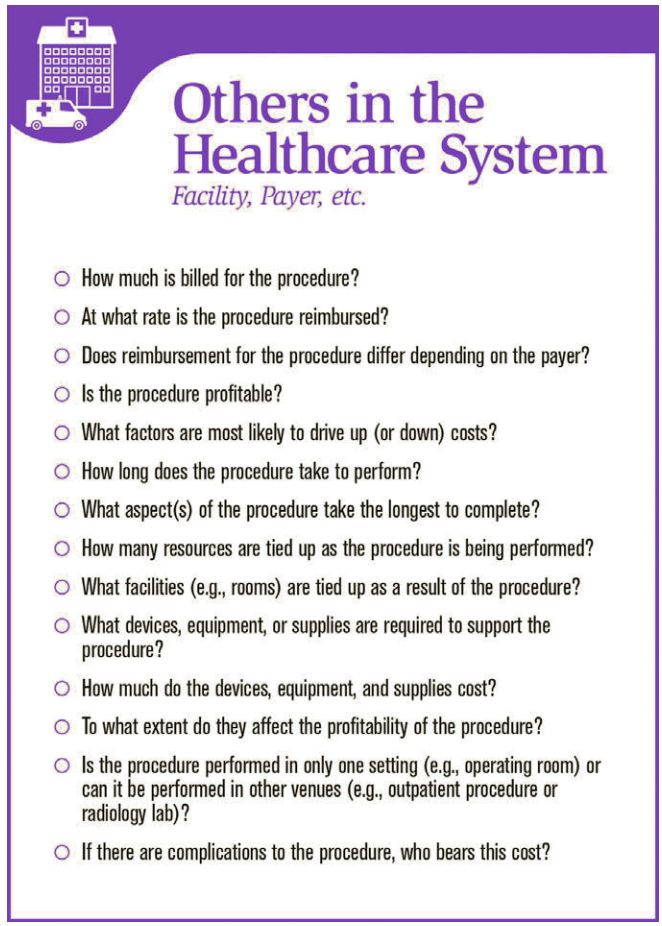

FIGURE 1.2.5
A checklist of illustrative questions for probing other perspectives during observation and interviews.

Background research can alert innovators to important "disconnects" like this one, and can serve as a guide for planning comprehensive observations and interviews.

When using research to prepare for observations and interviews, innovators must be thoughtful about how they frame their questions, since the way something is asked can influence or **bias** the answer. For example, when balloon angioplasty (a technique for inserting a catheter into a blocked or narrowed artery in order to inflate a balloon to reopen the vessel) was in its early stages of development, many cardiac surgeons were asked about the **value** of a technology that did not require a sternotomy for treating patients with coronary artery disease. Most responded that they simply could not envision the potential benefits of a procedure that did not allow them to visually access and directly repair the arteries by opening the chest, stopping the heart, and engaging cardiopulmonary bypass. However, when the question was reframed and cardiac surgeons were asked about the value of this approach for high-risk patients who could not tolerate coronary artery bypass grafting (CABG) surgery, most saw the potential for angioplasty to be useful as an alternative.

Observations

Clinical problems, populations, and desired outcomes come to life through direct observations. Typically an observation centers on a singular event that the innovator witnesses. In order to qualify as a real problem, meriting further attention in the biodesign innovation process, the issue raised in an observation should involve an insight about *recurring* situations in which doubt, uncertainty, difficulty, inadequacy, and/or undue cost are encountered. Consider an example that demonstrates how an observation can lead to the identification of a problem, as well as a population and desired outcome:

Observation: A medical resident in training struggles to intubate a patient (place a breathing tube into a patient's trachea) in the emergency room, leading to a drop in the patient's oxygen levels.
Problem: Difficulty placing the endotracheal breathing tube in an emergency setting.
Population: Untrained/unskilled practitioners.
Outcome: Ability to place an endotracheal tube in a timely manner without a dangerous drop in oxygen saturation.

Innovators must carefully assess their observations to ensure an appropriate opportunity is identified. For instance, in the example above, the innovator should ask whether the problem might be a concern for a larger population than just residents. The existence of a more widespread problem is possible, but that determination should only be made with further observations and data collection (i.e., the innovator may need to observe intubations performed by experienced physicians, paramedics, and other care providers). Further, all assumptions made in identifying the problem through an observation should be validated and tested. Again, in the example, the problem noted is based on the assumption that the resident's lack of skill led to the requirement of extra time to place the tube. If this proves to be incorrect (perhaps the problem is instead caused by certain types of patients with challenging anatomy and may not change with improved skill), the innovator could potentially invest time, effort, and money in pursuing a need that does not exist. Notice also that, in this case, reduced time is defined as the core of the problem. However, time may not be as important to patient care as a more specific clinical endpoint, such as minimizing oxygen saturation changes during the procedure.

A second example reinforces the relationship between observations, problems, populations, and outcomes:

Observation: When an elderly patient was discharged from the hospital after treatment of a cardiac arrhythmia (abnormal heart rhythm), his previous medications were modified and a new medication was added for treatment of the arrhythmia. When seen in the clinic for follow-up in a week later, there is confusion about the medications he is taking and concern about potential interactions between the medications that could be life threatening.
Problem: Directions for medication usage after discharge from hospital.
Population: Elderly patients discharged after hospitalization.
Outcome: Clearly defined instructions for medication use at hospital discharge that results in a reduction in hospital readmissions due to medication interactions.

In both examples, innovators should repeatedly validate the variables related to an issue before naming the problem, population, and outcome, and then subsequently translating it into a need statement (as described in chapter 1.3). This is especially important and potentially difficult for latent problems that have not previously been described.

Setting up observations

Innovators find that it can sometimes be challenging to gain access to appropriate clinical settings to perform observations. One of the main reasons that a large number of **medtech** inventions come from physician inventors is that their work allows them to directly observe relevant problems on a regular basis. Creating the opportunity to perform observations for non-clinician innovators can be difficult, especially given the many safeguards in place to protect patient privacy (see A Note on Ethics and Observations later in this chapter). One of the most effective access strategies is for innovators to leverage their personal networks (and often their

extended networks, i.e., friends of friends, distant family members, and introductions gained through casual acquaintances) to conduct observations in a diversity of relevant facilities. Another approach is to partner with a physician or medical professional to address the access issue. If these two strategies are not effective, innovators can make "cold calls" to facilities to request permission to make site visits (an approach that requires substantial patience and perseverance).

