2.3 Stakeholder Analysis

INTRODUCTION

A clinical need often begins with patients, their symptoms, and an underlying medical problem. But that is just the tip of the iceberg. Think about the physician and the nurses involved in the patient's care. Also, somewhere in the back office, there is a facility manager crunching numbers to decide whether or not to invest in the necessary equipment and infrastructure to support the patient's treatment. And then, perhaps a thousand miles away, is an insurance administrator or government official who decides whether or not to pay for the care that has been delivered. All of these are stakeholders – individuals and groups who are touched by the need and have a stake in how it is ultimately addressed.

OBJECTIVES

- Learn to identify all influential stakeholders.
- Understand each stakeholder's perception of the medical need (initially) and anticipate their reaction to a solution concept (eventually).
- Recognize which stakeholders are in conflict and/or alignment with one another and for what reasons.
- Recognize which stakeholders are the decision makers, who will be most critical to determining whether the solution to a given need is ultimately adopted.

In stakeholder analysis, the innovator systematically examines the direct and indirect interactions of all parties involved in financing and delivering care to the patient. The purpose of this analysis is to understand how these entities are affected by the need and to determine their requirements (or their stake) in how it is addressed. Stakeholders have different perspectives – for instance, some will benefit if the need is addressed, but others may be adversely affected. Uncovering these points-of-view and any potential conflicts is critical to shaping and refining the need statement and preliminary need criteria that have been identified. It also allows the innovator to anticipate resistance, as well as to define and prioritize the requirements that will shape the eventual solution to maximize its chance of adoption among the most important and influential stakeholders – often referred to as decision makers. For these reasons, stakeholder analysis should begin early in the biodesign innovation process, while needs are being identified and assessed. It can then be expanded as more information becomes known and progress is made toward a solution.

This is the first of two chapters focused on stakeholders. The output from the basic stakeholder analysis described here informs 5.7 Marketing and Stakeholder Strategy. The chapter is also closely linked to 2.4 Market Analysis. Among other topics, market analysis focuses on the assessment of competitors (i.e., businesses offering competing products) and other suppliers of products that address a given need. Competitors

obviously have an important stake in the need and could, as a result, technically be considered stakeholders. However, because they will always resist new solutions proposed by competing innovators, they are excluded from traditional stakeholder analysis and considered among the other market forces that can create barriers to the adoption of a new idea.

See ebiodesign.org for featured videos on stakeholder analysis.

STAKEHOLDER ANALYSIS FUNDAMENTALS

The need for **stakeholder** analysis is based on the multifaceted nature of healthcare systems and the fact that multiple groups and individuals – not just a single customer – drive the adoption of health-related products and services. Richard Stack, physician, inventor and investor, succinctly summarized the complex nature of medical innovation and reinforced the need for in-depth stakeholder analysis:[1]

> *You have to know who your customer is. Certainly you have to know what the patient wants . . .. But the person actually buying the product, you have to know that psychology very, very well.*

One of the early steps in performing a stakeholder analysis is to identify the many different parties involved in delivering and financing care related to the **need**.

There are two primary methods for identifying stakeholders in the medical field, which should be performed in conjunction. The first focuses on stakeholders involved in the **cycle of care** – patient diagnosis and the delivery of treatment. With this approach, innovators study how patients move through their healthcare experience, making note of all of the different players, their roles, and interests. The second method is concerned with stakeholders involved in financing patient care. In this analysis, the innovator follows the **flow of money** from one entity to the next as charges and payments are made. The results from these two methods can be triangulated by referring back to the observations made during needs exploration (see chapter 1.2), as well as the data collected as part of the disease state and existing solutions analysis (see chapters 2.1 and 2.2).

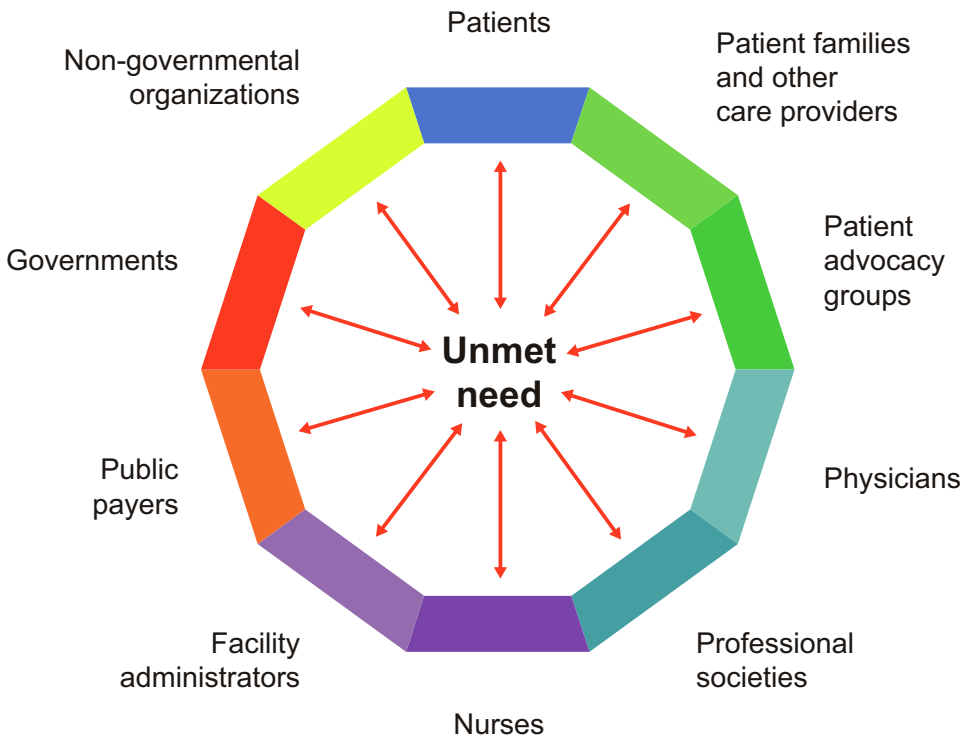

FIGURE 2.3.1
All stakeholders have the capacity to embrace or resist new medical technologies. While some exert more influence than others, all should be considered, particularly in a preliminary stakeholder analysis.

Figure 2.3.1 provides a detailed representation of the many different stakeholders with a potential interest in a new medical technology to address a defined need.

Cycle of care analysis

Cycle of care analysis is based on how patients interact with the medical system. The focus of this form of assessment is specifically on understanding the patient's diagnosis and treatment (not yet worrying about payments). Innovators should investigate who diagnoses the condition, who provides preliminary treatment, who provides next-level treatment if the condition progresses, what parties are involved in the ongoing management of the disease, and the role that patients themselves play in their care. It is especially important to pay attention to what different medical specialties are involved in this cycle, what referral patterns exist, and whether there is any tension as the patient moves between practice areas. The Working Example illustrates the cycle of care for end-stage renal disease.

Working Example

The cycle of care for end-stage renal disease

End-stage renal disease (ESRD) is characterized by chronic failure of the kidneys. The traditional cycle of care for this condition resembles the flow outlined in Figure 2.3.2. It starts with the patient developing certain symptoms that may trigger a visit to a primary care physician (PCP) or, in extreme cases, to the emergency room (ER). In both situations, a series of laboratory tests are performed that will be used by the attending physician to make a diagnosis. When ESRD is confirmed, the patient is referred to a nephrologist (specialist in kidney disease).

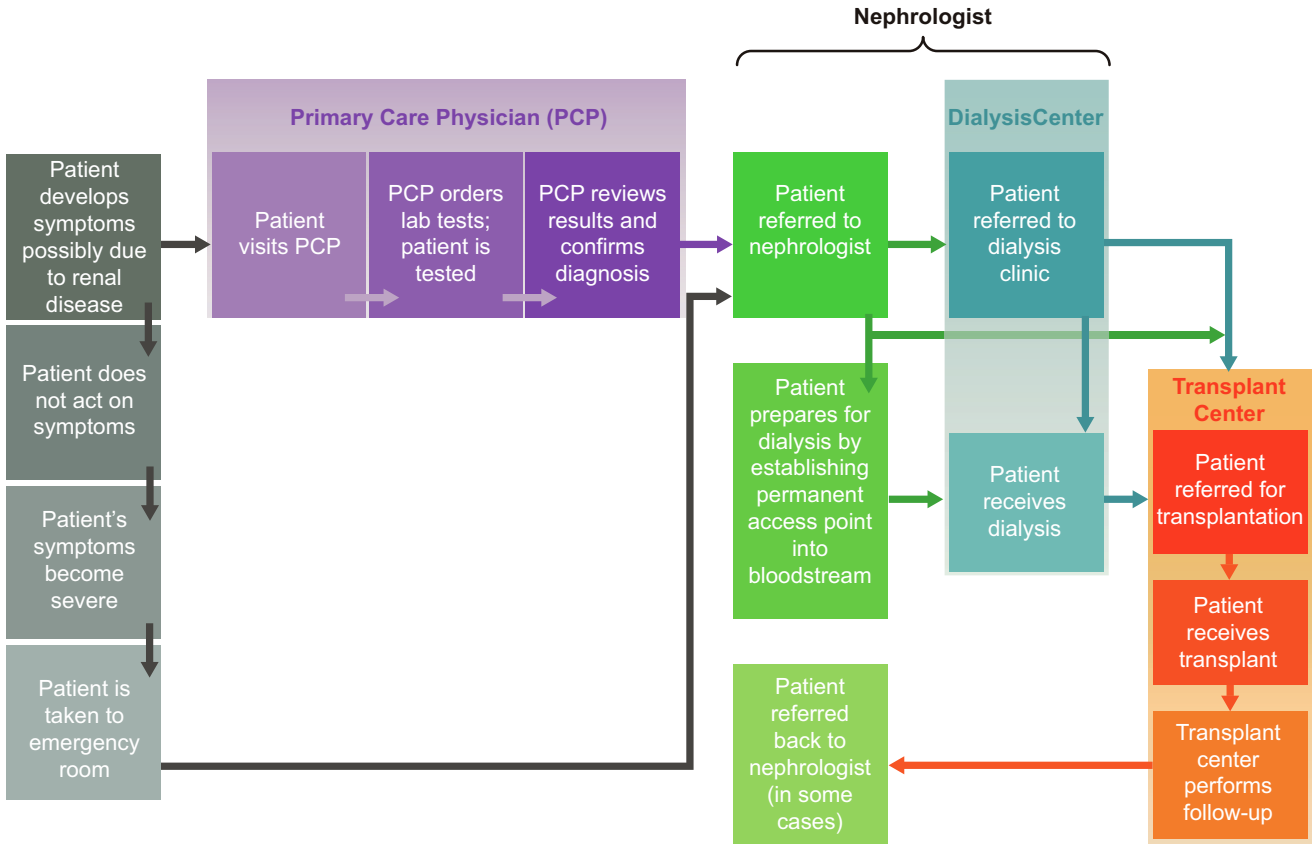

FIGURE 2.3.2

The cycle of care for ESRD can be relatively complex, involving multiple provider and facility types.

