4.4 Business Models

INTRODUCTION

"It seemed like such a good idea, but why did it fail?" asks the frustrated engineer. "Hospitals are capable of purchasing massive million-dollar imaging systems in this specialty, so why were they so resistant to buying disposables?" Even though the total cost per year of this innovator's idea was comparable to (or even less expensive than) the established device solution, there was a fundamental problem that he failed to overcome. The flaw was in designing and executing the business model. Sometimes an idea can be medically compelling, capable of clearing all regulatory hurdles, and manufacturable at a profit, but if the business model does not work, the business will fail. Innovators must consider the business model as one of the key factors that affects an innovation's success, and as an issue that requires as much vetting as the feasibility of the device.

OBJECTIVES

- Understand the different types of business models that are typically utilized in the medical device field, including their relative advantages and disadvantages.
- Determine how to choose an appropriate business model based on the unique characteristics of the innovation and its customers.
- Appreciate how to use business model risks as a screen for prioritizing concepts.

A business model broadly refers to how an offering (e.g., a product or service) is defined and the way it will generate revenue and deliver value to customers. In the medtech field, common business models include disposables, reusables, implantables, and capital equipment, although many others exist. With each of these models, offerings make money in different ways and, in the process, pose different challenges to the innovator in terms of how the company organizes its resources, operations, and business processes. The business model also dictates, to some extent, how interactions with customers and other external stakeholders should be managed to achieve mutually beneficial results. Just as a company needs to assess the intellectual property (IP), regulatory, reimbursement, and technical feasibility of its ideas, it should evaluate the appropriate business model before selecting a final concept.

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BUSINESS MODEL FUNDAMENTALS

The business model is often the forgotten axis of innovation, arrived at by default after all other aspects of the product or service are determined. If an innovator recognizes that considering alternative business models is yet another design variable to be utilized in achieving the customer's **needs**, the innovation will have its greatest chance of success.

Regardless of where in the world an innovator is working, the defining characteristics of any business model are:

1. The innovation, which could be a product, service, or blend.
2. The customer.
3. The primary interface between the two, or the way they interact.

The dominant factors that affect interactions between the customer and the innovation are shown in Table 4.4.1.

When innovators choose a business model, they must take these factors into account. The idea is to design an offering that plays to the strengths and capabilities of the company while providing the customer with a desirable interaction.

Choosing a business model

During the **concept** screening stage of the biodesign innovation process, selecting a business model starts with an evaluation of the match between the unique characteristics of the innovation and the defining aspects of the different business models. The revenue stream and manner in which the innovation will get into the customers' hands are two other primary considerations. The information necessary to more fully develop the business model will be extracted from the other steps in the process as the innovation continues to progress.

Table 4.4.1 Each of these factors can change dramatically based on the business model chosen for an innovation. Understanding the impact of the business model choice and its influence on these factors can allow an innovator to determine which business model is the most favorable and compatible with success.

Factor	Explanation
Revenue stream	How revenue is generated and its frequency.
Price	How much the business can charge for its products or services.
Margin structure	The profit to the company from sales (and its adequacy to support the inherent characteristics of the chosen business model).
Sales investment	The required mechanism for getting the innovation into customers' hands.
Customer training requirements	The extent to which specialized training is required to utilize the innovation.
Competitive differentiation	The degree to which the innovation is unique.
IP	The importance of IP protection to the success of the business model.
Other barriers to entry	Factors that could serve as barriers to adoption (e.g., high **switching cost**, brand or customer loyalty, access to distribution channels, etc.).
Clinical/regulatory hurdles	The complexity and duration of clinical requirements (e.g., trials) and the necessary regulatory pathway before commercialization can begin.
Reimbursement	The way physicians, surgical centers, and hospitals are paid.
Financial requirements	The level of investment necessary to develop and commercialize the innovation.
Culture/geography	The extent to which customer needs related to the same clinical area differ across geographic boundaries or different cultural environments.

An appropriate business model must allow the company to extract **value** for its innovation in a way that makes sense to the customer. For example, if a new company tries to market an MRI machine by charging for the equipment and then requiring hospitals to buy a disposable platform for each patient tested, it might have difficulty generating interest.[1] Even if the company offers to service the machine for free (creating an ongoing revenue stream through the sale of the disposables rather than through a service contract, as is typical in this field), it is likely that the buyer would object. Most customers understand the value of paying for a service contract to keep their expensive, high-utilization equipment in good repair. However, it is much harder to convince them to pay for something, such as a disposable in this case, for which they do not understand the need or appreciate the value – especially if the MRI machines from competitors do not have the same associated charge.

Acclarent, a company that manufactures and markets endoscopic, catheter-based tools to perform what is known as *Balloon Sinuplasty,*® a procedure in which a balloon is used to dilate various areas of the sinuses, provides a real-world example. In the ear, nose, and throat (ENT) specialty, companies have traditionally pursued models that are dependent on selling high volumes of inexpensive disposable materials and smaller numbers of moderately priced reusable products. Acclarent sought to change the field's dominant business model by selling higher-value disposables that cost more per patient but lead to improved results. Such a change is difficult, but not impossible if the innovation's performance is substantially better against one or more metrics that are important to the customer. As one board member described (prior to the acquisition of Acclarent by Johnson & Johnson in 2010):[2]

> *Whenever you try to extract more value from an established market, you have to be sure you can deliver more value through your product or service. The reason Acclarent has been successful in moving the market is that the products provide improved clinical performance and save money in the overall treatment of the disease.*

Of course, anytime a company seeks to change a dominant business model, it automatically takes on a market development challenge. Incremental investment (and often a significant commitment of time) is required to adjust customer expectations, modify their perceptions, and/or alter their behavior. However, the possibility of "changing the game" in an industry or field can also be the deciding factor that makes an opportunity interesting. Hypothetically, selling Acclarent's technology as a low-margin disposable might not have made a compelling business proposition. However, through the lens of a different business model (higher margins, lower volume), the opportunity became viable.