When thinking about access, keep in mind that it is important to make observations that span the entire timeline of care. When innovators watch only a few minutes of a surgery, for example, they are almost certain to miss important insights. Observers must understand what is involved in the preparation, procedure, and post-operative care to truly understand potential problems (and corresponding needs) in a focus area. For this reason, it is not enough to just gain access to the operating or examining room. Innovators should also make arrangements to observe waiting areas, laboratory areas, and even administrative spaces. Whenever possible, innovators should also explore environments where patients present with preliminary symptoms and receive follow-up care. To understand how a procedure or interaction is paid for or reimbursed, innovators should further seek access to the finance department of a hospital and/or the accountant in a doctor's office. Here the main focus is to gather high-level information about how the provider is paid and who covers the charges. In many cases, separate permissions may be needed to access each of these target areas.

Conducting observations

The next step is for innovators to immerse themselves in the clinical situation of interest. The process of observation is linked to an approach called **ethnographic research**. The basic ethnographic method involves the researchers becoming immersed in the activities of the people that they want to study with the goal of gaining the in-depth perspectives of that group, including clues about what they think, feel, and may need.[3] In the biodesign innovation context, this means trying as much as possible to assimilate with the group being studied to understand the perspective of the "insiders."

A core feature of modern ethnographic research is to devote considerable attention to establishing **empathy** for the people being studied – that is, sharing their experiences and feelings.[4] This requires that innovators figuratively step into another person's shoes and allow themselves to truly consider what it is like to think, feel, and experience everything that person encounters in a given interaction. One way to "get inside someone else's head" is to get creative about ways to better understand their perspective, above and beyond what is directly observed. For example, when exploring the needs of above-knee amputees in rural India, one team of students wanted a way to better understand the psychology of patients in the target population. To do so, they acquired a specialized device that one could strap to a bent knee to simulate a prosthesis. By walking on this device, particularly over uneven surfaces that would be common in remote parts of India, each engineer experienced first-hand what it would be like to depend on an artificial limb. "It was terrifying," recalled Joel Sadler, one of the team members. The insight they gathered from this experience was that many of the inexpensive prostheses available in the market were scary to use and that amputees could benefit from an alternative that would help them feel more confident walking with the device.[5]

Another important technique for gaining empathy is to "adopt a beginner's mindset." Discovery is partially about being in the right place at the right time. However, it is also about being receptive to new ideas and opportunities when they arise. If innovators go into an observation thinking, "I've already seen this before," it is unlikely that they will be in the state of mind necessary to pick up on the subtle insights that often lead to great ideas. Innovators' own assumptions may actually be misconceptions or stereotypes that can restrict the amount of real empathy that they can build. Adopting a beginner's mindset, by following the points listed below, can help innovators set aside their biases so they can approach observations with fresh eyes:[6]

- **Don't judge.** Try to observe and engage with stakeholder without the influence of value judgments upon their actions, circumstances, decisions, or any other issues that surface.

FIGURE 1.2.6
Two leaders of an ENT start-up company observing sinus surgery. Ideally, they will observe not just the procedure, but the complete episode of care that surrounds the procedure (courtesy of Acclarent).

- **Be truly curious.** Strive to assume a posture of questioning and curiosity, especially in circumstances that seem either familiar or uncomfortable.
- **Question everything.** Keep a running list of new inquiries stimulated by different observations.
- **Find patterns.** Look for interesting threads and themes that emerge across interactions with stakeholders.
- **Listen. Really.** Let go of any competing agenda and let the scene soak into the psyche. Absorb what stakeholders do, what they say, and how they say it, without thinking about anything else.

To be considered part of the team being studied, observers need to be willing to commit substantial time and energy to their observations. For example, if innovators are seeking to identify the problems associated with the use of a device in a certain surgical procedure, they need to arrive at the hospital when the surgeon does, watch several unrelated cases, and then observe the entire procedure and the post-operative routine (see Figure 1.2.6). If, instead, the innovators arrive just before the device is used and leave the room as soon as it is put away, they will miss important learning opportunities and potentially leave with an incorrect impression. The surgeon, nurses, and other assisting professionals are unlikely to share feedback and opinions that might reveal problems if they feel that the observers are not really engaged in the **episode of care**. But if the observers stand as long as the team members stand, rest only when they do, and join the team in the cafeteria after the case, people are far more likely to open up. These behaviors are just as likely to result in relevant insights regarding problems as watching the device in use. Usually this is not due to any *formal* statements that are made, but to information gleaned from watching members work and participating in their *informal* discussions. As noted, having some understanding of the medical situation being observed (through background research and a review of the medical literature) will also be viewed favorably and will help innovators present themselves in a professional, educated, interested manner.

One other issue to consider is known as the "observer effect." This refers to changes in the phenomenon being observed that are caused by the mere act of observation. For instance, physicians and other providers may perform tasks or respond to problems differently when they are being watched. Patients, too, may modify their behavior (e.g., their response to pain) when observers are present. As the observers become part of the team, the observation effect can often be diminished because

members feel more comfortable with their presence and less conspicuous about their actions.

Performing repeated observations across different settings is also an imperative. While common clinical problems exist throughout the healthcare system, there is tremendous variability in how similar problems are handled in different healthcare environments. For instance, innovators exploring hospital-related problems are likely to uncover significantly different issues in university teaching hospitals compared to community care hospitals. To illustrate this point, consider the process of closing a skin flap after plastic surgery, a practice that requires suturing by hand and can often take as long as three hours to complete. In a university hospital, the surgeon would complete a procedure and then turn the patient over to a resident to close the flap. With many residents on staff, all eager for experience, this time-consuming, labor-intensive process is not viewed as a problem. In a community hospital, however, there are no "extra" resources to complete these kinds of tasks. Surgeons close their own flaps, which ties up their time, potentially limits the number of cases they can manage on any given day, affects their ability to deliver other forms of patient care, and may lessen the overall amount of money that the physician and the facility can earn. Without this type of differential insight, an innovator could potentially miss a problem and an important driver of the related need.

Finally, during the observation process, certain types of events and behaviors can signal innovators about significant problems. These clues (as shown in Table 1.2.1) are often specific to one particular perspective. When these signals are observed, they should be investigated further as they can lead to the identification of opportunities. Although each type of clue is linked to a different perspective, too often the physician's perspective is given top priority, especially during observations, when there is much to be gained from taking another point of view. For example, instead of considering how to find *a faster way to cut during surgery*, the patient's perspective might well be to eliminate the need for cutting altogether. It can be equally helpful to consider problems by making observations from the **third-party payer's** perspective (public and/or private health insurance providers) and the facility's perspective (hospitals, outpatient clinics, etc.). Moreover, as all stakeholders become more focused on the *value* of the interventions they receive, perform, and/or pay for, innovators are well served to actively seek to identify problems and opportunities related to the affordability of care.