The nephrologist evaluates the patient and determines whether dialysis is needed. If so, s/he refers the patient to a dialysis clinic, as well as a vascular surgeon to prepare the patient's access for dialysis. (In dialysis, a patient's blood stream is accessed with a needle through a permanent access point established by a vascular surgeon. The blood flow is diverted through a filter in the dialysis machine to clear the toxins that the failing kidneys cannot eliminate. Dialysis involves three lengthy treatments per week.) Simultaneously, the nephrologist determines whether the patient is a good candidate for a kidney transplant (a surgical procedure in which an ESRD patient receives a new organ from a donor). If so, s/he refers the patient to a transplant center and a transplant surgeon. If the patient receives a transplant, the transplant center is initially involved in follow-up care with the involvement of a transplant nephrologist. Eventually, the patient may be referred back to the original nephrologist for long-term follow-up care.

Once the cycle of care has been mapped, as in the ESRD example, the innovator's objective is to examine who interacts with the patient, the nature of their relationships with the patient, and the duration and timing of the interactions. All of the individuals and groups in the cycle should be considered stakeholders in the process, including the patient. However, innovators should note that each stakeholder has unique needs, requirements, and interests. For example, patients almost certainly have a requirement to get a life-threatening medical condition under control, but may also have an interest in minimizing the effect of the disease on their **quality of life**. While other stakeholders involved in the delivery of care may share the first objective, they may not be as concerned with the second since it does not affect them in the same way and they routinely deal with patients who have made the life-changing move to dialysis.

Other stakeholders from the ESRD example include multiple clinical specialists (primary care physician, emergency care physician, nephrologist, transplant nephrologist, vascular surgeon, and transplant surgeon), different nursing specialties, and numerous facility types (doctor's office, ER, dialysis clinic, and transplant hospital). Not all of these stakeholders will be intimately involved with every need considered in the ESRD cycle of care. However, by using a method for identifying everyone with even a remote stake in a need (and how it is solved) innovators ensure that no one is overlooked.

In conducting this analysis, it is important to be aware that referral patterns in the cycle of care can be a source of potential conflicts between stakeholders, especially in cases where multiple specialties are involved. In the ESRD example, nephrologists lose their patients at the point when transplantation occurs, with only some patients referred back to them for long-term care (the remaining patients are cared for by the transplant center). A similar conflict exists between dialysis centers and transplant centers due to the loss of revenues to dialysis providers after patients receive transplants. So, it follows that if a new breakthrough becomes available that allows more patients to receive transplants, nephrologists and dialysis clinics might mount some resistance since the change could potentially lead to a substantial loss in their patient-care revenue.

This particular point of view is not entirely speculative. A study published in the *New England Journal of Medicine* confirmed that the likelihood of being placed on the waiting list for a renal transplant was lower for patients treated at for-profit dialysis centers than non-profit ones, which led to increased mortality in this patient group.[2] While this study and the previous discussion appears to suggest that healthcare providers and physicians may not always have the best interests of their patients in mind, the real message in the story is more nuanced. In the medical field, choosing the proper course of treatment for each patient requires the careful balance of the risks and benefits associated with the treatment options. Yet, this equation can be ambiguous and perspectives can vary from provider to provider. Transplantation, for example, may be perceived by some providers to be too risky for certain patients (based on their age, coexisting conditions, or other factors). The equation is further complicated when a provider has a financial incentive that makes one course of treatment preferable to another (dialysis versus transplantation). These situations create conflicts of interest that can affect the likelihood of

adoption of a particular treatment for certain high-risk patients. Such resistance can sometimes be overcome by understanding and addressing the motivations and concerns of the involved stakeholders. For instance, if ESRD patients are explicitly referred back to their initial nephrologists for ongoing care after transplantation (even though the transplant centers are capable of administering such services), then this may reduce resistance to high-risk transplantation among nephrologists and stimulate more transplant referrals.

To succeed in global markets, innovators need to recognize that the results of a stakeholder analysis will differ considerably depending on the country where treatment occurs. Importantly, they should not assume that a US-based stakeholder analysis will be adequate for understanding other markets. Detailed analysis of the countries of interest must be performed to ensure that subtle (and not so subtle) distinctions in stakeholder attitudes, preferences, and perceptions are understood. The principles and approach to the analysis will be the same as those described within this chapter, but the output will likely be different. For instance, the cycle of care for a group of patients would be remarkably different in China than in the US, Europe, or other Western nations. Services that are routinely part of healthcare delivery in one country may be considered non-health-related in another. For example, a heart failure patient might be prescribed ACE inhibitors in the US (to control high blood pressure), but not in some Southern European nations where such treatments are not as widely used. In China, treatments could differ even further, with a patient receiving traditional Chinese medicines in lieu of Western solutions.

In India, vast disparities in the quality and availability of care characterize the healthcare system and affect the stakeholder experience. State-of-the-art Indian secondary and tertiary care institutions attract both domestic patients who can afford their world-class services and approximately 350,000 medical tourists each year.[3] However, healthcare facilities without adequate supplies, staff, or capacity to provide affordable care are responsible for serving a large majority of the population. A significant percentage of the existing infrastructure, both public and private, is unreliable.[4] In rural settings, where the penetration of healthcare facilities has been low, patients often resort to traditional healers for healthcare.[5]

In China, the Ministry of Health administers public hospitals. Additionally, this organization cooperates with local governments to oversee the urban healthcare system, which traditionally has been hospital based. Hospitals are classified into Tier 1, 2, or 3, each with three sub-levels: A, B, and C.[6] The most sophisticated and well-equipped hospitals are awarded the highest rating: 3A. Tier 2 hospitals are usually found at the district level; and Tier 1 hospitals are small, community-based centers.[7] Outpatient services attached to these hospitals are the first point of care for most patients, for even minor ailments, which creates major bottlenecks in the system. Long lines and overcrowded waiting rooms are common.[8]

As this basic information suggests, each geography has unique factors that directly affect healthcare delivery and the cycle of care for any given condition. Such factors can introduce a diversity of stakeholders into the equation (some of which US-based innovators may not initially anticipate). They also underscore the importance of researching the cycle of care across multiple settings to ensure that stakeholder attitudes, preferences, and perceptions are comprehensively understood.

Flow of money analysis

A flow of money analysis identifies stakeholders who directly or indirectly finance the cycle of care. It focuses on who pays for the services and procedures performed in diagnosis and treatment of patients. In the process, it highlights all of the entities with a direct financial stake related to the need, including the patients and their families. Often this analysis is used by innovators to identify those stakeholders who are most likely to be decision makers.

When it comes to analyzing stakeholders in the flow of money, the simplest model is one in which the patient is also the one who pays for the procedure. This "**out-of-pocket**" payment structure can be found in every country in the world to varying degrees. Alternatively, payments can be made on the patient's behalf through public or private insurance programs (see 4.3

Reimbursement Basics for more information). The National Health Service (NHS) in the UK and Medicare in the US [administered by the Centers for Medicare and Medicaid Services (**CMS**)] are both examples of public health insurance programs financed by taxpayer money. Examples of private health insurers in the US include companies such as Blue Cross Blue Shield (**BCBS**), United Healthcare, and Aetna. Such companies provide insurance on behalf of their subscribers, who pay a premium in exchange for health insurance **coverage**. Many, but not all, procedures delivered to patients by physicians are reimbursed under these plans. However, in some countries with **third-party payer** systems, there is a strong trend toward shifting the burden of payment to the patient through deductibles and exclusions for elective procedures. Common exclusions include aesthetics (within dermatology) and certain reconstructive surgery procedures (within plastic surgery and dentistry), which are generally not covered unless they are deemed medically necessary. Otherwise, patients are required to foot the bill for these "elective" procedures.

The Working Example outlines some key points about how the healthcare financing systems works in the US.

Working Example
Overview of the US healthcare financing system

The US healthcare financing system is undeniably complex, involving both public and private **payers**. A simplified view of the stakeholders involved in financing the US healthcare system and their interactions with the stakeholders delivering and receiving care is depicted in Figure 2.3.3.

The US has two public insurance programs (Medicare for the elderly and disabled, and Medicaid for the poor), as well as a multitude of private insurers. Medicare and Medicaid are funded by individual and corporate taxpayer money and administered by the Centers for Medicare and Medicaid Services (CMS), with a significant state involvement for Medicaid. In many instances, both

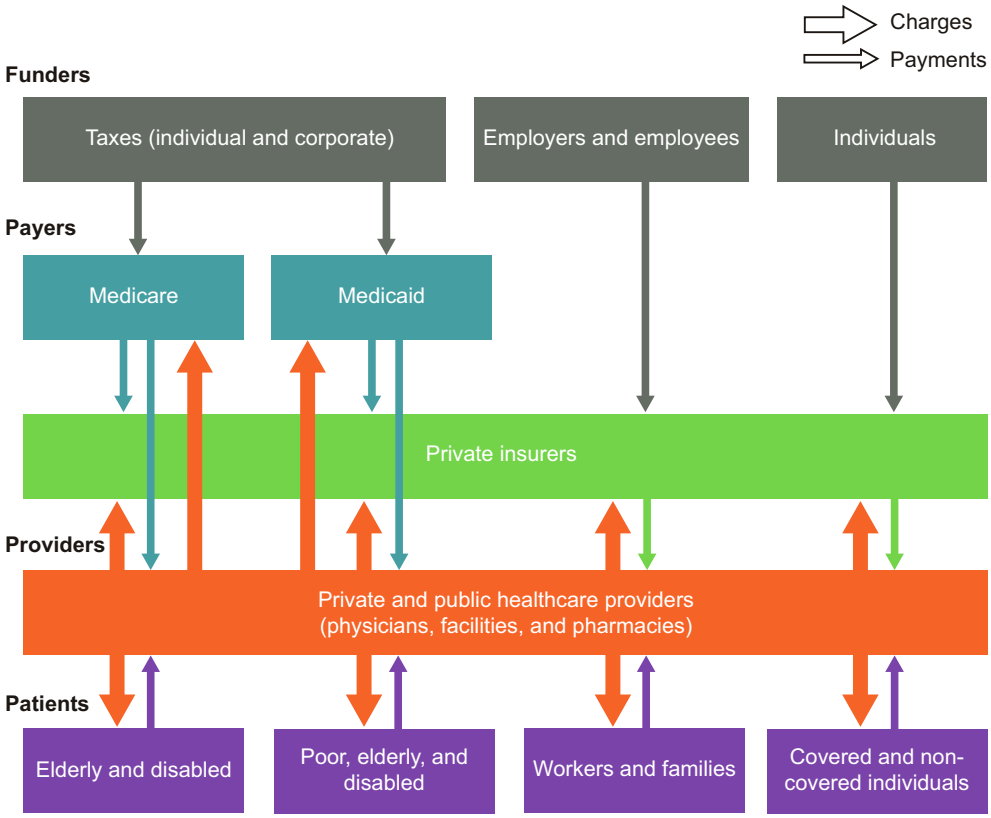

FIGURE 2.3.3
There are many interrelated entities involved in the flow of money in the US healthcare system (based on N. Sekhri, *Bulletin of World Health Organization*, vol. 78, no. 6 (2000): 832; reprinted with permission).

Medicare and Medicaid subcontract with private insurers for the administration of the benefits they cover.

Private insurers collect premiums from individual subscribers or from employers who provide health insurance benefits to their employees (historically, most of the employed non-elderly obtain health insurance through their employer, while some may purchase individual insurance).

Insurers (both private and public) then pay healthcare providers (facilities and physicians) for the services they provide to the individuals they insure. In many instances, the payments made by the insurers do not cover all of the charges made, such that the individuals receiving treatment must pay the balance (called a copayment). This is becoming increasingly common, with private insurance plans developing hybrid approaches that require individuals to bear a larger portion of their total costs through deductibles, copayments, and/or limits on coverage.