Importantly, many diverse business models are relevant within the medical device field. Investors have historically favored models that generate an ongoing revenue stream or an annuity (e.g., disposables, implantables, or capital equipment with an associated service contract), as opposed to pure capital equipment businesses. However, numerous **medtech** innovators have proven that different approaches can be successful. In some cases, making a creative twist to a traditional business model has been the factor that permitted a solution to succeed. For example, innovators have devised approaches where a technology is provided in advance at little or no cost and the **user** is only charged per use (regardless of the consumables required). Or, a device is offered in a "resposable" format that allows a certain number of reuse cycles before it is thrown away. Because some individuals and companies have shied away from novel business models in the past (seeking to attract investor interest more easily), innovative approaches to medical device businesses have inevitably been overlooked. For this reason, as technologies continue to advance, innovators and investors alike should anticipate the emergence of an increasing number of non-traditional medtech business models in the coming years.

Another trend is to play with the factors in Table 4.4.1 that affect interactions between the customer and the innovation in order to make traditional business models work under increasingly difficult circumstances. In fact, this movement is being led by innovators seeking to bring important medical technologies to underserved populations in low-resource settings. Again, the

FIGURE 4.4.1
The first baby treated using D-Rev's Brilliance device in Ogbomoso, Nigeria (courtesy of D-Rev).

fundamental business models are the same in these environments, but the ways in which they are implemented may be different. D-Rev, a non-profit product development company whose mission is to improve the health and incomes of people living on less than $4 per day, is one company experimenting with creative approaches to addressing these factors when defining business models for its products. With the Brilliance device, a reusable treatment for infant jaundice (see Figure 4.4.1), D-Rev used grants and other forms of philanthropic funding to underwrite R&D and operational costs to take pressure off the amount of revenue it would need to generate from product sales. This, in turn, contributed to the organization's ability to price the product affordably for healthcare providers in markets such as India (Brilliance would sell for roughly $400 per unit versus $3,000 for comparable products). To commercialize the device, D-Rev set up a manufacturing and sales partnership with Phoenix Medical Systems, a for-profit medical equipment distributor with well-established channels across the country, so it would have a reliable and sustainable way to get the product to the providers who needed it most. Phoenix licenses the technology from D-Rev in exchange for licensing fees and **royalties**. The D-Rev team got especially inventive in thinking about the margin structure that would underpin this agreement. To motivate Phoenix sales representatives to devote time and energy to selling Brilliance, the team knew it needed to offer fair but competitive rates. But to entice Phoenix to target providers in India's public and district hospitals who need the technology the most, rather than primarily higher-end, urban facilities that are easier to reach and better resourced for making equipment acquisitions, D-Rev believed it needed a special incentive. Ultimately, it devised an approach that would make Brilliance available to customers across all locations and market segments at the same price, but D-Rev would take a lower royalty on sales to public and district hospitals. By making interactions with this audience more lucrative, D-Rev hoped that Phoenix would be more focused on reaching these target providers.[3] While the approach appeared promising, only time would tell if it would yield D-Rev's desired results.

Types of business models

As noted, there are multiple types of business models for medical device innovators to evaluate and optimize to their unique innovations. When assessing each one, innovators should be looking for a good fit between the innovation and the business model such that a meaningful, growth-oriented, and profitable business can be envisioned. The 10 business models included in Figure 4.4.2 and described below in more detail are among the most commonly employed medtech models. While certain ones may be more common in different geographies, the fundamentals of the models are the same worldwide. Clearly, a model can only be considered to be functional in any environment once it has proven to sustainably permit the organization to grow profitably.

Disposable products

Disposable products are those goods that are used and then discarded without being reused. Low-cost disposables include items such as paper examination gowns and stopcocks (used with intravenous tubing), both of which might costs pennies per unit. A surgical stapler is an example of a more expensive disposable, which might cost $100 or more for a single per-patient use.

Business model	Margin structure	Sales investment	Importance of IP	Barriers to entry	Customer training	Clinical/ regulatory hurdles	Financial requirements
Disposable – High Cost	High	High	High	High	High	Neutral	Neutral
Disposable – Low Cost	Low	Low	Low	Low	Low	Low	Neutral
Reusable – Pure	Low	Low	Low	Low	Low	Neutral	Low
Implantable – Mid to High Cost	High	High	High	High	High	High	High
Capital Equipment – Pure or Combined	High	Neutral	High	High	Low	Neutral	High
Service – Pure or Attached to Product	Low	Low	Low	Low	Neutral	Low	Neutral
Fee per Use – Pure or Combined	Neutral	High	High	Neutral	High	High	Neutral
Subscription	Low	Low	Low	Low	Low	Low	Low
Over the Counter – Pure or Combined	Neutral	High	Neutral	Neutral	Low	Neutral	Neutral
Prescription – Pure or Combined	High	High	High	High	High	High	High
Physician-Sell – Pure or Combined	Neutral	High	Neutral	Neutral	Neutral	Neutral	Neutral

FIGURE 4.4.2

Every medtech business model has an expected set of opportunities and challenges that dramatically impacts the plan for the business.