Documenting observations

Thoroughly documenting observations is as important as conducting the observations themselves. Innovators often use an **innovation notebook** to capture their observations so that they can later perform follow-up analysis to identifying problems and insights. The sooner documentation is completed (i.e., during or immediately after the observation), the more likely it is that the data captured will be accurate and allow for key facts not to be forgotten or influenced by innovator biases. Moreover, although the innovators are not detailing any inventions during this early stage of the biodesign innovation process, they are establishing a pattern of documentation that may be useful when they eventually seek to protect their work (see 4.1 Intellectual Property Basics). In particular, capturing observations in the early pages of an innovation notebook helps innovators tell a holistic story of how their ideas came to fruition, which can be helpful if the invention is ever contested.

Importantly, while there is no specific or "correct" way to document observations, innovators should be detailed in their notes (see Table 1.2.2) and record only what is seen. For example:

> *The patient was laid flat on the table. The physician's assistant sterilized the groin area. Then, the doctor tried to gain vascular access through the groin. This took multiple attempts. The doctor mentioned that this was because the vessels were deep and nonpalpable. The patient seemed to experience pain each time the needle was inserted and the physician became increasingly frustrated.*

Ideally, innovators will complete their documentation on an ongoing basis (e.g., at the end of each observation session). In making notes, avoid the temptation to editorialize. Do not begin filtering or classifying information

Table 1.2.1 When conducting observations, innovators should pay special attention to these clues, which may signal opportunities.

The patient	
Pain	Watch patients throughout the cycle of care to identify any points at which they experience any suffering, which may range from mild discomfort to excruciating pain. Sometimes pain is caused by an issue that can be easily corrected (e.g., the patient is under medicated), but in other scenarios a larger problem with the current procedure or device may exist.
Complications	Complications take many forms, ranging from minor incidents that have a limited effect on patients to serious issues that may (in a worst case scenario) result in their death. Anytime a complication is observed, investigate how frequently it occurs and consider if it may be a preventable problem. Pay attention to big incisions, lots of blood, poor healing, and/or infections.
Stress	Stress refers to physical, mental, or emotional strain or tension. Watch patients throughout the cycle of care and seek to determine what aspects of the procedure create anxiety for them. It is also important to watch physicians and other members of the care team to identify when they experience visible stress (and the extent to which the timing or activities correspond to patient stress). Seek to understand what problem(s) might be causing the tension.
Time and convenience	It is not only the physicians' time that matters in a healthcare encounter. As patients exert increasing power as informed consumers (and purchasers) of healthcare, their time and convenience will become more influential factors. Pay attention to how long health encounters take and the time patients must spend away from work (often without pay) as a potentially important need area.
The provider	
Risk	Risk is exposure to the chance of injury or loss. Generally, in their quest to "do no harm," physicians seek to minimize risks when delivering care. If a physician (or other provider) advocates a treatment alternative with higher perceived risk, understand what problems have necessitated the riskier approach.
Malfunction	Whenever a device or other piece of equipment malfunctions, look closely at what caused the problem and how stakeholders respond. Consider the results of the malfunction, including the complications it created and any stress or pain that it caused. And think about whether inadequate training with the device, or a high degree of complexity in using the device, contributed to the malfunction.
Uncertainty	In addition to looking for stress, watch for instances in which a provider is unsure or indecisive about how to proceed. If there is a discussion at this point, listen carefully to identify what the core issue is – why this particular situation is different or particularly challenging. These occurrences may point to problems that have yet to be solved.
Dogma	Dogma refers to settled or established opinions, principles, or beliefs that may or may not represent optimal behavior. If an observer asks why a procedure is performed in a certain way and the provider says, "Because that's how I was trained to do it," or "This is always how it is done," this type of response may be a good indicator that the practice area or procedure may not have been evaluated critically in quite some time.

Table 1.2.1 (*cont.*)

Others in the healthcare system (facility, payer, etc.)	
Inefficiency	Consider the treatment process from the perspectives of the patient, the provider, and the system when seeking to identify problems of inefficiency. For example, in what instances must patients be held overnight while they await test results? Or when is additional staff required to perform only a small part of a procedure? View these issues from the perspective of what a consumer-friendly business outside the healthcare sector would provide to its customers.
Information gaps	The transfer of information and activities from one individual or group to another can be a source of error and stress. Watch particularly for handoffs of information, paying special attention to which parties are involved, why the transfer of information is required, and how much time and energy is needed to complete the transition.
Cost	Cost typically cannot be directly observed. However, innovators can observe certain factors that are drivers of cost, including staffing levels and the skills levels of care providers involved in a procedure, the venue in which it occurs, resource utilization, waste, etc. Watch to understand the role that each participant plays and how the setting and other resources contribute (or not) to the effectiveness of the work being performed. (See the section "Value Exploration" for a more detailed treatment of this topic.)

at this point. And, do not risk trying to interpret information before adequate data is collected. Stay focused on capturing raw data for analysis and interpretation at a later date. (More information about documentation is provided in chapter 4.1.)

Table 1.2.2 The following types of information should be routinely recorded as part of the observation process.

Documentation guidelines
Date, time, and place of observation.
Who was present (name of doctor, number of nurses and other staff members by type, etc.).
Specific facts, numbers, details of what happens at the site.
Sensory impressions: sights, sounds, textures, smells.
Personal responses to the fact of recording field notes (i.e., did someone comment when this particular effect was noted?).
Specific words, phrases, summaries of conversations, and insider language.
Timing of various steps of a process, procedure, or interaction; often good to have a stopwatch available.
Questions about people or their behaviors to be investigated later.

If, during observations, innovators get ideas regarding an invention, they should capture them briefly. Then, it is time to leave these ideas alone until later in the biodesign innovation process (3.1 Ideation). More than anything, innovators should not anchor on any particular solution until more work has been done to understand the real problem – or need – that must be addressed.

A note on ethics and observations

When scheduling and performing observations, it is essential to remain professional at all times and respectful of the approach/limitations of key contacts. People seek medical care due to illness and, therefore, the medical environment is fraught with fear of the unknown and the possibility of impairment or death. Patients and families are fragile during these periods, and providers are ethically obligated to provide them with a safe, respectful environment when delivering care. For these reasons, innovators must remain sensitive to privacy-related issues while working in the medical environment and also the boundaries that providers and healthcare facilities may put into place to protect their patients.

For instance, under the Privacy Rule set forth by the Health Insurance Portability and Accountability Act

(**HIPAA**), patients are provided with comprehensive federal protection for the privacy of their personal health information.[7] This rule, which took effect in 2003, establishes regulations for the use and disclosure of an individual's protected health information (**PHI**) and has resulted in a climate of caution with respect to sharing patient information, including granting admission to observers in the clinical environment. Any individual seeking to perform observations that involve patients and/or patient data should have a thorough understanding of HIPAA regulations and demonstrate sensitivity to the healthcare provider's constraints and limitations under the law. Most facilities and providers require an observer to become HIPAA certified, which is accomplished through a several-hour long training session. Others may request that the observer get written patient consent. As a rule, innovators should be responsive and resourceful in responding to these requests in an effort to increase their likelihood of gaining permission to conduct observations. When in doubt, they should always seek guidance before entering a patient care environment.