Until the passage of the Affordable Care Act (**ACA**), individuals without any insurance coverage had to pay for all of their healthcare services out-of-pocket. As of 2014, however, the individual mandate stipulates that most adults will have to purchase health insurance or face a financial penalty. For more information about healthcare financing and **reimbursement** in the US, see 4.3 Reimbursement Basics.

Despite the involvement of multiple players and the many handoffs between participants, the flow of money in many treatment areas tends to follow a standard path in the US. For instance, most patients who receive an implantable cardiac defibrillator for the treatment of heart rhythm disorders are covered by private insurance until they turn 65 years of age (or become disabled), at which time they are covered by Medicare. However, because there are always idiosyncrasies and variations within the system, innovators should be cautioned about making assumptions regarding the flow of money. For example, many ESRD patients without private insurance are covered by Medicare three months after they begin dialysis and continue to be covered until three years after transplantation, regardless of their age. Most ESRD patients with private insurance are covered under their private health insurance policy for the first three years of treatment, but then convert to Medicare (again regardless of age).[9] In this scenario, it would be imperative for an innovator working in the ESRD space to understand the role of Medicare in the flow of money for the treatment area and then focus on this group as a primary stakeholder, even if the innovator's solution targets a subset of the population under the age of 65.

A recent shift in the US healthcare financing landscape is worth noting because of its effect on the financial incentives of various stakeholders. An increasing number of provider/payer networks have emerged which combine the provider (a direct participant in the cycle of care) and the payer (the direct source of payment in the flow of money). One of oldest and most well-known examples of this type of collaboration is Kaiser Permanente, which is an integrated delivery network (IDN) that includes the Kaiser Foundation Health Plan, Kaiser Foundation Hospitals, and the Permanente Medical Group (which represents the physicians). Kaiser serves eight regions in the US and has become significant in large markets like California where the organization holds a 40 percent share of individual and employer health insurance customers.[10] However, more recently, in response to the Affordable Care Act, voluntary consortiums of *independent* physician groups, hospitals, and insurers have been developed as Accountable Care Organizations (**ACOs**). These groups agree to share the responsibility for caring for a defined population of Medicare beneficiaries over a defined period of time. In the process, they can earn incentives for saving money through more coordinated care that avoids duplicate or unnecessary procedures and tests.[11] The proliferation of these provider/payer networks is important because it changes the interests of the involved stakeholders as well as their receptivity to certain types of innovations. For instance, because the participants of an integrated delivery network or ACO are jointly accountable for the patient's longer-term cost of care, they may be more amenable to preventative care technologies or solutions that incur a higher near-term

cost but promise savings over a greater time horizon. Integrated networks also tend to be more focused on innovations that can lower treatment costs while maintaining outcomes. Moreover, they are more motivated by **value** than by volume.

It is also important to note that many of the world's largest corporations have recently begun to function in much the same way as the integrated delivery networks and ACOs. Gaining control of their rapidly rising healthcare costs has become a necessity in order to preserve their overall cost competitiveness. Because they often carry the burden of insuring the long-term health of hundreds of thousands of employees and their retired former employees, these companies are motivated to make different decisions surrounding wellness and preventive care than stand-alone providers or payers might make.[12]

In other countries, particularly in the developing world, the health expenditures may look significantly different based, in part, on variability in public versus private payments as well as the role of health plans versus out-of-pocket health expenditures (see Figure 2.3.4). For example, in India, the role of third-party public and private payers is significantly diminished and patients bear a much larger portion of the healthcare payment burden. In 2011, just under 70 percent of all healthcare payments in the country were made by private individuals.[13] In contrast, government expenditures on healthcare accounted for approximately 25 percent of total spending. On a per capita basis, government spending on healthcare in India was only $56 compared to $208 in China and $964 in Brazil in 2010 (all figures in US dollars).[14]

The availability of health insurance is rare but growing in India. In 2003, only 55 million people were covered by a health insurance policy but, by 2010, this figure had increased to 300 million people, mostly below the poverty line. Still, only 3–5 percent of individuals in the country have full or substantial coverage.[15] Both government and private insurers are working to address this problem, and analysts estimate that about half the population will enjoy some level of health insurance coverage by 2020.[16]

In China, health insurance coverage is more widespread. Roughly 87 percent of China's population had some form of health insurance coverage as of 2008;[17] by 2010, this figure had grown to 90 percent, with the government aiming for 100 percent coverage by 2020.[18] Despite these advances, out-of-pocket payments made by patients are still the predominant source of private healthcare financing, accounting for 44 percent in private payments in 2011.[19] Insured individuals' out-of-pocket payments remain high in China because insurance plans do not adequately cover large healthcare expenditures.[20] For example, copayments for inpatient care can be as much as 10–35 percent of the total cost of care.[21] As a result, patients are cost-conscious and exercise considerable influence over the medical devices used in their procedures.[22]

Stakeholder interests

Once all key stakeholders with an interest in a need have been identified, innovators can next dive in to understanding the barriers that might cause a stakeholder to resist the adoption of a new innovation, as well as the improvements or benefits that may drive their acceptance (chapter 2.4 includes a discussion of how improvements can subsequently be translated into value for key stakeholders). An effective analysis assesses the factors that *directly* and *indirectly* affect stakeholder behaviors. Direct factors may include a loss/gain in revenue, decrease/increase in profitability, decrease/increase in time away from work. Indirect factors may include impacts on reputation, ease of use, and especially **opportunity costs** (which are defined as the cost and benefits of giving up one alternative to pursue another).[23] Understanding the drivers of stakeholder behavior is essential to being able to influence stakeholder actions. The following sections articulate some of the common drivers of stakeholder behavior for four primary groups: patients, physicians, facilities, and payers.

Patients

Patients are the ultimate gatekeepers as to whether or not they will agree to undergo a specific test or treatment. Traditionally, their decisions have been made based on

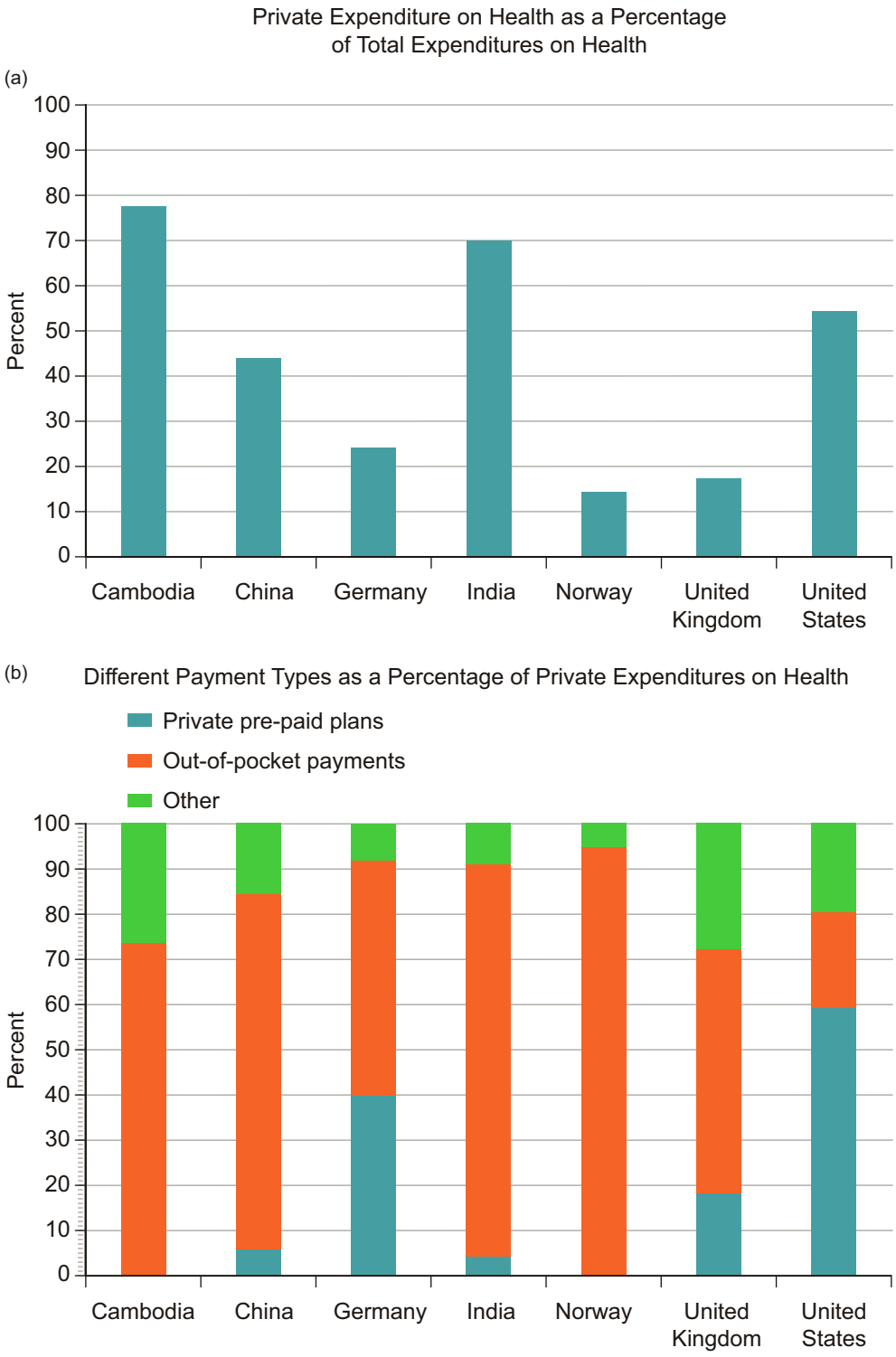

FIGURE 2.3.4
Innovators can expect to see great variation in the relative prominence of public, private, and out-of-pocket health payments in different countries around the world. (compiled from "Health Financing: Health Expenditure Ratios by Country," Global Health Observatory Data Repository, World Health Organization).

information and advice received from physicians. However, patients are now more empowered than ever and have access to vast quantities of medical information directly from other resources (e.g., advertisements, online knowledge bases and blogs, bulletin boards, and discussion and support groups). Accordingly, they may play a more active role in making health-related choices based on the information available to them (even though

not all available data may be credible). In the US, 50 percent of hospitals and 40 percent of physicians in ambulatory practices offer some sort of Internet portal for patient use.[24] In addition, pharmaceutical companies, medical device manufacturers, and health insurance companies are increasingly seeking to influence patient behavior through financial means (copayment requirements), as well as non-financial mechanisms (direct-to-consumer advertising).

In locations like India, patient power may extend even further. For example, in many non-tertiary healthcare settings, patients requiring a stent in their coronary arteries might be informed by the doctor of the product choices. These patients would then go to a local vendor of medical products to evaluate the available stents, which typically include options made in-country as well as those manufactured by multinational corporations. Medical products made by the multinationals tend to be perceived as higher quality, but are significantly more expensive. More often than not, patients purchase the most expensive product they are able to afford and then bring it with them on the day of the procedure to be placed. In this way, they exercise an unparalleled level of control over their treatment. Cost tends to be the primary driver of the decision, with the recommendations of the physician and/or vendor having a secondary effect on patient behavior.

A patient's family is another related stakeholder group to carefully consider. Particularly in developing countries, family members tend to be much more involved in delivering care, both at home and directly in the hospital. They also may be the ones to decide about health-related expenditures. Especially in environments with high patient-pay requirements, it is often the patient's son or daughter who must take on a second job or make other sacrifices to fund the patient's treatment.