Disposables can also be attached to major medical equipment, such as ablation catheters used in combination with generators that produce the energy for ablation. Additionally, they can be coupled with reusable devices (used several times before requiring replacement), such as disposable razor blades for reusable surgical shavers.

Whether they are attached to medical equipment or reusables, low-cost disposables:

- Require high sales volumes (to compensate for low margins).
- Must be easy to use.
- Should be marketable through low-cost distribution channels (e.g., medical equipment catalogs).

Higher-cost disposables typically require specialized training to use and, as a result, demand significantly higher margins in order to support a technical sales force and ensure a reasonable level of IP coverage. To justify a higher-cost disposable, the innovator must achieve competitive differentiation (e.g., enabling superior clinical results or establishing key barriers to entry to the competition). Gross margins are usually favorable for most high-cost disposables and can be in the 70–80 percent range (or better). If pricing for a disposable is pegged in such a way that it is unrealistic to achieve margins close to this range, it may be an indicator that this is the wrong business model for a given technology.

In terms of their advantages, disposable products generate a regular revenue stream since customers must acquire them on an ongoing basis. In addition, as the volume of procedures increases (a goal of most healthcare providers), so too does the volume of the

disposables used. Often, their value is directly correlated with a specific event, so it is easy for customers to understand – for example, every time a provider draws blood, a disposable syringe is required. Finally, based on their relatively low cost and rapid turnover, there is little risk to the buyer in trying a disposable. This can make it much easier to convince decision makers, such as purchasing managers or physicians, to place an initial order.

On the downside, there are ethical issues to consider that are associated with the environmental consequences of disposable medical devices. Innovators must also be aware that, in some cases, disposable products can easily be displaced by reusable products that meet the same need, if the **value proposition** is compelling.

The Concentric Medical example below highlights some of the issues relevant to a disposables business model.

FROM THE FIELD CONCENTRIC MEDICAL

Pioneering devices in the stroke market using a disposable model

According to Gary Curtis, former CEO of Concentric Medical, stroke affects more than 700,000 people in the US each year. Approximately 85 percent of those patients experience an ischemic stroke (caused by blockage in an artery supplying blood to the brain). Yet, despite the large number of people suffering from ischemic stroke each year, "The **standard of care** for 95 percent of these patients is aspirin and a dark room," said Curtis. Intravenous recombinant tissue plasminogen activator (t-PA), a medication used to dissolve the clots that cause blockages, can be used in some cases of ischemic stroke, but only if it can be administered within three hours from the onset of symptoms. For everyone else, Curtis continued, "they have to wait passively to see how the stroke resolves so that then, a day or two later, a neurologist can consult with the patient's family and tell them their Aunt Martha is lucky enough to go home. For Uncle Harry, on the other hand, his stroke didn't resolve itself and he's going to a nursing home. Dad is kind of in between. He'll need some rehab and then maybe he'll get some of his normal function back."

Concentric Medical is seeking to change that model. "We are trying to change passive to active," explained Curtis when he was at the company's helm. Using the Concentric's Merci Retrieval System™ (see Figure 4.4.3) to restore blood flow in ischemic stroke patients by removing blood clots in the neurovasculature, "We can now intervene within a reasonable time period. Our trials

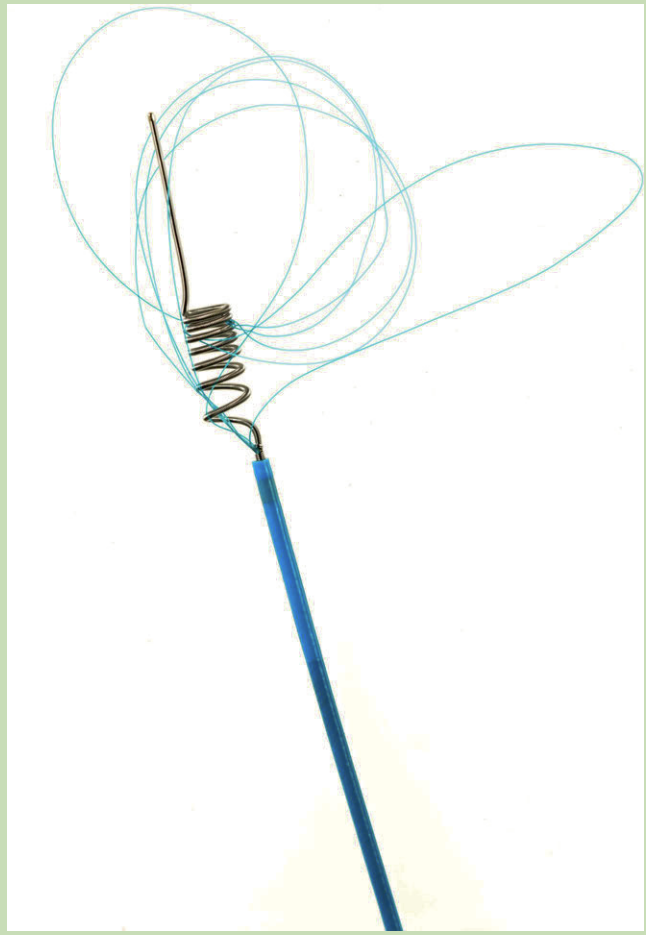

FIGURE 4.4.3
The Merci Retrieval System (courtesy of Concentric Medical).

showed that if we intervene and reopen an artery within zero to eight hours, less damage is done. We can change the course of events. It's the first time that's been done," he noted.