Remember that it is a privilege for an innovator to gain access to a healthcare team and patients to conduct observations. The people on the healthcare team are providing real medical care to patients in need during observations. As a result, the innovator's purpose or agenda must always be secondary to allowing the normal pace and manner of healthcare delivery to occur. The innovator must gauge where and when it is appropriate to be present and ask questions. This can be determined by talking with the healthcare team during more informal, less critical periods to gain a better understanding of the team's expectations of the innovator during observations.

Interviews

Once a critical mass of observations have been conducted and documented, innovators can begin organizing and reviewing their data to begin thinking about interesting problems and related insights. In doing so, they should be looking for data points that are particularly memorable or thought-provoking. If working in a team, one way to accomplish this is to do a "story share-and-capture." Ask each member of the group to explain what stood out most about all the things they saw and heard during their fieldwork. Even if all team members were present during the same observations, different problems and insights are sure to emerge from their varying points of view. By listening and probing for more information, team members can draw out more nuance and meaning from the experience than they may have initially realized, which starts the synthesis process. Capture each headline, quote, surprise, or other interesting bits of information on sticky notes somewhere the team can continue to reflect on the information.[8] Over time, innovators can prioritize what has been learned and identify the most compelling problem/insight to pursue. Importantly, though, innovators should seek to synthesize their findings rather than accepting one team member's view over another's. In particular, innovators should be careful not to place more value on the observations of team members with medical training over those from other backgrounds. They should also watch out for information that is incomplete, contradictory, or confusing. These issues may signal the need for additional observations as well as interviews to clarify what is really going on.

Interviews are an essential part of needs exploration, but this activity comes with a few potential pitfalls that are worth noting. In particular, what people *say* about who, what, when, where, how, and why they do something can be somewhat misleading. As Thomas Fogarty, inventor of the embolectomy balloon catheter, as well as dozens of other medtech devices, said:[9]

> *Innovators tend to go out and ask doctors what they want rather than observe what they need. When you talk to physicians, as well as others involved in the delivery of care, you've got to learn the difference between what they say, what they want, what they'll pay for, and what they actually do.*

For this reason, innovators should not rely on interviews in isolation of observations. Instead, they should think about the two techniques as working best in combination.

To prepare for interviews, innovators should go back to their research and the questions they outlined, then update and modify them based on what has been learned through observations. Then they should prepare a unique interview guide for each of the specific people they will be talking with, making sure it includes an appropriate number of questions for the allotted time,

as well as those that are best aligned with the perspectives and expertise of the interviewee.

When conducting the actual interviews, keep these guidelines in mind:[10]

- **Ask why.** Even if they think they know the answer, innovators should ask people why they do or say things as the answers can sometime be surprising. Let a conversation started from a single question go on as long as it needs to.
- **Never say "usually" when asking a question.** Instead, ask about a specific instance or occurrence, such as "tell me about the last time you _____."
- **Encourage stories.** Whether or not the stories people tell are true, they reveal how they think about the world.
- **Look for inconsistencies.** Again, what people say and what they do can be different. Watch for these inconsistencies as they can often hide interesting insights.
- **Pay attention to nonverbal cues.** Be aware of body language and emotions.
- **Do not be afraid of silence.** Interviewers often feel the need to ask another question when there is a pause. If innovators allow for silence, a person can reflect on what they've just said and may reveal something deeper.
- **Do not suggest answers to questions.** Even if interviewees pause before answering, don't help them by suggesting an answer. This can unintentionally get people to say things that agree with your expectations.
- **Avoid binary questions.** Binary questions can be answered in a word; you want to host a conversation built upon stories.
- **Be prepared to document.** Always interview in pairs or use a voice recorder. It is nearly impossible to properly engage a **user** and take detailed notes at the same time.

Knowing when to stop and transition to the next step

The process of exploring needs is inherently unpredictable and inefficient. Innovators may have to watch dozens (or even hundreds) of procedures before any significant issues are revealed. In some cases, even that might not be enough. There are certainly instances of smart people exploring interesting focus areas without uncovering any meaningful needs. This potentially means that there is a mismatch in the fit between the focus area and the innovator. Rather than pursuing one strategy indefinitely, there may be times when one is better served by going back and reevaluating the chosen focus area (see 1.1 Strategic Focus).

Because it is difficult to provide an estimate of how much time innovators should devote to needs exploration, an example may be helpful. In the Stanford Biodesign Fellowship (which usually spans about one year), innovators spend approximately two months doing background research, performing observations, conducting interviews, and validating what they have learned. In general, they commit roughly three weeks of this time to a preliminary round of research, observations, and interviews; they then spend the remaining weeks more deeply exploring particular areas of interest (which frequently involves a return to the clinic for more observation and conversation). After that, the flow of ideas tends to taper off. A sign of this may be that there are fewer and fewer *new* observations or insights and a few others that come up repeatedly. If that is not the case, and the innovators are still searching for problems that they perceive to be clinically important, it may be time to move on to another focus area.

When preparing to take the next step and begin translating problems, opportunities, and outcomes into needs (as outlined in chapter 1.3), be certain to maintain good relationships with the patients, providers, and representatives of the system who have been observed. Once a need statement has been developed and additional research performed, it will be necessary to return to the clinical environment to validate the need before concept generation begins. Having these relationships to leverage in the validation process is extremely helpful.

The following story about a multidisciplinary innovation team at the University of Cincinnati provides an example of how needs exploration can effectively be performed.

FROM THE FIELD UNIVERSITY OF CINCINNATI MEDICAL DEVICE TEAM

Observing problems as part of needs exploration

Mary Beth Privitera, an associate professor of biomedical engineering, is always on the lookout for problems in the medical field. As the co-developer of the University of Cincinnati's Medical Device & Entrepreneurship Program, she is responsible for bringing together students in their senior year from biomedical engineering, industrial design, and the business honors program, dividing them into multidisciplinary teams, and assigning them real-world medical issues to investigate as part of a year-long innovation process. Each academic year, these projects are sponsored by companies and/or physician researchers in the medical device field and guided by experienced faculty from the colleges of design, art, architecture and planning, engineering, medicine, and business.

In the fall of 2006, Privitera was approached by Respironics, a medical device company with a focus on sleep and respiratory solutions, to identify the problems and needs of sleep apnea patients. Obstructive sleep apnea (OSA) is a condition that causes an individual to stop breathing repeatedly during sleep because the airway collapses. The most common symptoms of OSA are loud snoring and restless sleep, but it can also cause headaches, forgetfulness, depression, and anxiety, as well as other mood changes. In severe cases, sleep apnea causes pressure on the heart that can ultimately lead to heart failure or stroke. Approximately one in five Americans suffers at least minor sleep apnea.[11] Although some patients undergo surgical procedures to modify the airway mechanics, most patients opt for a non-invasive solution. Continuous positive airway pressure (CPAP) is a mask-like device worn during sleep, which supplies a constant stream of pressurized air to prevent the airway from collapsing (see Figure 1.2.7).