In more developed environments, innovators should also evaluate relevant patient advocacy groups. These entities have the ability to influence patient opinions. They are also frequently sponsored by major corporations whose interests may be served or threatened by the new innovation. Consider the sponsors' interests alongside the interests of the advocacy groups and the patients they are intended to serve.

Patient behavior with respect to accepting a certain treatment is often driven by the following *direct* factors:

Clinical outcomes Patients are interested in the treatment that will best resolve their primary problem. However, they are also concerned with the elimination of symptoms and the avoidance of unintended consequences from the treatment. The order of importance of these factors is likely to be different for each patient. For instance, when considering a patient's reaction to a new treatment alternative that may have clear benefits, it is still necessary to think about the amount of pain the patient will experience, whether or not the patient's appearance will be altered, and/or other potential side effects that might be associated with one treatment but not another. Also, the innovator should evaluate the benefit of living longer if a treatment helps delay mortality.

Safety While procedures and their associated risks may be considered routine from a physician's perspective, the idea of undergoing certain treatments can be traumatic for a patient. Patients must consider whether the "cost" of living with a disease is higher than the risk of being treated, based on the safety profile of the treatment and a patient's own individual preferences.

Economic impact In the case of new technologies, patients are often required to cover a larger portion of the total treatment cost. Or, in some cases, they are required to cover all treatment expenses. Determine what out-of-pocket expenses a patient should expect to incur relative to other treatment alternatives and evaluate this cost against the anticipated change in clinical outcome. Keep in mind that roughly 100 million people each year are pushed under the poverty line because of healthcare payments, with more than 90 percent of these individuals living in low-income countries.[25]

Convenience The impact that a new treatment may have on a patient's life can vary from inconvenient to life-changing (in a positive or negative way). In deciding on a treatment, patients often think about whether the treatment is available nearby, how easy it is to schedule,

what impact it will have on days off work, and the long-term implications on their quality of life.

Indirect factors influencing patient behavior include:

Opportunity cost Innovators should consider what patients could do with their time, money, and energy if they elected to have one solution over another. Think about this question on both a near-term and long-term basis. Also, remember to include a patient's choice to do nothing about the problem as one potential alternative.

Perceived risk Sometimes perceived risk can be a major factor in a patient's decision-making process, even if the actual risk associated with the treatment is relatively low. Particularly for experimental treatments, consider how the perceived risk is likely to affect a patient's behavior. It is also important to take into account the psychological effect that the new treatment is likely to have on the patient relative to established treatments.

Importantly, not all patients facing the same medical need will perceive it the same way. It can be useful for innovators to differentiate between patient types by developing a series of patient profiles. Within these profiles, patients will view a need similarly and have comparable reactions to different treatment alternatives. However, across profiles, patient perceptions of the need and how it is treated will be distinct. To understand how these profiles can be developed, refer back to the case example in 1.2 Needs Exploration, which describes how a biodesign team from the University of Cincinnati created different patient personas to better understand needs in sleep apnea. Identifying these types of profiles will also prove helpful in 2.4 Market Analysis, where one of the goals is to define clear segments of patients with uniform perceptions towards the need.

Physicians

Because physicians are the primary individuals recommending patient treatment, they are critical stakeholders for almost every medical treatment option. While physicians are first and foremost driven by the desire to provide patients with the best possible treatment, they also face the need to earn a living. Innovations that make new procedures possible can often help physicians achieve both of these desired outcomes.

Yet the influence of physicians on adopting new technologies can vary significantly and depends on the type of organization in which they practice medicine (e.g., a private practice, integrated delivery network such as Kaiser Permanente, or non-profit, community-based hospital or clinic). Historically, in large markets like the US, physician preferences primarily drove device usage. However, as hospitals face increased pressure to contain costs, many have adopted **value analysis committees** (VACs), also known as technology assessment committees, to assist with decision-making. In a survey of 4,500 US hospitals, nearly 75 percent of respondents either had a strategy for standardizing physician preference items (**PPI**) or were working on developing one. Additionally, and that 64 percent of hospitals were using value-analysis teams to evaluate and select PPIs and other supplies.[26] This strong trend toward more centralized purchasing, which is almost certain to continue with the expansion of ACOs and a system-wide focus on cost containment, can be expected to further erode the individual influence of the physicians on purchasing decisions, even while they remain on the front line of patient care.

In assessing and anticipating physician behavior, keep in mind the potential for conflicts to arise. For instance, if a technology shifts patients from one specialty to another, this may cause "turf wars" between physicians and create serious obstacles to the technology's adoption. Another scenario that might raise a conflict is one in which a new technology requires the skill set of one specialty, but this specialty is not currently involved in the cycle of care for the given disease state. As physicians become increasingly specialized within a single field, these kinds of conflicts are becoming more common. Guy Lebeau, a physician and businessman who led the growth of Cordis Corporation's cardiology, endovascular, neurovascular, and electrophysiology businesses, commented on the benefits of this trend, using the field of cardiology as an example:[27]

> *I think the fact that we are no longer going to have one cardiologist with one set of knowledge, but*

probably 10 different types of cardiologists who are going to focus their energy on treating one type or one part of the disease, is excellent because this creates a situation where the learning and the competency of physicians is going to be higher.

The downside is that, as new technologies disrupt referral patterns, they create "winners" and "losers," particularly among physicians within these narrowly defined subspecialties. When considering physicians as stakeholders, the innovator must be on the lookout not just for the relevant specialties, but the potential subspecialties that exist within them. Then the interests of all such stakeholders need to be taken into account.

Another issue that may emerge is related physician willingness to try new devices and the procedures they enable. Certain specialists (e.g., cardiologists) are known for their receptivity to new technologies. But other physician groups may be more risk averse and, as a result, less willing to adopt new ways of working. This conservative stance toward technology can be particularly pronounced in certain geographies. For instance, Stanford Biodesign Fellows working in India sometimes express frustration that it can be difficult to find physicians who are open to trying new devices. These innovators report that they must expend considerable time and energy to identify one or two key doctors who will act as early adopters of an invention.

The role of professional societies is another important factor to consider. For most well-established medical fields, there are multiple associations that address the area within which a need exists. Physicians involved in these groups are often considered thought leaders in their respective fields and are likely to have strong opinions on the benefits and costs of any new developments in the field.

Physician behavior with respect to the potential utilization of a new treatment is generally driven by the following *direct* factors:

Agency The mandate of physicians is to represent the best interests of their patients. As an agent of the patient, a physician's treatment recommendations must carefully balance the risks and benefits to patients and take into account patient preferences. Medical ethics underlie this relationship (see the section of this chapter entitled "Ethical Considerations in Stakeholder Analysis").

Clinical outcomes Clinical outcomes refer to the manner and degree to which physicians will be able to improve medical results through the use of a new solution. In partnership with agency, this is one of the most persuasive factors for getting physicians to adopt a new technology.

Economic impact The financial impact on the physician of adopting a new treatment is an important consideration. This includes how (and how much) physicians might be reimbursed or otherwise compensated for the treatment and the number of treatments they would perform annually. These calculations must be understood relative to existing technologies and their significance within a physician's practice. For example, resistance may be encountered if a new solution requires substantial training, disrupts existing work flows, requires major equipment purchases, or renders existing (costly) equipment obsolete.

Mobile health (**mHealth**) and remote monitoring technologies provide an example of how the lack of direct financial incentives can slow the adoption of new technologies. Many digital devices and applications, with the promise of improving care while reducing cost, have been introduced in the US. However, they have not been widely reimbursed under the traditional fee-for-service payment scheme. Some physicians have gradually gravitated toward them anyway, justifying the expense based on the efficiencies and quality improvement that the technologies enable. But larger-scale adoption will only be achieved when payment is assured. The move toward value-based reimbursement under ACOs and patient-centered medical homes will potentially act as a catalyst for this shift.[28]

Risks The risks to the physician of adopting a new treatment include any potential increase (or decrease) in clinical uncertainty (e.g., safety risk and side effects for patients). It also covers malpractice liability and/or

the liability of not complying with evidence-based guidelines, as well as the impact of the change on the physician's malpractice insurance. In some cases, new innovations can reduce physician risks and malpractice liability.

Physician behavior with respect to the utilization of a new treatment is also driven by a series of *indirect* factors:

Opportunity cost In determining how a new treatment might fit into a practice, innovators should analyze how the physicians currently use their time. Understand how long current treatment options take to administer, how many providers are involved, and how many procedures are typically performed within a given period of time. This information can then be used as a benchmark as more becomes known about the need and the solution that will eventually address it. Specifically, when physicians adopt a new solution, the revenue they would earn per unit of time should be at least the same as the revenue currently generated from the same unit of time. Otherwise, the opportunity cost associated with adopting the new treatment alternative may be perceived as being too high to make its adoption appealing. In these cases, the clinical benefit would have to be extremely compelling to make the desired change in physician behavior feasible.

Workflow While all new treatments may not carry with them significant capital expenditures (e.g., investments in new equipment), almost all will require a change in workflow (or the process by which they are used). Consider how disruptive a new treatment may be to established physician practices, or whether it can be integrated relatively seamlessly into common processes and if so how much this may cost. It is important to remember that it is much more difficult to get physicians to adopt a new treatment if it requires a significant change in their accustomed workflow, compared to one that can be integrated easily into their existing daily routine.

Ease of use Evaluate whether or not a new innovation is likely to make the physician's job easier or harder to perform. While workflow takes into account the process by which a device is used, ease of use considers how difficult or easy the device is to use at each stage of that process. In terms of costs, the innovator should consider what training might be required to perform a new treatment and any new or special skills that physicians may need to develop. On the benefit side, identify the ways in which an innovation might make it easier for physicians to provide effective treatment. Ease of use can be a potent advantage for a new technology and a factor that can rapidly drive acceptance. This was demonstrated when Guidant Corporation introduced a new bare metal stent to treat coronary artery disease. Because it was so much easier to use (and did not require nearly the same amount of physician experience and skill to effectively place within a patient's artery), it quickly displaced the market leader, a bare metal stent marketed by Cordis Corporation, despite the fact that Cordis was first to market with its product.

Reputation Consider whether the adoption of a new innovation might be perceived positively or negatively by patients and, in turn, what its effect might be on a physician's standing in the physician community. If physicians are known for being leaders in their field, evaluate the indirect benefits (e.g., visibility) to their practices of adopting the innovation. Conversely, if a physician is risk averse and takes pride in providing proven treatments, consider the reputational cost of adopting an exploratory solution. There are significant differences in perceptions of new technologies and their impact on physician reputation among both physicians and specialties. For example, while interventional cardiologists pride themselves on being quick adopters of new technologies, cardiac surgeons are more conservative in their approach. This may explain why the adoption rates of new technologies vary dramatically between these two specialties.

Facilities

The primary interests of facilities, such as hospitals, surgical centers, laboratories, and other settings where care is delivered, are largely financially driven. However, their perspectives on a need will be heavily influenced by how their operations are organized. If they are

participants in a single-payer system (e.g., Norway), an integrated delivery network (e.g., Kaiser), or an ACO (e.g., Cedars-Sinai Accountable Care), their financial motivations will be more complex than if they are organized as a more traditional fee-for-service facility. Yet, this simple truth will remain constant: innovations that increase procurement costs are most likely to meet resistance from this stakeholder group, while those that reduce procurement costs and are assured of third-party reimbursement are most likely to be accepted.