When Curtis became Concentric's CEO, the company was working on multiple projects but was having difficulty getting funding. Recognizing the stroke market as the largest unmet need with the most compelling technology in development, he quickly cut all other products in the development pipeline, gained funding for the Merci Retrieval System by promoting the company's improved sense of focus, and led Concentric to the first **FDA** approval of a device to remove thrombus in ischemic stroke patients.

In terms of a business model that would best support Concentric's product, the company's choices were somewhat limited due to the sterilization issues associated with products that come into contact with the bloodstream. "It has to be guaranteed sterile when you use it," said Curtis, which led Concentric to a single-use (disposable) model. "We never even contemplated another model. The device also has to have mechanical performance expectations that are exactly the same every time. Device performance can be compromised as you're cleaning, sterilizing, or repackaging it. If we offered a reusable, all those activities would lessen the ability of the physician to predict how the product is going to perform."

According to Curtis, a business model built around a single-use, disposable device offers many advantages. "Clearly, the recurring revenue is a benefit. Once you get surgeons trained in how to perform the procedure safely, they're going to order the device again and again. We had spent roughly $35 million by the time we completed our first **clinical trial** to get the product approved before we got our first dollar of revenue. We're now trying to recoup that cost. Knowing that there would be this predictable revenue stream is one way we got the venture capital community to invest."

On the downside, he noted that single-use devices are costly to the healthcare system: "A hospital will pay $5,000 to us for every patient treated with our device. If we had a reusable product, they wouldn't have to pay that much." However, he commented, the costs associated with the disposable device are more than offset by the extreme long-term expense of caring for stroke patients "who survive, but survive poorly." That said, competitors are working on reusable technology to address the same need that is targeted by Concentric's device. For example, earlier in Concentric's development, one company was working on a device to break up the clots non-surgically by using focused ultrasound. "People are trying to develop reusable solutions to make treatment less costly," said Curtis, "but no one has proven that you can."

When asked if he worried about the environmental impact of disposable products, Curtis responded quickly: "I don't think two seconds about it. Not when I'm saving a life."

Importantly, Curtis confirmed that there is a difference between the business model used to support high-cost, single-use devices versus low-cost, high-volume disposables. With low-cost disposables, there is a constant, never-ending pressure from investors and customers regarding ways to reduce the cost of the product. "It's all about how you change your manufacturing costs from 5 cents to 4 cents, so you can make that extra margin," he said. "That's not our business model." Instead, Concentric remained focused on what Curtis called a value creation model. "All the pressure I [had was] how to make it more effective. How do I change from 50 percent to 60 percent to 70 percent to 80 percent success rate in restoring flow in these patients?" As a result of these efforts, and the efforts of Curtis' successor, Maria Sainz, Concentric was acquired by Stryker in late 2011.

Reusable products

Reusables are multi-use products with a moderate lifespan, but their cost is orders of magnitude smaller than a capital equipment item. Scalpel holders, laparoscopic graspers, and endoscopes are examples of products that can be reused for a period of time before they eventually wear out and need to be replaced. Reusables can be attached to a disposable (e.g., the surgical shaver mentioned earlier that is used with disposable razor blades) or a service (e.g., servicing of flexible endoscopes).

Business models built solely around a reusable product tend to have no sources of recurring revenue other than replacement. As a result, they generally cannot support a specialized sales force and are commonly sold through medical catalogs and/or through major distribution companies. Although the margins for reusables can actually be quite good – also in the 70–80 percent range – the lack of a sustained flow of cash, as compared to disposables, usually makes the size of the associated business opportunity smaller. Reusable products also carry with them a higher level of risk since customers use them for an extended period. The product is not "factory fresh" each time it is used (as is the case with disposables), so the user faces a greater chance of failure. For example, if surgical scissors become dull or are damaged during a procedure, they may not perform effectively the next time they are used. Many providers of reusables attempt to address this concern by providing service for their products. However, because the products have a finite lifespan (which is much shorter than the lifespan for capital equipment – see below), customers are typically unwilling to pay a great deal for maintenance. This contributes to the factors that make reusables a difficult business model to profitably sustain and grow.

Some entrepreneurs have attempted to force a disposable business model onto a technology that is clearly reusable (and there is no good case for disposability). However, this can be a risky move. If the reusability of an item is discovered, as it usually is, the business model can quickly change from disposable to reusable, outside the innovator's control. This, in turn, can have a negative impact on the business and significantly affect perceptions and expectation of the company. On the other hand, in some cases it may be appropriate for products that were originally designed to be reusable to become disposables. Syringes provide one compelling example. Despite relatively widespread awareness that syringes reuse contributes to the transmission of blood-borne pathogens, including hepatitis B virus, hepatitis C virus, and human immunodeficiency virus (HIV), up to 40 percent of worldwide injections continue to be given with syringes and needles reused without sterilization. This problem is particularly severe in low-resource settings where reuse rates can be as high as 70 percent.[4] The development and dissemination of single-use syringes is one way that manufacturers are helping to address the issue, and it represents an appropriate shift from a reusable to a disposable model.