While CPAP is effective in preventing the symptoms of sleep apnea, many patients find the device uncomfortable and difficult to use. As a result, "Respironics was particularly concerned with patient compliance and promoting a more positive patient experience during device use," recalled Privitera.[12]

FIGURE 1.2.7
A patient with obstructive sleep apnea demonstrates how he wears the CPAP device (courtesy of Mary Beth Privitera and the University of Cincinnati; note that the patient is disguised to protect his privacy).

Privitera assembled a team of biomedical engineers and industrial designers to better understand the problem. Despite the availability of sleep clinics that provide an environment in which a patient's sleep patterns can be carefully monitored, Privitera, along with Respironics and a team of faculty guided the students to interview and observe patients in their homes. "I'm a firm believer that the problems people have don't happen in a lab," she said. While carefully controlled experiments have their place in observing problems, Privitera felt that the student observers would learn more by being able to see how patients interact with their CPAP devices in the environment where they use them. "I always try to send students to the location where the problems really occur," she said, emphasizing that this approach is

consistent with the focus on ethnographic research that she advocates in her courses.[13]

To gain a clinical perspective on the problems associated with non-invasive treatment of sleep apnea, the faculty team suggested that students should also meet with the specialists treating sleep apnea patients in the sleep centers as part of the observation process. To prepare for these interactions, the students researched sleep apnea and acquainted themselves with the current CPAP devices. Privitera highlighted the importance of prior research before beginning to interview doctors: "We don't expect a physician to talk in laymen's terms. I want the student to speak in the language of who they're interviewing, and who they're observing."

The students also developed extensive interview protocols to ensure consistency in the observation and data collection processes. "With multiple people on the team, we needed to do everything we could to achieve consistency across interviews," Privitera said. "The research protocols outlined specific questions they would ask, and then specific activities that they would observe. For example, in patient interviews the team would ask what they liked and disliked about the device, what improvements they would recommend, and how they used the apparatus. They would also observe the patient using the equipment, cleaning it, and performing other common behaviors.

When this background work was done, the next challenge was to identify patients and physicians willing to participate in the observation process. "I'm a firm believer that students need to learn how to make these contacts themselves," explained Privitera. Working with nothing more than a list of sleep centers in the area, the students made "cold calls" to the clinics to schedule appointments and gain access to lists of patients who might be willing to participate.

Reflecting on common pitfalls associated with the observation process, Privitera noted that knowing when to stop observing can be a challenge. "Typically you have enough information when you start to recognize repeat patterns of behavior," she said. "It might be after 12 hours, or it might be after 30 hours, but you have to stop at the point when the same situation repeats itself a couple of times." She also cautioned observers to take their time and let the patients [or physicians] do the talking. In her experience, observers are often eager to volunteer information to show their knowledge. They can also have a tendency to anticipate people's answers or misinterpret a response if it differs from what they are expecting.

As with every needs exploration process, the students on the sleep apnea project identified problems that they did not initially foresee. Through careful observation, it became clear that sleep apnea patients were actually quite diverse in the issues they faced and the extent to which these problems affected their compliance with their recommended treatment regimen. This led the team to develop a series of different "personas" to help differentiate patients and their needs. Privitera explained, "When we put forth our plans for the quarter, we didn't expect to develop the personas, but it happened. We saw different interrelations that led us to these six categories of users, which did not necessarily reflect one person, but were combinations of people that had some of the same sensitivities and were like-minded" (see Figure 1.2.8).

These personas helped the team define much more detailed patient problems, populations, and desired outcomes that varied by segment. For example, the Hipster persona was young, single, socially motivated, and concerned about appearances. To address the specific concerns of this group, a solution would have to be quiet (so as not to disturb roommates), compact and easily camouflaged for communal apartment and/or dorm room living, non-institutional in appearance, and customizable in its fit and style. In contrast, the Metro persona was health conscious, spiritual, concerned with personal fulfillment, and interested in enhanced experiences. The desires of this segment would be driven by a serene user experience and could include criteria such as a built-in sleep mask (to block out light) and integrated audio (for "white noise" or other soothing sounds). The Dude persona had a completely different

FIGURE 1.2.8
The six personas identified by the team: Nomad, Hipster, Metro, Dude, Gramps, and Trucker (courtesy of Mary Beth Privitera and the University of Cincinnati).

perspective. Members of this segment were relatively unhygienic, unconcerned with their appearance, and motivated by convenience above all else. This led to an interest in a disposable contact interface, a rugged and durable device, self-cleaning functionality (or some mechanism that provided automatic feedback when it was time to clean or replace it), and an exceptionally easy user experience.

As the biodesign innovation process progressed, the team used this information to develop individual need statements and, later, specific need criteria for each persona. They presented this information to the company, giving Respironics the opportunity to potentially develop unique solutions for the segments of greatest interest.

A focus on value exploration

A central theme throughout this text is the critical importance of maximizing economic value in developing new medical technologies. A strong value orientation begins during needs exploration. Although delivering a clinical improvement at a reasonable cost has always been a goal for innovators, healthcare stakeholders of all types are placing increased weight on the cost of new products and services in the value equation. Today, it is not unusual to hear investors or companies say that they are only really interested in technologies that can actually *reduce* cost (not "merely" deliver more health at a reasonable cost). This profound shift in emphasis creates a new set of opportunities and challenges for innovators – and a new emphasis for needs exploration. As innovators conduct their observations, they should be actively searching for waste, inefficiency, and other sources of undue costs that can be eliminated. This activity, which can be thought of as "**value exploration**," involves scanning for need areas where costs potentially can be reduced while holding quality/outcomes steady, or even reducing outcomes to a small, acceptable degree.

Some of the target areas outlined in Table 1.2.2 can help innovators identify value-related opportunities.

However, there is a more specific set of practice-based markers or value "signposts" that innovators can observe during their clinical immersion, as shown in Table 1.2.3.

Many of the examples included within this text follow the direction of at least one of these value signposts. The development of coronary angioplasty described earlier in this chapter is a classic example. Angioplasty gradually replaced much of bypass surgery in certain patient populations due to its positive patient outcomes and the improved value it offered through cost reduction. Savings were realized in a number of ways, as summarized in Table 1.2.4.

Value exploration is an even greater priority for innovators working in severely resource-constrained environments. As is the case for all types of needs exploration, it is important for the innovator to have a direct experience of the value environment – as illustrated in the story of a team's experience in India (see next page).