Innovators should also understand that there can be significant differences in financial motivation and behavior depending on type of setting in which treatment occurs. Economic calculations can differ greatly if an institution is a non-profit versus a for-profit organization; or an academic training center versus a community hospital.

In some geographies, such as the US, facilities also can be sensitive to innovations that shift the location where a treatment, procedure, or test is delivered since the revenue they receive is often adjusted based on the location. As an example, consider point-of-care (**POC**) testing for hemoglobin A1c (HbA1c), a variant of hemoglobin (an oxygen-carrying molecule of blood) that can be used as a marker of glucose control in diabetics. Testing for HbA1c typically requires a patient to go to an outpatient lab. POC testing would change the venue of testing from the lab to the clinic (or the doctor's office). For such tests, the stakeholders include not only the physicians who would perform the POC tests, but also the laboratories that previously provided this service. Following approval by the **FDA** of one such POC test, the Metrika InView, a series of studies were performed (not managed or influenced by the manufacturer) that compared the results from the POC tests to those from tests performed in the lab, with lab tests considered the "gold standard." The studies showed that the correlation between the results was high, but not high enough to make the POC test a substitute for the test in the lab.[29] An editorial accompanying one of these studies, written by a professor of pathology, stated that there are numerous issues to consider when evaluating a new method for HbA1c point-of-care testing, including whether or not the method is NGSP-certified,[30] how well it performs in a field setting, and if it is free from common interferences.[31]

Such a response demonstrates that pathologists working in labs have a stake in the adoption of POC testing. When their views appear in medical journals, they have the potential to hinder or catalyze the adoption of a new test. Innovators should try to anticipate such viewpoints and develop a strategy to preempt them, for example, by securing appropriate certifications and by carefully designing clinical studies that may go beyond FDA requirements.

While facilities would hope for all of their procedures to be profitable, it is not uncommon for some to be designated as "loss leaders" – procedures billed for less than they cost because they generate business (patient traffic, additional revenue) in other areas of the facility. For example, at many dialysis centers, the delivery of dialysis is performed at a loss since it allows profits to be generated from other services, such as the administration of epogen, a drug necessary to stimulate red blood cell production and help control anemia, which is typically administered while patients receive dialysis. If an innovation will not be profitable for the facility where it is administered or utilized, the innovator should think creatively about related products/services that can be bundled with it, modified, or eliminated such that the innovation results in a net benefit to the facility.

Participation in an ACO is another factor that can influence the procedures, tests, and treatments in which facilities invest. Hospitals and other providers that form an ACO are eligible for the Medicare Shared Savings Program, which rewards the consortium for lowering its aggregate growth in healthcare costs while meeting performance standards on quality of care and "putting patients first."[32] Providers in the ACO continue to receive reimbursement payments under Medicare fee-for-service rules but, if they meet or exceed defined quality standards relative to an established benchmark and achieve savings at or above a Minimum Savings Rate (MSR), they share in the total savings based on their quality scores.[33] Thirty-three quality metrics have been defined using nationally recognized measures in four key domains:[34]

- Patient/caregiver experience (7 measures)
- Care coordination/patient safety (6 measures)
- Preventive health (8 measures)
- At-risk population:
  - Diabetes (1 measure and 1 composite consisting of 5 measures)
  - Hypertension (1 measure)
  - Ischemic Vascular Disease (2 measures)
  - Heart Failure (1 measure)
  - Coronary Artery Disease (1 composite consisting of 2 measures)

Importantly, this construct begins to provide traditional fee-for-service providers with a sound financial rationale (where one previously did not exist) for shifting their care priorities from a strict focus on volume to improved results. For example, facility executives have indicated increased interest in new programs and technologies to actively manage patients upon discharge to prevent hospital readmissions and reduce emergency room usage; create more robust chronic disease management programs; improve the management of patient care transitions from hospital to home (or other care venues); and experiment with patient-centered medical home models.[35]

As noted, many groups shape the treatment (and purchasing) decisions of a facility, including physicians, facility executives, and purchasing professionals. However, because physicians are evaluated separately, innovators should place their primary focus on understanding how management and purchasing respond to the need during stakeholder analysis.

Direct factors driving facility stakeholder behaviors for adoption of a new treatment include:

Economic impact Depending on how the costs of a new treatment will be covered, innovators should begin thinking about whether a potential change may increase, decrease, or hold constant the overall cost of treating a given disease state. Since traditional facility payments for treatments typically do not adjust higher for increased costs that may be incurred (i.e., facilities typically receive fixed payments for a treatment), a new innovation must reduce ancillary costs associated with the treatment to decrease overall cost or have a neutral effect on a facility's budget. For example, reducing a patient's length of stay in the hospital following surgery can provide large financial incentives for a facility to adopt a new treatment if the facility's payment for the surgery is fixed and does not increase with a longer stay (see 4.3 Reimbursement Basics). Also, think carefully about innovations that may change the location where treatment is administered (i.e., takes business away from a facility), as the POC example illustrates. If the facility is part of an ACO, recognize that they are likely to be receptive to needs that, if addressed, will help them not only save money but meet the quality standards that act as a hurdle in the Shared Savings Program.

Risk Consider the effect of the new treatment on a facility's risk profile. Some procedures may significantly reduce facility risk while others may increase it. An increase in risk can carry with it direct financial costs by affecting liability and insurance.

Indirect factors influencing the behavior of facility representatives regarding the adoption of new treatments include:

Opportunity costs Facilities have limited resources in terms of their providers, support staff, and physical space in which to provide care. If a new treatment will change the number of procedures performed each year, it may create or consume procedural time in the operating room or other settings. This is time that could be used on other procedures. Therefore, the potential profit that could be generated per unit of procedure time should exceed the profit generated by existing procedures.

Reputation Being seen as a leader in a certain field can attract patients to a facility. If an innovation serves as a magnet for a facility to draw additional patients, the facility may be willing to make trade-offs in other areas to achieve the benefit of additional patient traffic, especially if the additional patient traffic results in the need for additional ancillary services, such as testing. The DaVinci robot, an innovative surgical robot that can be used to gain improved surgical results and make procedures less invasive, provides a good example of a

technology that was used by the hospitals that were early adopters to enhance their reputation.

Payers

If payers grant adequate reimbursement for a medical innovation, it is a powerful force in stimulating adoption in settings where insurance systems dominate the payment landscape. On the other hand, if payers deny, delay, or restrict reimbursement, it can be extremely detrimental to the success of a new treatment unless the treatment is attractive enough to get patients to pay for it directly. In many cases, identifying a path to reimbursement has become equally or more critical to success as developing an approach to gain regulatory clearance. Importantly, innovators and medical device companies must appreciate that the data required for regulatory approval is sometimes not enough to make a compelling case to payers. (4.3 Reimbursement Basics and 5.6 Reimbursement Strategy provide more details on payers, their reimbursement decisions, and how innovators can influence them.)

Historically, many new innovations have been synonymous with increased costs from the payer's perspective. The reason that payers have continued to fund new interventions is the promise of better outcomes, especially when this is coupled with the possibility of lower long-term costs for a given patient (e.g., fewer hospitalizations, surgeries, or other expensive forms of care). However, if the cost burden becomes too great or the perceived clinical benefits are not significant enough, both public and private payers may deny coverage and/or limit the number of patients eligible for a new treatment by dividing the patient population into subgroups and restricting reimbursement to a specific subgroup. Another potential scenario that payers use is implementing step-therapy guidelines, which force physicians to try alternative therapies before utilizing the new treatments.

In general, payers are most likely to cover new medical technologies if they are proven (through robust **clinical trials**) to improve hard clinical endpoints (mortality, **morbidity**) and/or achieve comparable clinical outcomes at significantly lower cost – with this latter factor increasing in importance. Softer endpoints, such as patient convenience, physician convenience, or quality of life, are less likely to gain reimbursement unless the improvements are shown to be medically necessary (and medical necessity is a rather ambiguous concept that can often be shaped by the innovators as part of their reimbursement and marketing efforts – see 5.6 Reimbursement Strategy and 5.7 Marketing and Stakeholder Strategy). Payers also need to be convinced that new technologies do not add risk to the treatment paradigm.

In some countries, payers already have embraced clear, evidence-based approaches to making decisions about healthcare spending. The National Health Service (NHS), through its National Institute for Health and Care Excellence (**NICE**), provides the most well-known example. Through a formal technology appraisal process, NICE assesses clinical evidence to evaluate how well a new treatment works, along with economic evidence that measures how well it performs relative to its cost. Based on this assessment, a recommendation is made that the NHS is legally obliged to follow.[36] The purpose of these appraisals is to eliminate reimbursement uncertainty and help standardize access to healthcare across the country.[37] However, technology appraisals also allow the NHS to make unambiguous decisions about the most effective use of its finite resources. NICE relies on an internationally recognized method to compare different treatments and measure their clinical effectiveness: the quality-adjusted life years measurement (called the **QALY**). A QALY provides an estimate of how many extra months or years of life of a reasonable quality a person might gain as a result of new treatment. Cost-effectiveness is then determined by calculating how much the treatment costs per QALY. Each intervention is considered on a case-by-case basis, but NICE generally stipulates that if a treatment costs more than £20,000-30,000 per QALY (about $49,000), then it is not considered cost effective.[38]

The trend toward using evidence-based analysis to justify treatment reimbursement is increasingly being embraced by payers and governments around the world. While a comparable approach has yet to be widely adopted in the US, where the idea of "rationing healthcare" has been politically unpopular and vilified in the press, it is clear that the cost-effectiveness of new treatments and technologies – and the value they deliver – is becoming paramount in today's budget-constrained environment. One challenge with these approaches can

be the extra time required to conduct a definitive comparative analyses or, alternatively, to gather data from use of a technology in clinical practice to justify favorable reimbursement decisions. A good example is the case of the Guglielmi Detachable Coil (GDC) for catheter-based treatment of brain aneurysms. The device received FDA approval in the US in 1995, but hospitals using it initially lost money on related procedures due to inadequate reimbursement payment levels. It was not until 2003 that the product's manufacturer, Boston Scientific, was able to present analysis of Medicare claims data to CMS that demonstrated the extent to which hospital costs exceeded payments. In 2004, CMS agreed to a change that doubled the average payment level (see 5.6 Reimbursement Strategy for more information).

Payers and manufacturers will sometimes need to use creative approaches to demonstrate value while maximizing patient access to new innovations. For example, consider Genomic Health, a company that developed a high-end genetic test to help determine if women with early-stage breast cancer will benefit from chemotherapy (a commonly prescribed treatment that is effective in only a small percentage of patients). Although the effectiveness of the diagnostic is backed by strong clinical evidence, its value to payers is realized only if women with a negative test result choose *not* to receive chemotherapy (thereby saving money in administering ineffective treatment). However, according to one payer, UnitedHealthcare, too many women were still receiving chemotherapy even if the test suggested they did not need it. For this reason, United entered into a conditional agreement with Genomic Health under which it covered the cost of the test for an 18-month trial period while the outcomes were monitored. If enough women with low scores on the diagnostic did not abstain from chemotherapy, then United had the opportunity to negotiate a lower price with Genomic Health on the grounds that the test was not having the intended impact on actual medical practice. According to Dr. Lee N. Newcomer, senior vice president for oncology at UnitedHealthcare, this arrangement was designed to make the manufacturer more responsible for how its product was used in the medical marketplace.[39] Following the trial period, UnitedHealth extended coverage for the test for patients with estrogen-receptor positive, node-negative carcinoma of the breast[40] (see chapters 2.4 and 5.7 for more information about Genomic Health).