In terms of advantages, customers intuitively respond to reusable products and often favor them over disposables when the business case makes sense. For example, one would not consider anything other than a reusable weight scale or reusable stethoscope in a doctor's office – the cost/benefit ratio of these devices is essentially unbeatable. Once reference devices such as these are introduced into a marketplace, a new technology which seeks to challenge the business model, even at a modest cost increase, is often highly scrutinized and has a greater risk of failure. This should not deter one from investigating improvements which deliver dramatically better outcomes or a significantly lower cost under these types of circumstances, but the innovator needs to realize that the bar will be set relatively high.

Implantable products

Implantable products are typically mid ($1,000–$5,000) to high (> $5,000) cost items. An example of a mid-cost implantable device is a coronary artery stent. Examples of high-cost implantable devices are pacemakers and artificial joints. Implantable products can be pure, or they can be associated with a service, such as pacemaker follow-up service. Implantable products tend to have high margins – in the 80 percent range or better – and these prices have traditionally been supported due to the high barriers to entry associated with the technology, such as the regulatory pathway, **reimbursement**, and IP requirements. However, a shift is underway in the segment. As these high-margin devices slowly go off

patent, new opportunities emerge for innovators to create generic versions. This causes the implants to become less differentiated and their prices to decline. Companies looking to preserve their margins must, in turn, focus on addressing new needs or creating different offerings that clearly deliver value to their intended users.

Implantable products require the highest level of clinical validation and, as a result, can present significant clinical hurdles to their developers. Because a major investment will be required to support comprehensive, long-term clinical trials, the market for implantable devices must be significant so that investors can recoup relatively sizable returns over a long-term payback cycle. Being able to ensure ongoing IP coverage is another essential aspect to the business model for implantable products.

One benefit of a business model focused on implantable devices is that there is a direct pairing of the value proposition and the procedure – every patient that receives the procedure gets one or more implants. As a result, implantables have an ongoing revenue stream whose growth is linked directly to the increase in the number of procedures performed each year. Additionally, since certain devices eventually wear out due to continuous use (e.g., heart valves) or battery consumption (e.g., pacemakers), patients may need replacement devices and, thus, provide a source of recurring revenue (although this may take many years to capture).

From a risk perspective, however, implantables represent a recurring liability to the company that manufactures and markets them. The challenge to the company is to design an implant that can be replaced or otherwise taken out of service before it malfunctions. Many implants serve a primary function, which is useful for a period of time and then yields to other physiologic processes which persist even after the implant is no longer functional (i.e., drug-eluting stents or resorbable drug delivery systems). However, even in these cases, the residual impact of the presence of the implant may present some risks that need to be managed and accounted for by the company. In addition, implantable products often require a **direct sales** force at the point of care to stay in touch, answer questions, and provide follow-up – a requirement that can be costly for a company to maintain. Although there may be some limited protection offered by legal provisions such as "preemption," under which devices approved in the US via the premarket approval (**PMA**) pathway are exempt from common law claims that impose requirements different from or in addition to FDA's requirements,[5] companies offering implantable products will continue to face liability risks.

FROM THE FIELD ST. FRANCIS MEDICAL TECHNOLOGIES

The challenges of being a pathfinder with an implantable device

St. Francis Medical Technologies focused on the discovery, development, and commercialization of novel treatments for degenerative spinal disorders until the time of its acquisition by Kyphon in January 2007. The company's first product, the X-STOP interspinous process decompression system, was developed to alleviate the symptoms of lumbar spinal stenosis (LSS). LSS is a common spinal problem that primarily affects middle-aged and elderly adults, causing significant pain in the back and legs.

Traditionally, the most common surgical solution to LSS was laminectomy. In this procedure, the surgeon trims and removes part of the bone of the vertebrae to reduce the pressure on the spinal nerve root (which causes the pain and other debilitating effects associated with stenosis). According to Kevin Sidow, former president and CEO of St. Francis, the idea for the solution that eventually became the X-STOP®

FIGURE 4.4.4
The X-STOP implant (courtesy of Medtronic Spinal & Biologics).

emerged when two orthopedic spine surgeons, Jim Zucherman and Ken Hsu, were pursuing the need for *a less invasive way to treat the symptoms of spinal stenosis*. "They had a couple of older patients who had experienced short episodes of dementia as a result of the general anesthesia," explained Sidow. Based on this undesirable side effect of the procedure, "They were hoping to find a way to treat patients under a local anesthetic," he added.

All of the solutions that Zucherman and Hsu conceptualized to address the need involved the use of an implant (see Figure 4.4.4). As a result, when the experienced spinal device executives who co-founded St. Francis began thinking about a business model based on Zucherman and Hsu's leading concepts, they knew that they would be dealing with this type. Highlighting the benefits of the model, Sidow said, "The upside is that implants have a very straightforward revenue recognition process. There are also strong distribution networks that you can easily tap into in order to market the product, that have great credibility with spine surgeons."