Looking back at the practice-based value signposts, the team in this example was able to significantly reduce the resource use associated with limb immobilization. By making a device that was simple and intuitive to use correctly, they also were able to equip care providers to more effectively perform their work and prevent more highly trained professionals from having to intervene as they sometimes were required to do with more complex splints.

Opportunities for greater value realization can be found in almost any environment. Again referring to the story, the emergency department at Stanford was most likely just as ripe with possibilities for reducing costs; however, the "clues" were more apparent in the Indian setting. The key is to think critically about the **standard of care** and question why activities are undertaken in the prevailing manner. For instance,

Table 1.2.3 These observable value exploration signposts can point innovators to opportunities to reduce the cost of care.

Practice-based value signposts
Potential to keep a patient out of the hospital and/or emergency department.
Potential to change the location of care to a less expensive venue.
Potential to shorten a patient's length of hospital stay.
Potential to reduce the procedure time or resource use for a given intervention.
Potential to shift a procedure or service to a lower-cost provider.
Potential to reduce the number of staff and/or intensity of labor necessary to administer a given intervention.
Potential to diagnose a condition earlier to reduce complications and/or slow/prevent disease progression.

Table 1.2.4 The transition from CABG to angioplasty created economic value for healthcare stakeholders in multiple ways.

Practice-based value signposts	Example of value realized through the shift from CABG surgery to angioplasty
Potential to change the location of care to a less expensive venue.	Procedure moved from the operating room to catheterization suite. Patients discharged home or to ward rather than to the ICU or post-anesthesia recovery unit.
Potential to shorten a patient's length of hospital stay.	Over time, elective angioplasty became primarily an outpatient procedure.
Potential to reduce the procedure time or resource use for a given intervention.	Both resource usage and procedure time were reduced with the elimination of cardiopulmonary bypass.
Potential to reduce the number of staff and/or intensity of labor necessary to administer a given intervention.	Angioplasty is typically performed by a single cardiologist with a nurse and technician assistant, compared to a full surgical team (including multiple OR nurses and a pump perfusionist).

FROM THE FIELD HICARE LIMO

Needs exploration with a focus on value

Darshan Nayak and Pulin Raje were Stanford-India Biodesign fellows when they conducted clinical immersion at the Stanford University Medical Center. The focus area for their fellowship was emergency medicine, and they spent several weeks observing clinical practice in the Stanford emergency room and with its ambulance service looking for unaddressed problems and opportunities. When asked to summarize some of the key take-aways from these observations, Nayak commented. "The settings in which we performed our observations were relatively well-resourced, with highly trained staff members, state-of-the-art equipment, and an abundance of supplies. Everybody seemed to have what they needed."

When Raje and Nayak returned to India, they had another chance to conduct observations in a variety of emergency medicine environments. Through their mentors at the All India Institute of Medical Sciences (AIIMS), they gained access to five different settings: the AIIMS emergency department, the AIIMS trauma center, a local ambulance service, rural district hospitals, and primary care centers. The two men were struck by the differences they observed. In stark contrast to their US experience, ERs in India were overcrowded and severely under-staffed. Nayak recalled, "There could be multiple patients arriving at the ER for treatment every few minutes, with just a small number of doctors responsible for delivering care. It is extremely difficult to triage and treat patients in this scenario, and clear protocols often do not exist or are not followed." Additionally, they found that staff members were often less well-trained. And in most settings, especially outside of tertiary-level urban centers, facilities lacked necessary equipment, supplies, and other resources necessary to provide high-quality care.

Raje explained how fragmentation among the players in emergency medicine further contributed to suboptimal care: "Unlike the US where everyone knows to call 911 and there is an unbroken chain of care between the ambulance and the ER, in India the patient's first contact after a trauma maybe the rickshaw puller who brings him to the hospital." One other factor complicating the landscape is that health insurance is practically non-existent, with most Indian patients paying out of pocket for medical procedures and devices. In this environment, both the patients and the providers are extremely cost conscious. According to Nayak, everyone is thinking, "Is this really needed or not?"

Nayak stressed that the system in India, though under-resourced, was not "bad," but "simply different." "We had to set aside what we saw at Stanford and start with a blank slate, rather than comparing what we saw here to what was observed in a different setting," added Raje. Importantly, they believed the environment was rich with opportunities to add value by improving care quality while bringing down costs.

One problem that caught the team's attention stemmed from multiple observations. Nayak and Raje first saw a patient come in to the district level hospital in Vallabhgarh, outside New Delhi, after a road accident. "He was taken off the rickshaw and carried in by three people, who were not hospital staff. He had a broken limb, which had not been supported or immobilized since the accident. The first responder in the hospital was a ward boy, followed by a junior resident who checked the patient's airway and circulation," Raje described. Since the hospital did not have an orthopedic specialist, the patient was informed that he could not be treated at this facility and that he would have to get himself to a different center. This time, to help immobilize the injured leg during transport, hospital staff strapped a wooden plank to his leg using gauze and bandages. Later, at the AIIMS trauma center, a tertiary-level facility where patients like the man with the leg injury are often referred, Nayak and Raje observed the same problem from a different point of view. Patients routinely arrived at the trauma center with dangling limbs or make-shift splints attached to their broken limbs. A relatively small percentage of patients arrived on an ambulance with a proper splint. However, the team noticed that these

devices were often not used correctly. Subsequent investigation revealed that many care providers in emergency medicine did not understand basic concepts of limb immobilization and found available splints difficult to fit to injured patients.

Nayak and Raje spoke with ambulance attendants to get their point of view on the issue of limb immobilization. Through these discussions, they uncovered important information. As Nayak explained, "Ambulance services are accountable for the equipment they own. Even though they have access to existing splint technologies, the attendants often won't deploy them because of the high cost associated with the splint." The team also observed scenarios in which an ambulance attendant would fit the patient with a splint during transport but then retrieve the device before leaving the patient at the hospital. Unfortunately, the removal of the splint often aggravated the patient's injury. After further investigation, Nayak and Raje discovered that many hospitals and primary care centers were similarly reluctant to part with the splints they had in inventory.

Sensing that they had hit on an area where they could add value for patients and providers alike, the team became interested in improving limb immobilization (problem) in trauma patients (population) to prevent the aggravation of their wounds during transfer (outcome). "The key insight was that the splint had to be affordable enough to give away, while also being effective and easy-to-use," said Raje. To gain a better understanding of what would be required to change existing patterns of behavior, Nayak and Raje again spoke with ambulance attendants, as well as procurement teams at ambulance companies. "We learned that available leg splints cost about Rs. 1200 (approximately US$20) and that an ambulance attendant would try to use one device three to five times before discarding it or leaving it with a patient," Raje stated. This information indicated that if they could devise a better solution that cost roughly Rs. 300 (US$5), they would potentially be able to stimulate adoption.