Direct factors driving payer behavior regarding adoption of a new treatment include:

Clinical outcomes Innovators should consider both the near-term medical benefits, as well as the longer-term effects of ongoing treatment in improving outcomes relative to any existing treatment alternatives. The elimination of symptoms and side effects that often require separate treatment can also be significant from a payer's perspective. In the US, the standard for proving clinical outcomes has gradually risen with many payers now requiring two separate **randomized controlled clinical trials** to be published in **peer-reviewed** journals before they will act on a reimbursement decision.

Economic impact Be prepared to evaluate the total cost of any new treatment relative to existing treatment alternatives. When more is known about a potential solution, the innovator can start with the payment per treatment (how much the payer would be willing to reimburse for the new procedure) and then multiply this by the anticipated number of treatments per year. Compare this to data for alternative treatments to calculate by how much the new treatment will increase payer costs. In some cases, an innovator may be able to evaluate whether the innovation can decrease near-term or long-term costs to payers by reducing other services requiring reimbursement, such as hospitalization or additional testing (e.g., blood test or X-rays). Another way to think about the financial impact to payers is the incremental increase or decrease to its cost per member per month. If the per procedure increase is large – but the relative size of the patient pool is small – then payers might be less sensitive to the marginally higher cost of a better outcome. Conversely, if the increase in cost is small but the patient pool is large, the innovator can anticipate resistance. It is also important to consider if a new treatment could potentially expand the market for treatment in such a way that significantly more patients will seek treatment, which can represent a sizable cost increase to payers.

Indirect factors that can also influence payers regarding adoption of a new treatment are:

Competition Payers often move as a group. Consider competitive dynamics among payers in making reimbursement decisions (particularly in the private sector) and think about the benefits (e.g., in terms of market share) and costs of being the first (or last) payer to cover a new solution.

Reputation It can also be helpful for the innovator to think about the effect on the payer's reputation of offering the new treatment. If any new treatment is widely perceived as being ground-breaking, the payer will have a more difficult time justifying a decision not to cover it. Conversely, if a new treatment is marginally effective yet costly relative to available alternatives, a payer will have little incentive to justify reimbursement in a cost-conscious environment where its own internal and external stakeholders would be critical of such a move.

Relative power and linkages between stakeholders

As the forces that drive stakeholder behavior are understood, stakeholders can be classified based on their unique characteristics, motivations, and level of potential impact. Importantly, all decision makers are stakeholders, but not all stakeholders are decision makers when it comes to the adoption of a new solution. It is essential for innovators to identify which stakeholders fundamentally will be the gatekeepers to an adoption decision and which ones will play an influencer role. Generally, more time, effort, and resources should be devoted to understanding and managing the involvement and commitment of decision makers, with a secondary emphasis placed on influencers.[41]

Relationships between key stakeholder groups should also be explored. In the medical environment, no single stakeholder group operates in isolation from the others. For example, purchasing professionals within facilities have their own issues, priorities, and considerations but also must satisfy the needs and demands of their associated physicians and align their efforts with the strategic priorities set forth by executives at the helm of the organization. Patients typically follow the instructions of their physicians, but are increasingly exercising greater control over medical decision making, including treatment alternatives and locations. Physicians and patients may seek to embrace a new innovation but have their adoption hindered by the decision-making process of the payer system. As a result of these types of interconnected issues, the prioritization of stakeholder interests is critical because it can determine the order in which these interests are addressed.

Innovators should keep in mind that the forces that shape stakeholder behavior are dynamic and constantly evolving. Trends like provider/payer consolidation, accountable care, and value-based reimbursement incentives can have a profound impact on stakeholder motivations over the many years that are often required to bring a medical innovation to market. Those innovators who consider how tomorrow's landscape may look are likely be more successful than those who optimize exclusively for today's situation.

The following story of InnerPulse, Inc. demonstrates how stakeholder analysis works in practice and highlights some of the linkages between stakeholder groups with varying degrees of relative power and influence.

FROM THE FIELD — INNERPULSE, INC.

Anticipating and managing stakeholder reactions in the innovation process

When it was founded, InnerPulse, Inc. (formerly Interventional Rhythm Management) was focused on developing PICDs™ (percutaneous implantable cardioverter defibrillators), or miniaturized ICDs, that could be placed via a catheter-based approach. ICDs are used to prevent sudden cardiac death by issuing a lifesaving jolt to the heart when a patient suffers sudden

cardiac arrest. The company's product is made of a chain of pencil-thin components measuring 56 centimeters in total length. The device can be placed in the vascular system percutaneously (across the skin), using a standard catheter-based approach, in under 10 minutes. PICDs are differentiated from conventional ICDs in two ways: their size and delivery method. Conventional ICDs are roughly the size of a hockey puck, and are usually surgically implanted in the upper chest of a patient. Because of the complexity of ICD devices and the accompanying procedure, implantation is usually only performed by a small group of heart rhythm specialists known as cardiac electrophysiologists (EPs). In contrast, the PICD, due to its less invasive delivery method, can be implanted by EPs and interventional cardiologists (ICs), who typically use catheters to treat blockages in blood vessels. As a consequence, it can be made accessible to a much larger group of defibrillator candidates who would potentially benefit from ICDs (see Figure 2.3.5).

There are two primary groups of patients who benefit from ICDs: (1) **secondary prevention patients** – patients with a prior episode of sudden cardiac arrest; and (2) **primary prevention patients** – patients at high risk of sudden cardiac arrest who have a weakened heart manifested by a left ventricular ejection fraction <35 percent (normal ejection fraction is typically ≥ 55 percent). The primary prevention market dramatically increased as a result of two clinical trials [MADIT-II (2001) and SCD-HeFT (2004)], which showed that ICDs dramatically reduced the mortality rates of these patients. Based on these results, the indication for ICD implantation expanded to more than 1 million similar individuals at risk for sudden cardiac death. However, the large number of primary prevention patients seeking ICDs is currently overwhelming the 1,800 EPs nationwide. The consequence of this problem is that only 10 to 20 percent of all patients who would potentially benefit from an ICD have received the device. PICDs have the potential to unlock this large, previously untapped market. This under penetration of the market due to the limited number of EPs available to initiate

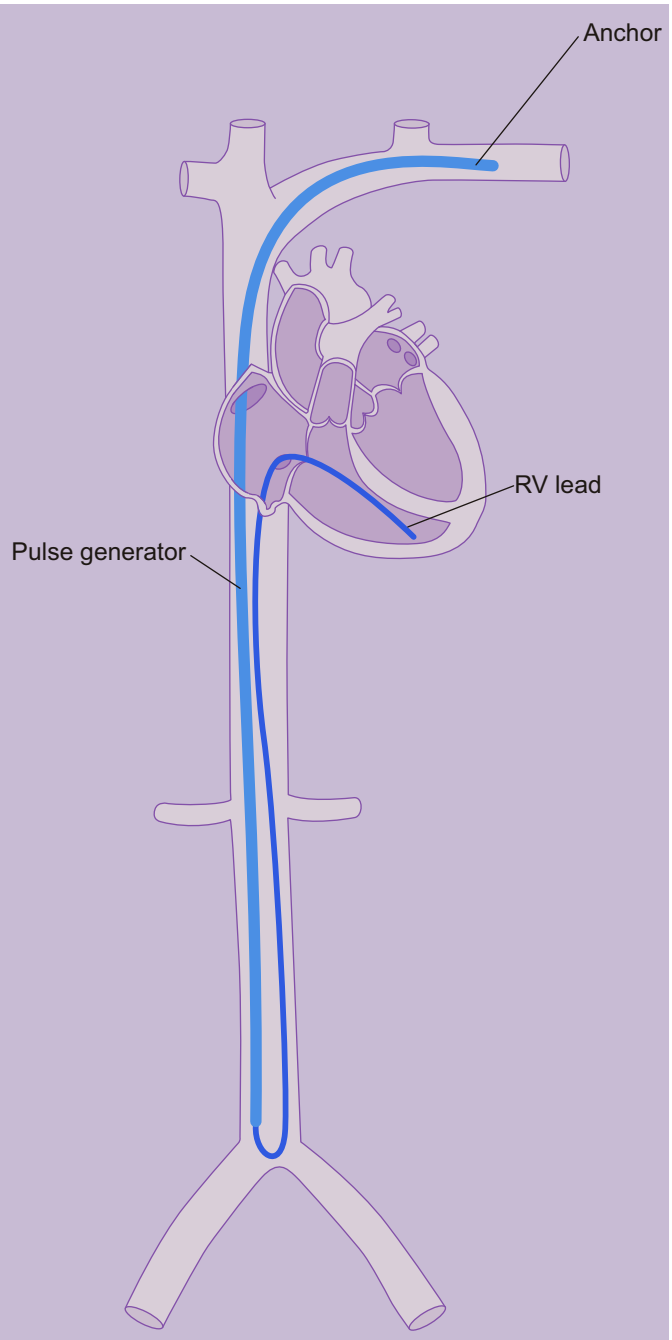

FIGURE 2.3.5
Schematic of the InnerPulse PICD (courtesy of InnerPulse, Inc.).

defibrillator therapy was an important factor in helping understand the role PICDs could play.

Because PICDs can be administered by ICs, instead of just EPs, they raise some important stakeholder issues. When InnerPulse was initially pursuing the *need to*

develop a less invasive way to prevent sudden cardiac death, it had to consider the effect a non-surgical implant would have on stakeholders in the field. There is an unwritten conventional rule in medical devices that if a new device "steals" business from one specialty to benefit another specialty, conflicts between the specialties may ensue, creating obstacles to the adoption of the new technology. For example, the tension between cardiac surgeons and ICs that followed the introduction of balloon angioplasty as a minimally invasive alternative to invasive coronary artery bypass surgery was legendary. The team at InnerPulse had to ask itself if the introduction of a less invasive technology implanted by non-EPs would create similar tensions with EPs, who controlled the traditional ICDs market.

Bill Starling, chairman of the InnerPulse board, company co-founder, and an early investor in the venture, believed that turf wars could be avoided in this case if the need for a less invasive solution was focused on the primary (as opposed to the secondary) prevention market. He explained: "The great opportunity here is the primary prevention market. Electrophysiologists have traditionally ignored this market because they do not see these patients. EPs only see the secondary prevention patients who have developed an arrhythmia. Primary prevention patients are seen by the interventionists [ICs]. Primary prevention patients usually have coronary artery disease. The cardiologists put in stents, give them some drugs, and send them home because there is nothing more they can do. With a less invasive solution, the interventionist [IC] would now be able to do something more for the patient. And remember, these are patients that the EPs would not see anyway."[42] Thus, the fact that a patient would typically see a cardiologist or IC for some initial treatment or evaluation prior to being referred to an EP was key in understanding the stakeholder relationships. Without referrals from colleagues in other areas of cardiology, an EP would not have patients requiring ICD implants.

According to InnerPulse, the argument in favor of pursuing the need that eventually led to the PICD was even stronger than this. The company predicted that addressing this need would not only create new business for ICs, but it would expand the market for EPs, as well. Using an analogy shared by the company, PICDs are like an air bag: they prevent death when an accident (sudden cardiac arrest) occurs, but they also lead to additional service and maintenance work. When a patient with a PICD experiences an electric shock, he will visit his IC. Chances are he will then be referred to an EP, since this is what ICs do for their patients with an arrhythmia. Coming back to the airbag analogy, the IC installs the airbag (PICD), but when the airbag inflates (sudden cardiac arrest), the patient – now a secondary prevention patient – is sent to the EP for treatment/repair, potentially with a more complex, traditional ICD.