On the other hand, he acknowledged, there are some sizable risks associated with implants that need to be considered early in the biodesign innovation process. Among those he mentioned, "The first is the regulatory hurdle, especially with a brand-new therapeutic option. This is really hard because everyone is incented to say 'no' to new things or extend the pivotal trial timelines," Sidow noted. When he joined St. Francis from Johnson & Johnson, the company expected to receive FDA approval shortly thereafter. In fact, just two months later, St. Francis was notified by the FDA that its PMA application for the X-STOP implant had been turned down. Under Sidow's leadership, the company completely regrouped its US business to address the issues raised by the FDA. Reflecting on the situation, Sidow explained, "It really was a function of a lack of understanding. People at the FDA have an incentive to turn things down if they don't understand them perfectly. Nobody at the FDA gets rewarded for getting products to market quicker to help patients, but people get punished for Vioxx®-like results." When he elevated the matter to a higher level within the agency, "it was a much more objective, straightforward process," and the X-STOP was approved by the FDA.

Sidow emphasized another risk: that new implantable technologies have to anticipate issues associated with getting physicians in the target population to adopt the product. "Laminectomy was a big operation that was well reimbursed," he said. "The surgeons were very skeptical of this little company coming out with this new device. To make matters worse, all the big players in the business – J&J, Medtronic, Stryker, etc. – have very close relationships and tremendous credibility with these doctors. And they each had hundreds of sales reps telling the physicians that the device was a gimmick and that we were a nobody." Extensive efforts were required of St. Francis to overcome this skepticism and resistance in the field. When a new

implant hits the market, "the large, incumbent companies have a strong incentive to battle it," Sidow reiterated.

In addition to anticipating regulatory and adoption hurdles, Sidow advised companies with new implants to think carefully about reimbursement before getting too far in the biodesign innovation process. "It is becoming more and more critical to be proactive regarding reimbursement, all the way back to the point that you're designing your clinical studies," he said.

Ultimately, the device that St. Francis brought to market could be surgically implanted via a less invasive procedure performed in under an hour. According to Sidow, in the company's first year following FDA approval, it had $58 million in worldwide sales. At the time of the Kyphon acquisition, the X-STOP device had been implanted in more than 10,000 patients. St. Francis sold the business to Kyphon for $725 million.[6]

Capital equipment products

Capital equipment products are, in essence, another form of reusable products. They require customers to make a capital expenditure in order to obtain a technology that they will use to repeatedly produce/sell a product or provide a service over an extended period of time (i.e., more than one year). Capital expenditures come from funds used by companies or entities, such as hospitals, to acquire or upgrade physical assets to maintain or increase the scope or competitiveness of their operation.[7] In the medical field, capital expenditures are often made to obtain equipment such as MRI or CT scanners,[8] blood analytics equipment, or ultrasound machines. Capital expenditures can also be made for important software programs such as electronic health records systems, as well as facility-related expenses.

A pure capital equipment business model depends on the sale of the equipment, with little or no ongoing interaction between the company and the customer until it is time to purchase new equipment. However, as noted earlier, these products can also be associated with a service (e.g., technical support and maintenance contracts) or disposables. In these scenarios, it is not uncommon for the equipment to be sold at or near cost, with the expectation that greater, recurring revenue will come from the sale of the service and/or disposables.

Capital equipment purchasing decisions usually occur at the administrative level in the healthcare system. For example, while physicians (as the users of the products) may be the targets for the sale of many disposable, reusable, and implantable technologies, hospital purchasing committees are almost always involved in buying decisions for capital equipment. These transactions still require the buy-in and support from doctors in one or more specialties. However, the decision to invest the funds will be made by committee, based on the broader priorities of the facility. As a result, the sales cycle can be long (as much as 18 months) and may require the vendor to support the sale with a careful business case for the purchasing decision (a plan for how the purchaser will recoup the investment in the capital equipment).

An advantage of capital equipment businesses is that sale of the technology usually represents a long-term commitment by the purchaser. The switching costs of moving from one MRI provider to another, for example, are extremely high. As a result, unless there are significant problems with the equipment, customers tend to be loyal to the company once the buying decision has been made.

The example of Gradian Health Systems demonstrates some of the dynamics associated with capital equipment models, as well as creative ways these products can be made more accessible in resource-constrained environments.

FROM THE FIELD GRADIAN HEALTH SYSTEMS

Blending commercial and philanthropic approaches to make capital equipment accessible in low-resource settings

Globally, 2 to 3 billion people lack access to adequate surgical care.[9] This problem is particularly prevalent in developing countries, where inadequate infrastructure often renders hospitals unable to provide safe surgery. Dr. Paul Fenton, a British anesthesiologist, became frustrated with this situation over his 15 years as Head of the Department of Anesthesia at a busy teaching hospital in Malawi. After observing too many unnecessary deaths caused by surgeries that were interrupted or canceled due to the unreliability of his hospital's anesthesia equipment and infrastructure, Fenton designed a machine that could deliver safe, reliable anesthesia even in the midst of a power outage. The device, which he called the Universal Anaesthesia Machine (UAM), also generated its own oxygen from an integrated oxygen concentrator, which eliminated reliance on expensive cylinder or pipeline gas. If no electricity or other source of oxygen was available, the UAM continued operating, defaulting to room air with integrated oxygen monitoring to ensure the safety of the gas mixture (see Figure 4.4.5).[10]

Fenton began using the **prototype** in his hospital in Malawi. When he saw how well the device performed in this environment, he sought to expand production so that other health facilities could benefit from the device. Unfortunately, Fenton was unable to convince investors to provide funding to further develop the technology. He was also unsuccessful in identifying a buyer or licensee to bring the idea forward. At the time, those he spoke with were either hesitant to get involved in a business based in Africa or they did not perceive capital equipment targeted at low-resource healthcare providers to be commercially viable.