Raje and Nayak went on to develop a new lower-limb splint that is effective, easy to use, and inexpensive enough for providers to leave with patients after transfer. The device is manufactured using a special pressed paper, coated with protective plastic layer. It is longitudinally reinforced to provide excellent structural support for immobilizing the limb. The device conforms to multiple limb sizes, as well as both the left and right limbs, and it is fitted to the leg using a series of simple Velcro straps (see Figure 1.2.9).

The composition of the splint is entirely radiolucent, so the device does not have to be removed during X-ray imaging (preventing further exacerbation of the wound). Finally, the device is easily stacked for space-efficient storage in an ambulance or ER setting, and it is disposable after use. In 2013, they licensed the technology to a major Indian manufacturing company called HLL Lifecare Limited. Now available in the market under the brand name HiCARE LIMO, the manufacturer hoped to capture market share based on the value delivered by the innovative and affordable solution.

Reflecting on the important role of observations and needs exploration in their experience, Nayak and Raje emphasized that it is critical to view an interesting problem from multiple points of view. "You don't want to only think about problems from only the clinical perspective," noted Raje. By looking beyond care delivery processes to the purchasing and cost factors that drive then, the team was able to identify a meaningful need. They also noted that sometimes significant value can be generated by addressing "a simple problem that requires a simple solution."

FIGURE 1.2.9
A patient using the HiCARE LIMO splint as part of a clinical trial (courtesy of Pulin Raje, Darshan Nayak, and Stanford-India Biodesign).

when observing a doctor diagnosing a patient in an office visit, watch for the presence (or absence) of factors that make that face-to-face interaction essential. Later, when it is time to begin thinking about possible solutions, innovators can question whether the in-office diagnosis could potentially be replaced with a less expensive encounter – or perhaps some other form of communication.

Beyond these practice-based value signposts, innovators should be aware of a second set of value indicators that are emerging in the medtech field (see Table 1.2.5). These budget-based signposts are not found by direct observation in the clinical setting, but instead are identified as part of the background research that innovators complete in preparation for clinical immersion, as well as the interviews they conduct to clarify potential problems and opportunities. Given the economic nature of these signposts and the fact that relevant information can sometimes be buried deep within facility budgets and/or institutional documentation and reports, identifying budget-based signposts can require a certain level of in-depth investigation. Contacts within the finance departments of hospitals and other care facilities can be useful in this exercise.

By exploring these signposts through different forms of inquiry, innovators will potentially uncover additional problems which, in turn, may be worthy of direct observation. For example, a report by the US Institute of Medicine found that the single greatest driver of geographic variation in Medicare spending is post-acute care expenditures (i.e., the use of home health services, skilled nursing facilities, rehabilitation facilities, long-term care hospitals, and hospices).[14] This is a budget signpost, meaning that innovators may discover opportunities to improve economic value by focusing on post-acute care (for example, care for patients following myocardial infarction, congestive heart failure, or hip fracture). To begin to dig into the issues, innovators could conduct observations in facilities that fall above the average spending level, as well as those that fall below it. They should develop an understanding of the major drivers of cost at these facilities and understand what accounts for key differences. Importantly, they should also understand how evolving policies from Medicare or other payers may impact the way caregivers and facilities are reimbursed for this kind of care.[15]

Table 1.2.5 Budget-based value signposts may not be directly observable, but they can point innovators to areas that are ripe for innovation and where observations can be performed.

Budget-based value signposts
Diagnostics, treatments, or procedures that are outliers in terms of their cost-effectiveness.
Diagnostics, treatments, or procedures that represent big line items in health system, payer, facility, or physician practice budgets.
Diagnostics, treatments, or procedures that are routinely unprofitable.
Diagnostics, treatments, or procedures that are significantly less expensive in other geographies.
Diagnostics, treatments, or procedures in which technology is a high percentage of the total cost.
Conditions for which the life-long cost of care is especially high.
Areas where providers are challenges to achieve quality measures linked to shared savings goals for Accountable Care Organization (see chapter 2.3 for an introduction to ACOs).
"Never events" – complications or outcomes where a reimbursement penalty has been (or will be) implemented.

Another example of how a budget-based signpost can lead to an interesting need is found in David Green's experience conducting needs exploration in India. When he was working with the SEVA Foundation, whose mission is to prevent blindness and restore sight worldwide, he became intrigued by the work of Dr. Govindappa Venkataswamy. "Dr. V," as he is known, mortgaged his home to establish the Aravind Eye Hospital and provide free and low-cost cataract surgery to Indians who otherwise would not be able to afford treatment. The hospital performed an impressive 5,000 surgeries in its first year.[16] However, studying the model, Green realized that the number of surgeries Dr. V could complete was constrained by the high cost of the replacement lenses

required for each patient. At up to $150 per pair from US manufacturers,[17] Aravind was limited in the total units it could purchase without jeopardizing the sustainability of its model. The value signpost here was the fact that the technology accounted for such a high proportion of the total cost for the episode of care. In response, Green invented a new manufacturing solution that allowed him to produce comparable lenses for just $10 per pair,[18] significantly reducing the cost of the technology as a percentage of the overall procedure. Due in part to Green's work, the cost of cataract care in an Aravind center is now sustainably provided at a fraction of the cost of surgery in a Western facility. This striking geographic variation (for outcomes that do not appear to be substantially compromised) could now potentially signal another round of innovation for improved value realization in developed markets.

New opportunities related to the budget-based value signpost associated with **reimbursement** penalties are also gaining increased attention in the US. In fiscal year 2013, the Centers for Medicare and Medicaid Services (CMS) implemented its Hospital Readmissions Reductions Program. In the first year, this program withheld up to one percent of regular reimbursements for hospitals that exceed pre-defined patient readmission rates within 30 days of discharge for three medical conditions: heart attack, heart failure, and pneumonia. At one percent, these penalties amounted to $280 million. However, at the time of this writing, the maximum penalty was scheduled to increase and the program was expected to expanded to include readmissions for other medical conditions.[19] Innovators like Xiangwen Zang, founder of AirCare, are capitalizing on these penalties (and the demand they create among healthcare stakeholders seeking to avoid them) by developing technologies and systems to improve patient monitoring post-discharge and facilitate more targeted interventions that keep patients healthy and out of the hospital. Zang described his needs exploration process in an interview: "I went about looking at how to fix the healthcare industry, and realized readmissions is such a big issue for hospital systems – it's one of the top priorities for any hospital executive, and that's because the readmissions penalty alone has the potential to wipe out a third of hospitals' profits."[20] The solution that his company ultimately devised allows patients to fill out a checklist of symptoms and indicate whether they have taken their medication as prescribed using an Internet and tablet-based application. Nurses can review this information without having to place outbound calls to the patients, which saves them significant time. The technology also provides them with a list of at-risk patients so that they receive timely follow up. To date, the company is primarily targeting the reduction of heart-failure readmission rates.[21]

Global considerations in exploring needs

The fundamental aspects of needs exploration are the same in any geographic location. However, there are some important considerations to take into account when innovators are not originally from the region in which they intend to work. Before conducting any observations or interviews, it is imperative to understand the dominant cultural norms in the environment where they will take place. By adapting their approach based on relevant customs, innovators can dramatically increase their effectiveness. For example, something as simple as knowing how to dress appropriately and the level of formality to use when interacting with physicians, nurses, patients, and other healthcare stakeholders can help make an interview or a day of clinical immersion much more successful and productive.