Despite their early hypothesis that both IC and EPs would respond favorably to the need for a less invasive solution, Starling and cardiologist Richard Stack (the other company co-founder) did not leave anything to chance. Toward the beginning of the biodesign innovation process, they assembled an advisory board of internationally recognized scientific thought leaders. They used this group of five ICs and five EPs to test their basic assumptions. Through this process, they confirmed that both the ICs and the EPs could see that a solution like the PICD would expand the practices and markets for both specialties. Also, it became clear to them that ICs would want to use these devices. Since EPs would be central to the early adoption of the technology, the clinical trials would be largely managed by EPs. This was partly a pragmatic business decision (EPs have deep experience running trials with ICDs, so the trial design would be more readily accepted by the FDA). However, it was also a savvy business strategy that would create a greater sense of buy-in for the device among EPs (by positioning the PICD as a device for them, yet one that could also be used by ICs in patients that the EPs did not normally treat), thereby helping to minimize any potential conflicts.

Beyond that, Starling and Stack were careful in considering all other possible stakeholders in deciding to move forward. A summary of the key stakeholders, their concerns, and how the company ultimately believed each stakeholder would respond to the PICD is shown later in this chapter in Table 2.3.1.

One stakeholder "wild card" that emerged when the company was about five years into development was the reaction of payers to the new technology. While reimbursement codes were in place that would cover PICDs, there was always the risk that once PICDs become widely adopted, major payers would seek to revise the payment levels downwards to physicians and facilities, in order to reflect the lower duration and lower complexity of using and implanting PICDs compared to ICDs. In fact, following the release of MADIT-II, there was widespread informal agreement among major payers that if the technology achieved 100 percent penetration it would have a significant negative effect on their income statements. InnerPulse wondered if payer reactions to the introduction of PICDs could create obstacles to their vision of expanding the market for ICDs.

Starling was convinced that any payer-related issues would be minimal and could be managed by the company. ICDs addressed such an important medical need that efforts by payers to reduce reimbursement or restrict coverage would backfire, he asserted. History seemed to support his belief: Medicare analyzed the results from the MADIT-II and SCD-HeFT trials to argue that not all primary prevention candidates should get ICDs. However, clinician opposition was so strong that Medicare had to backtrack shortly afterwards. Starling maintained that the same dynamics that overcame payer resistance in the past would play to InnerPulse's advantage in its quest to expand this market.

Unfortunately, InnerPulse hit a bump in the road that had little to do with its assessment of the stakeholder landscape. During animal tests, the team uncovered problems with the lead that connects the PICD to the heart. According to Stack, "Addressing the problems with the lead will take a lot of time and a lot of tests,"[43] which has delayed the company's market launch indefinitely.

As noted, the InnerPulse team believed that if there was sufficient interest on the part of the adopting physicians – the interventional cardiologists – it eventually would be able to win the support of Medicare and other payers. However, since the time this case was written, gaining reimbursement has become increasingly challenging. As a result, the importance of payers as stakeholders and critical decision makers should not be underestimated. Innovators should keep in mind that the relative power of stakeholders can change significantly over the extended period of time required to develop and commercialize a new medical device and factor these dynamics into their stakeholder analysis when possible.

A second story about Daktari Diagnostics, Inc. provides another example of important learnings through stakeholder analysis. In this case, the role of another important stakeholder – governments – is emphasized. In some settings, governments are dominant gatekeepers to many activities that affect the adoption of new medical technologies. For instance, in China, the private sector currently does not play a sizable role in healthcare delivery as the government has vastly expanded its role in healthcare delivery over the last decade. Private-sector hospitals account for less than 10 percent of care delivered to patients in urban facilities. Private grassroots clinics treat 50 percent of patients in rural China.[44] The Ministry of Health is responsible for the bidding and tendering system used in public hospitals to purchase new medical equipment. Tenders, which are issued at the province level, set prices that are subject to a ceiling in most parts of China. They also provide medical device manufacturers with a point of entry into hospital procurement departments. Since 1999, China has required a

formal tendering process for public health centers to purchase medical equipment. This has increased the transparency of purchases and reduced prices for end **users**. However, this approach raised costs for device makers (through tendering fees and bid bonds), lengthened purchase cycle times, and increased bureaucratic red tape. The tender process favors domestic manufacturers, which benefit from wide distribution networks, cultural affinity with government officials, and highly competitive prices. For instance, Shanghai authorities in recent years fixed the ceiling price for procedures using coronary stents at a level below the price of imported stents. As a result, only patients who can afford to pay the price difference normally choose an imported stent over a locally made one. Similarly, reimbursement rates for imported devices, which vary by locale, may be less than the rates fixed for domestic devices.

In contrast, the role of the government in India is much more fragmented, primarily because the health system is so heavily privatized. As in China, public healthcare facilities use central government or state level tender processes to procure medical supplies. These processes vary from state to state and can be bureaucratic and difficult to break into for new companies. And, unfortunately, the medical device manufacturers that invest the resources to navigate these time-consuming tenders only gain access to a small percent of the total market. Less than 10 percent of care is delivered in public facilities in India. Although exact figures vary by region, the private sector accounts for roughly 90 percent of all hospitals, 85 percent of doctors, 80 percent of outpatient care, and 60 percent of inpatient care.[45] To access the rest of the market, innovators and companies have to find points of entry to the scores of private hospitals and clinics that differ in their procurement practices. As a result, many end up engaging regional distributors that have devoted years to developing relationships with doctors and procurement personnel in private facilities.

In Africa, where Daktari Diagnostics has been working, many of the major markets are truly consolidated, with the government acting as both the primary provider of modern healthcare and sole purchaser of medical technologies. As a result, the government is the key decision maker. If a company is able to convince the Ministry of Health to adopt a new offering, it has access to the vast majority of the country's population. However, these kinds of agreements must be negotiated on a case by case basis across Africa's 55 internationally recognized states. And, as illustrated by the Daktari example below, convincing a government to make an adoption decision can be a complicated undertaking in its own right.

FROM THE FIELD — DAKTARI DIAGNOSTICS

Understanding governments in Africa as a key stakeholder and critical decision maker

Sub-Saharan Africa bears nearly 70 percent of the global HIV burden, with approximately 23 million infected people living in the region.[46] Fueled by the widespread availability of rapid HIV-antibody diagnostic testing, African countries and other low-resource settings have seen significant increases in the number of adults who have had an HIV test and know their status.[47] Support from governments and international organizations has also led to the expanded availability of antiretroviral (ARV) medication to treat HIV+ patients. In 2011, 6.2 million people in the region – or 56 percent of all eligible patients – received ARV therapy (compared to a global average of 54 percent).[48] In less than a decade, access to HIV treatment in sub-Saharan Africa increased more than 100-fold.[49] However, to initiate, stage, and sustain ARV treatment requires careful monitoring of the patient's CD4 antibody count. While flow cytometry diagnostic tests for CD4 cell counting exist in the market, they are expensive, complex, and not broadly accessible to patients and their care providers in low-resource settings.

More than a decade ago, Bill Rodriguez was among the global health pioneers working to expand access to ARVs in a variety of low-income areas, such as Haiti, Vietnam, and South Africa. As an HIV specialist at Harvard Medical School, he advised Ministry of Health officials in several developing countries on how to test and treat HIV+ patients, and ran training programs for healthcare providers there. Later, he became a member of the World Health Organization (WHO)'s HIV Guidelines Committee, which produced global guidelines for HIV care. Through these interactions, he learned first-hand about the barriers associated with CD4 cell count testing, which prevented healthcare providers from delivering adequate care. "I repeatedly heard, 'We need a better test for measuring a CD4 cell count. It needs to be simple and easy to use by doctors and nurses in the field. It needs to deliver results in 15 minutes. And it needs to be inexpensive,'" Rodriguez recalled.

When Rodriguez joined the Clinton Foundation in 2003 as its Chief Medical Officer, he was part of the team that brokered large-scale deals between pharmaceutical companies, diagnostic providers, and Ministries of Health, initially in various African countries, and then throughout the developing world. Even as these discussions progressed well, and affordable ARVs became widely available, he continued to receive the same feedback about CD4 cell count testing, but now it was coming from Ministry officials and representatives from multilateral organizations like the **WHO**, as well as clinicians in the field. "In my role as CMO, I would get emails and phone calls on a daily basis," Rodriguez said. "It was a variety of voices, all saying the same thing, which is that we are desperately in need of new technology for diagnostics." Eventually, he felt the unaddressed need in this space was too great to ignore. Rodriguez left the Clinton Foundation and founded Daktari Diagnostics to develop simple, affordable, and accurate diagnostic tests for developing country settings. The CD4 cell count test is the organization's first project.

Relying on his extensive global health experience, Rodriguez focused on five main stakeholder groups with an interest in the CD4 cell count test. "The patients are the primary stakeholders, because they are the ones who are dying in the absence of adequate care," he explained. While not decision makers about what test will be used, patients are relatively influential given their prominent position in the cycle of care. Patients are often represented by advocacy groups such the Treatment Action Campaign (TAC) in South Africa, or The AIDS Support Organization (TASO) in Uganda. Next are healthcare providers, including physicians, nurses, and community health workers. These individuals would utilize the test to prescribe and manage ARV therapy for their patients. Front-line healthcare providers are the ideal source of information about the clinical need and requirements for a new test. Like patients, they can influence decisions, but are usually not decision makers themselves. In many African countries, most healthcare is delivered through the public sector, particularly to the poorest people. Representatives from the Ministry of Health (MoH) are the key decision makers for the selection and procurement of medical products that are made widely available. Ministries of Finance also have to be persuaded to pay for new technologies, but they generally follow the recommendations of the MOH technical specialists. Finally, global government and international development agencies such as the WHO, the Global Fund for TB, AIDS, and Malaria (GFATM), the Joint United Nations Programme on HIV/AIDS (UNAIDS), Médicins Sans Frontières (Doctors Without Borders) and the US President's Emergency Plan for AIDS Relief (PEPFAR) are also major stakeholders. They tend to be influential in recommending which technologies should be used and how they can be effectively deployed. In some cases, they also provide subsidies to developing world governments, and some non-governmental organizations, to help underwrite the development of new technologies and/or make them more affordable to their intended audience.

Daktari initially focused its information gathering on patients and clinicians, to better understand the need for an improved CD4 cell count test. Rodriguez and his team talked at length with representatives of these stakeholder

groups, and began creating use cases to better understand the requirements for the solution Daktari would ultimately develop. Sharing an example, Rodriguez said, "Consider a healthcare worker. Her name is Molly. She packs her bag in the morning with batteries, gloves, and the equipment she needs. The bag weighs 3.5 kilos, and contains her diagnostic device and all the supplies she needs for a day's work. Her work environment varies between 10 and 40 degrees Celsius. She visits 30 patients a day, walking through dusty or rainy roads, or traveling by car or motorbike. And so on." The team tested these use cases with experts in the field, and then leveraged them as a guide for creating detailed design specifications, market requirement documents, and product requirement specifications for the new test.