FIGURE 4.4.5
A healthcare provided in Malawi delivers anesthesia using Gradian's UAM (courtesy of Gradian Health Systems).

It was not until years later, after he had retired, that Fenton had the opportunity to bring the idea forward. After meeting with Fenton about a program in Nepal, a private philanthropy called the Nick Simons Foundation (NSF) offered to provide seed funding to develop the UAM into a viable model for use in other hospitals. They identified a manufacturer in the UK who took it through the CE certification process, and then NSF tested it in hospitals the UK and Nepal. Crucial to the UAM's success was its effectiveness in all environments – from resource-constrained health facilities to highly sophisticated medical centers with the highest performance standards. "The UAM was designed very distinctly to not be a 'poor person's machine,'" emphasized Erica Frenkel, who later became involved in the project.

Based on positive results from all testing sites, the Nick Simons Foundation was enthusiastic to bring the device to market. It spun out a wholly owned subsidiary from the

Foundation – called Gradian Health Systems – to dedicate itself to this goal. Foundation leaders established a legal structure for the new organization that would afford them flexibility and protection from the liability risks associated with any medical device company by setting up Gradian as a single member limited liability corporation (LLC).[11] From a tax perspective, the organization was considered a "disregarded entity," which meant the IRS would "disregard" the company as being separate from its owner and roll up its financials into the Foundation's financials so that Gradian would be also tax-exempt.

Gradian's first big challenge was designing a business model to support the UAM. Steve Rudy, a medical device industry veteran, and Erica Frenkel, a global health expert, were hired to run the organization. Together Rudy and Frenkel considered numerous hybrid models for structuring Gradian's approach.

Anesthesia machines are typically priced upwards of $50,000. The target price for the Gradian UAM was significantly less, about $15,000 per unit,[12] but it still qualified as capital equipment and represented a major expenditure for the low-resourced hospitals and surgical centers that comprised the target market. Gradian had to define a blended model for addressing the upfront sale of the UAM, plus the ongoing training, service, and maintenance associated with the device. "Previous thinking suggested that to be a non-profit working in this space you had to just donate machines and all the peripheral services they require – that there was no way to use pricing and sales to build an organization. We felt strongly that a non-profit could incorporate traditional business strategies," Frenkel explained.

Ultimately Rudy and Frenkel determined that Gradian would cover the production and distribution of the UAM by selling it to non-profit organizations and governments at roughly its cost. This would ensure that the company could achieve scale as the team started building demand for the product. "If you're giving away the machines, you can only produce as many as your budget allows. But if you're selling the product and covering your costs, you can produce and distribute as many as the market demands," Frenkel noted. Funding from the Foundation would then be used to support other aspects of getting the business off the ground during its first few years in operation, as well as to underwrite the expensive but essential work of training anesthesia providers to use the machine and covering the technology's ongoing service and maintenance requirements for customers. Gradian saw this as an imperative differentiator for its offering since donated machines rarely included training or support, and companies selling new machines were notorious for offering only the most basic support, without in-country support representatives, at prices that were largely unaffordable.

With the fundamental business model defined, Gradian still had to address issues related to revenue realization and the sales cycle. As with most capital equipment models, the sales cycle for anesthesia equipment is lengthy. Further, Gradian realized that the timing of anesthesia machine sales is important. "A hospital may buy one anesthesia machine this year and not purchase another for three years or more." Accordingly, the company's revenue for sustaining operations would be uneven and a missed sales cycle could mean a lost opportunity for multiple years.

In addition, Gradian's small team had to market and sell the UAM to four distinct but interconnected **stakeholder** groups: users, hospitals, Ministries of Health, and donor organizations. The direct users of the product are the anesthesia providers who, in the developing world, are often not medical doctors. Instead, they are mid-level healthcare practitioners with specialized (although sometimes minimal) training in basic anesthesia delivery. These providers personally experience the challenges created by the unreliable and unsafe equipment used in low-resource operating rooms. They are perhaps the easiest to convince of the UAM's benefits but, as Frenkel pointed out, "They're not the ones with the resources or decision-making power." Those with the ability to make purchasing decisions resided at the hospital administration or Ministry level. However, a significant

percentage of facilities and Ministries in the developing world are severely resource constrained, with operating budgets that cannot accommodate regular capital investments. To acquire new equipment, such as anesthesia machines, many hospitals depend on non-governmental organizations (**NGOs**) or international donor organizations to make these purchases. Decision makers within these organizations are furthest from the problem and sometimes lack adequate information about the field of anesthesia or the needs and constraints of the facilities they are intended to serve. "The users and hospitals that know what they need are often not even involved in the decision-making process for the equipment that they're going to get," Frenkel said.

To operationalize its capital equipment business model, Gradian determined that it needed a coordinated and highly strategic marketing plan that would align the interests of key stakeholders in the purchasing process. Ideally, anesthesia providers would report to hospitals what they required; and hospitals, in turn, would pass this information along to their governments and donors who would use it to make their purchasing decisions. To move the market toward this optimal model, the Gradian team would pursue a multi-part plan that included: (1) publishing meaningful results in **peer-reviewed journals**; (2) building a network of key opinion leaders; (3) connecting with other users through conferences and professional societies; (4) applying for large-scale tenders; and (5) researching donor organizations.