It is also important to take factors unique to the geography into account when planning research, observations, and interviews. One graduate from the Stanford-India Biodesign Innovation Fellowship, Ritu Kamal, shared her experience conducting needs exploration in India to highlight the types of issues that should be considered. "Healthcare facilities across India are incredibly heterogeneous, so it's critical to conduct your clinical immersions at a wide variety of sites in order to fully observe clinical practice," she said. Healthcare delivery varies by state and region, but also between tertiary, secondary, and primary care facilities, public and private institutions, and healthcare providers in rural and urban

settings. For instance, in leading tertiary care facilities in urban areas, such as the Narayana Hrudayalaya hospitals and clinics, innovators encounter state-of-the-art technology and healthcare professionals whose training is on par with physicians in the US and Europe. At the other end of the spectrum, primary care clinics in more remote and poorer locations might depend on a single healthcare provider (who may or may not be a licensed doctor) doing his/her best to care for community members with little more than a stethoscope and a blood pressure cuff in the way of devices (pharmaceutical products are much more widely available than medical technologies). Moreover, while clear standards of care exist in higher-end facilities, they may be lacking or absent in public and rural settings, making it significantly more difficult for innovators to confidently discern routine procedures and processes. The cost of care can also vary dramatically, along with the ability of patients to pay for diagnosis and treatment. These extreme differences contribute to dramatic inconsistencies from setting to setting when it comes to the problems being experienced, the populations they affect, and the improved outcomes that are needed.

Mark Bruzzi, director of the BioInnovate medical device training program at the National University of Ireland, underscored a similar theme when innovators are working in Europe. It is important, he explained, to know enough about how healthcare is delivered in the target geography to pursue the right settings for observations. For instance, while innovators sometimes overlook primary health settings for clinical observations in the US, that would be a mistake in parts of Europe. "In Ireland and the UK, primary care physicians often act as the gatekeepers to hospital and specialty services. It's often not possible to self-refer to specialists, so these physicians play an important role in directing treatment. And their decisions have a tremendous impact on how the patient is managed from presentation through post-operative care," he said.

Another issue raised by Kamal had to do with access. "In India, there are very few rules governing things like patient privacy, so if a physician agrees to take you around to perform observations you can basically go anywhere and see everything," she commented. This scenario allows for tremendous learning during needs exploration, but requires innovators to act responsibly, self-monitoring to ensure that patients are treated with dignity and respect and that sensitive information is treated confidentially. "You also have to be careful that people don't mistake you for a doctor," Kamal added. "Doctors are so revered and their time is so difficult to get that people may approach anyone in a lab coat or with an identification badge to ask for their medical advice." If this happens, she advised, innovators should quickly redirect the patient to someone in the facility who is authorized to help.

In Ireland, gaining access to clinical settings to perform observations also relies heavily on doctors. As Bruzzi explained, "With respect to the Irish system, people are very open to innovators going in and observing, but it's very much led by the clinician." However, he added, "I would emphasize that clinical nurse managers have significant power and influence regarding what goes on in the wards and the operating theaters, so getting to know these individuals can be very useful."

Other stakeholders may play unexpected roles in unfamiliar regions. Again using India as an example, Kamal said, "Patients often travel long distances to get to the hospital or clinic, and it's not unusual for them to bring their entire family with them. So you'll see big groups of family members camped out in waiting areas or at the bedside. And they're much more involved in helping deliver care at the hospital and in the home." Accordingly, in some settings, innovators may be well served to consider families as a key stakeholder group and observe their involvement in the delivery of patient care. However, cautioned Kamal, "Be sure to ask permission of the physician who's hosting you before directly approaching a patient's family. It may seem strange to have to worry about this since observers are generally granted such broad access, but there's something different about engaging with family members and you need to be sure it's acceptable to your host."

A final issue worth noting has to do with understanding how medical technologies are regarded in different

environments. Innovators should not assume that stakeholders are receptive or comfortable with devices, or that their presence necessarily corresponds to their use. In some low-resource settings, innovators will be struck by the lack of devices, or that devices manufactured for a single-use are being sterilized and re-used on different patients. In other locations, they may discover that devices have been made available to address important needs, but they are not being used appropriately (or at all). For instance, when team members at D-Rev became interested in the problem of infant jaundice, they initiated a detailed assessment of the phototherapy landscapes in India and Nigeria. From that work, D-Rev confirmed that jaundice was a challenge in rural areas, where equipment to treat the condition was virtually non-existent. But the team discovered that the situation was also problematic in urban hospitals and clinics in those countries. In these settings, phototherapy equipment was typically available, but a full 90 percent of the devices evaluated by D-Rev (in collaboration with the Stanford School of Medicine) were ineffective. The vast majority of solutions designed for these low-resource settings failed to meet international quality standards and offered suboptimal performance. Some healthcare providers even relied on homemade solutions that were not only unproductive but dangerous to the infants that they were intended to treat. Another factor that rendered phototherapy solutions ineffective in these settings was the cost to operate and maintain them. In D-Rev's research, one out of three phototherapy devices had at least one bulb missing or burned out, with many healthcare providers unable to reliably procure or afford replacements.[22]

Bruzzi provided a contrast to this scenario in describing the environment in Ireland. "In general," he said, "the vast majority of doctors are very interested in new innovations and in engaging with innovators. They're eager for new and better ways of doing things and open to trying new technologies." The point is that stakeholder receptivity to device-based tests and treatments can vary significantly, as can the skill levels of healthcare providers to use complex technology. Issues such as these must be explored when conducting a clinical immersion.

Online Resources

Visit www.ebiodesign.org/1.2 for more content, including:

Activities and links for "Getting Started"

- Perform background research
- Set up observations
- Conduct observations
- Document observations
- Refine problems/insights through interviews

Videos on needs exploration

CREDITS

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NOTES

1 In a sternotomy, a vertical incision is made along the sternum and it is cracked open to access the heart or lungs during surgery.

2 All cartoons by Josh Makower, unless otherwise cited.

3 "Understand Mixtape: Discovering Insights Via Human Behavior," Hasso Plattner Institute of Design, Stanford University, 2012, http://dschool.stanford.edu/wp-content/uploads/2012/02/understand-mixtape-v8.pdf (September 26, 2013).

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

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