The Daktari team also began to engage with decision makers at the MoH in several African countries to understand their point of view. As noted, government stakeholders had generally expressed interest in a more cost-effective CD4 cell count test. But when Rodriguez began talking with them in more concrete terms, they voiced an unexpected amount of skepticism that a device could be built at a low enough price point to be widely deployed in the field. Rodriguez highlighted that this could be one of the difficulties faced by young organizations: "They think, 'Why are you, a start-up company, going to be able to solve my problem, when none of the large medical equipment manufacturers have been able to do it?'"

Daktari decided to press forward with product development despite the skepticism. However, the team committed itself to learning more about the unexpected opposition it was getting from key decision makers in government. As Rodriguez and his colleagues gained a more sophisticated understanding of the government's role, they realized that by developing a field-based, point-of-care (POC) test, they would be creating a "major headache" for program managers at the MoH. As he described, "Imagine a Central Program Manager at a MoH, who is used to having every CD4 test happening in a centralized facility near her. She can check the results, see if the test results are accurate, the equipment is working properly, the technicians are up-to-date on their training, and if the treatment decisions are appropriate. A POC test puts the care provider, the patient, and the test result in the same room at the same time," but reduces the visibility and control of the program managers. "They feel blind," Rodriguez added. In order for a new test to be adopted, the team would have to find a way to give the program managers better visibility and on-demand access to the information they needed to stay actively involved. "We envisioned a dashboard, accessed online or on a mobile phone, that shows where things are going right, and where things are going wrong," he stated. This became an important part of the **need specification** because, without the program managers on board, "there was no product."

Another factor that the Daktari team wrestled with early in the biodesign innovation process was how much value a new test would have to deliver in order to compel the various stakeholders to change their behavior and embrace the new technology. Initially, Rodriguez thought about this issue in terms of a basic cost-effectiveness trade-off. The CD4 cell count tests performed by central labs were extremely accurate, but expensive and slow. A POC diagnostic would be fast and inexpensive, but inherently less accurate. Daktari believed that its test had to strike a perfect balance between accuracy and cost that would satisfy clinicians, decision makers, funders and payers alike. Rodriguez explained, "We framed the tradeoff not as between perfect and imperfect information, but instead between no information and really good information." He and his teammates "shopped around" various scenarios, but ultimately had to trust their own instincts about which value equation would be persuasive enough to MoH representatives to get them to purchase the test, while also meeting the very specific, important needs of patients and clinicians.

When asked for his advice on effectively pursuing a need that involves governments in developing countries as a primary stakeholder, Rodriguez shared a number of ideas. First, he noted that the purchasing process can take some time. In particular, MoH representatives will often want to conduct a local study to generate clinical

data specific to their environment. Even if the manufacturer has run clinical trials in a neighboring country, the MoH is likely to conduct an independent trial. "Every country wants its own small study, in their environment, to vet the product," he said. The organization will be asked to provide the product and offer support, yet it may be given little control over how the study is designed. Additionally, Rodriguez stated that having a **CE mark** or FDA regulatory approval is a necessary pre-condition of submitting a government bid for most medical products. ISO 13485 certification is also required. He also mentioned that one way organizations can differentiate themselves in the tender process is by anticipating the government's need for post-market service and maintenance of medical products. "Governments are used to lots of broken, unused equipment. Innovators have to be able to convince the MoH that they have a plan for servicing their product."

Finally, Rodriguez pointed out that in pursuing government customers, "There are a lot of relationships involved. And it's a pretty complicated stakeholder landscape." More than anything, he said, innovators should seek to add individuals to their teams who have significant, first-hand global health expertise and the deep stakeholder relationships that only can be acquired through years of work in the field. "If I were an innovator with a global health technology, I would be very hesitant to go after this without someone experienced, who had worked in global health for a few years. By now, there are many people out there with the requisite experience from working with foundations, multilateral organizations, drug companies, or governments. And I would turn to them for their expertise."

FIGURE 2.3.6
Health workers with the Daktari CD4 in the field (courtesy of Daktari Diagnostics).

As of late 2013, Daktari had developed a fast, easy-to-use diagnostic designed specifically for low-resource settings that uses microfluidics and electrochemical testing to provide CD4 cell count results in the field (see Figure 2.3.6). The Daktari CD4 test is in late-stage product development and testing, with its first commercial sales expected in mid-2014.

Output from stakeholder analysis

After a stakeholder analysis is complete, an innovator should compile the information into a comprehensive summary of the stakeholder environment. Table 2.3.1 provides a sample of that output for InnerPulse. It summarizes the key stakeholders, identifies the decision maker(s), outlines the primary benefits and costs associated with a new solution to address the defined need, and provides a subjective assessment of the overall net impact of a new technology on each group. Importantly, this example deals with a stakeholder analysis for which the solution is already known. In most cases, at this stage in the biodesign innovation process, the innovator should not yet have defined a solution. As a result, the

Table 2.3.1 The sample stakeholder analysis for InnerPulse demonstrates how the key take-aways from a stakeholder analysis can be summarized in a concise, actionable format.

Stakeholders	Role	Primary benefits	Primary costs	Assessment of net impact
Payers	Decision maker	Expansion of life saving technology to many patients who could benefit from it.	Increased costs.	**Negative**: Total cost of delivering defibrillator therapy will go up. Will they try to reduce reimbursement for ICDs and/or PICDs, given that PICDs can be implanted more quickly?
Physicians: interventional cardiologists (ICs)	Influencer	Expanded practice and market, additional revenue. Allows for retention of primary prevention patients without need for EP referral.	Learning of new procedure.	**Positive**: ICs are typically quick to embrace new technologies that expand their market, especially if combined with an attractive reimbursement.
Physicians: electrophysiologists (EPs)	Influencer	Expanded overall referrals from ICs of primary prevention patients who develop arrhythmias and thus become secondary prevention patients.	Possible loss of primary prevention patient referrals.	**Neutral**: EPs seemingly are interested in using PICDs and, by nature, prefer to focus on complex arrhythmia cases not seen by ICs; but any loss of patient referrals could be perceived as a threat.
Facilities: EP labs and IC catheterization labs	Influencer	Increase device implantation volume for EPs and ICs.	Overall costs, including expensive components, for EPs and ICs become similar.	**Positive**: As long as reimbursement for PICDs remains the same as for ICDs.
Patients	Influencer	Reduced invasiveness compared to traditional ICDs. More convenient, shorter recovery time.	Need for re-implantation after a documented arrhythmia.	**Positive**: Reduced invasiveness expected to increase patient's comfort with the procedure – but ultimately will defer to advice from physician

stakeholder summary would capture the *potential* factors that might stimulate adoption or resistance. As more becomes know about the eventual solution, the stakeholder summary can be made more specific until it resembles the example. At this point, it can serve as the foundation for developing specific stakeholder management strategies and to facilitate decisions about how much time and energy should be invested in winning over each stakeholder group. It can also be leveraged to help forge important relationships and develop key messages appropriately targeted at various stakeholder groups (see 5.7 Marketing and Stakeholder Strategy).

Ethical considerations in stakeholder analysis

As described in 1.1 Strategic Focus, ethics focus on the intentional choices people make and the basic moral principles they use to guide their decisions. They do not provide a specific value system for making choices, but rather a set of basic principles to follow in decision making and in ethically managing the conflicts of interest that these choices may create.[50]

Stakeholder analysis informs the innovator about the types of interests that could be affected by a given decision, and can help identify potential conflicts that may arise. Personal interests (what is best for the individual making the decision), social interests (what is good for a community or society at large), and professional interests (what is good for the company or the patient/client) are factors that usually need to be considered when making almost any decision. At times, these interests are aligned and the level of conflict is low. At other times, they directly conflict and the "right" answer may not be obvious. For example, how will dialysis centers react to an innovation that makes kidney transplants more available?

As a general rule, innovators must make every effort to avoid putting stakeholders in a position that might potentially compromise their ethics. This can be accomplished if the innovator systematically uses a code of well-established ethical principles in interacting with each stakeholder group and making choices available to them (this involves treatment options offered, but also treatment options withheld). As profiled in 1.1 Strategic Focus, key ethical principles for medical device innovators include truthfulness, fairness, beneficence, non-maleficence, respect, and confidentiality.

An appreciation of these principles by innovators not only helps them think through their own choices, but can explain why stakeholders might potentially resist the adoption of a new innovation if it presents an ethical dilemma according to these guidelines (e.g., trying a new treatment if there are questions about its efficacy or safety as compared to other options). For example, this issue was seen in the case of left ventricular assist devices (LVADs), which are mini-pumps implanted into the chest to help a patient's failing heart pump blood. LVADs were initially approved as a temporary "bridge" to help maintain the functioning of the heart while patients with severe heart disease awaited heart transplantation. The FDA eventually approved LVADs for permanent use in terminally ill patients who were not eligible for a heart transplant due to comorbidities or age.[51] However, despite the fact that the LVAD manufacturer had completed FDA approval, achieved relatively strong clinical data that showed improved survival rates compared to drug therapy, and launched an aggressive marketing campaign, physicians resisted widespread adoption of the treatment based, in part, on poor economics (the procedure was reimbursed at a fraction of its actual cost).[52] More importantly, physicians raised concerns about LVAD-related infections, which often were quite serious. Without effective clinical evidence to verify the magnitude of the infection risk, physicians did not perceive the potential benefits to their patients as adequate to justify the increased safety risk under the guideline of beneficence, or the obligation to do no harm. As a result, they were slow to adopt the innovation in large numbers.

While this response alone created significant resistance to the technology, the interpretation of the LVAD example is even more nuanced. With healthcare budgets continually being squeezed, physicians increasingly recognize that expensive technologies strain patient access to care. In the case of LVADs, one could reasonably argue that certain physicians resisted their adoption because they considered it unjust in the face of severe budget constraints. Some questioned the fairness of spending upwards of $200,000 on a device with a questionable benefit and serious safety issues while other patients had difficulties obtaining access to more basic care. Although such megatrends are always in the background of decisions, it is inevitable that individual physician judgments will play a role in decisions that impact patients. Innovators should try to anticipate how such individual value judgments may affect the adoption of a new innovation.

As noted previously, the risk–benefit ratio associated with a new technology ultimately drives its adoption. Medical ethics dictate that physicians carefully balance and discuss the risks and benefits of any treatment with their patients. Regulatory authorities make decisions to approve devices by evaluating evidence on their safety and risk at an overall system level. However, when physicians evaluate the same data one-on-one with a patient, the risk–benefit ratio might look significantly different. Physicians in the field are empowered (and obligated) to

make their own decisions, together with their patients. Their own personal experiences in successfully and (perhaps more importantly) unsuccessfully treating a disease may often be a stronger force in their decision making than clinically validated evidence, especially with regard to issues of safety. When the risks are grave, they may not recommend a treatment to a patient even if, for example, it has been shown statistically to prolong the life of a terminally ill patient, as the LVAD example illustrates. While there is a certain group of "early adopters" in any medical field, the majority of medical personnel require evidence of safety and effectiveness demonstrated in a substantial number of patients before implementing a new technology. This extends to including a broad spectrum of patients with any condition to be addressed in studies to demonstrate the benefit of the innovation. These ethical issues need to be applied to considerations of each stakeholder: the patient, the medical personnel applying the technology, those buying the technology, those paying for the technology, and the support groups.

Online Resources

Visit www.ebiodesign.org/2.3 for more content, including:

Activities and links for "Getting Started"

- Identify stakeholders
- Outline benefits and costs for each stakeholder group
- Summarize net impact and key issues for each stakeholder group
- Classify stakeholders and assess trade-offs

Videos on stakeholder analysis

CREDITS

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