As a top priority, Gradian would continue to conduct field studies of the UAM in collaboration with well-known, respected partners to produce high-quality clinical data demonstrating the efficacy of the device. In parallel, the company would actively seek to expand its network of "champions" – respected users and hospital personnel who had direct experience with the value that the UAM delivered – in Gradian's target geographies. Their advocacy was extremely valuable, particularly for a large capital equipment purchase like the UAM. They could be engaged to answer questions about the UAM and share their experiences with other users and hospitals, either on their own or at Gradian's request. As Frenkel put it, "It's very influential and boosts our credibility in the sales process when we're not the ones saying that it's a great machine." Gradian would also seek to build a broader base of advocates in the user community promoting the UAM through medical conferences and professional society activities.

Because capital equipment purchases by governments in African countries are often conducted through tender processes, Gradian would also invest significant time and energy into better understanding the needs of the governments and financing institutions issuing the tenders so it could optimally present the UAM in its proposals. "Part of it is understanding how the decision-making processes work for these major organizations," Frenkel said. Another key aspect was raising awareness among these entities that affordable, appropriate technologies like the UAM even existed. To assist, Gradian hired an outside consultant with deep global health experience in Africa "to help us learn how to really speak to these types of organizations," she noted. In terms of reaching high-volume purchasers outside the tender process, Gradian planned to develop a list of the wide variety of organizations that made capital equipment purchasing decisions for individual hospitals. For example, "In Malawi, we targeted a number of organizations that we had worked with, and in Uganda we're starting to get a sense of organizations that train users but also fund equipment," Frenkel said. The Gradian team gathered information about these organizations and also started tracking what it could about their purchasing cycles so that a team member could approach them at an appropriate time. "The idea is to get ahead of the organizations, before they make a decision about anesthesia equipment, so we can make them aware of the UAM, begin a dialog, and answer their questions," she explained.

Reflecting on Gradian's strategy to make capital equipment more accessible in low-resource settings, Frenkel noted that, "It's like a huge knot we're trying to untangle. I wouldn't say by any stretch of the imagination that we've solved it, but we're working on it." The early phases of this plan had enabled Gradian to expand the sites where the UAM was being used from two to over 15 countries over its first two years in operation.

The Gradian story highlights how innovators are devising creative approaches to making new technologies more accessible in low-resource settings – a movement that extends beyond just capital equipment. However, innovators should note that they will face additional risks regarding the long-term sustainability of their organizations if the selling price of their products and/or services does not completely cover the cost of operating the business.

Service

A service is work performed by one person or group for the benefit of another. A long-term care facility is an example of a *pure* service model. Dialysis service centers commonly provide another example of a pure service model. However, in some cases, the companies that provide these services also play a role in providing capital equipment and disposables. As a result, organizations in this market may have a blended product/service business model. A service plan to maintain and support an MRI machine after it has been installed represents one example of a blended product/service model.

A notable characteristic of blended product/service models is the fact that companies may frequently sell a product at or near cost (with very low margins) in order to generate service revenue. It is not uncommon for companies such as General Electric, Philips, and Siemens to maintain relatively slim margins on their capital equipment in order to stimulate the sale of more service contracts, which typically have high margins and provide a recurring revenue stream. Once in place, these contracts tend to be extremely stable given the high switching costs mentioned earlier. In some ways, service contracts on equipment can be thought of as insurance policies. Customers buy them to ensure that their equipment will be properly maintained and quickly repaired in the event of a problem. However, both the customer and the company benefit if little or no service (beyond regular maintenance) is actually required because this means that the equipment experienced no unintended downtime, which can be costly and a source of risk for the customer.

In contrast to their blended counterparts, pure service models can be challenging. They are highly dependent on having the right management capabilities, organization tools, resources, and staff to make the model a success. Furthermore, customers tend to be sensitive to changes in management and company leadership, often valuing their personal relationships with individuals within the company higher than the service the company provides. Additionally, there are few economies of scale that can be realized in a service business. Unlike the production of a physical device (which allows a company to simply "turn up" manufacturing as it adds new customers), service businesses must add staff to keep pace with the acquisition of new customers. As a result, they face increasing risk in managing their costs during periods of volatility. Another substantial source of risk comes from having to recruit, hire, train, manage, and retain human resources.

Although service contracts for capital equipment can be lucrative (with high profit margins), pure healthcare services tend to have lower margins that are often squeezed by **third-party** public and private **payers**. Moreover, services that focus on or utilize technologies or procedures that the company itself does not manufacture or control are further at risk if there is a major change in the external environment. For example, if a company sets up a business servicing some piece of capital equipment (but does not produce the machine itself), its business would evaporate if the technology was suddenly replaced by a new innovation in the market. While this model is relatively uncommon in the device field, it highlights the need for companies using service models to stay attuned to changes in the external business environment and be prepared to adapt their business models.

The Radiology Partners story provides an example of how a service offering can be designed to potentially overcome some of the challenges typically associated with this model.

FROM THE FIELD RADIOLOGY PARTNERS

Building a national service model in radiology

For nearly a decade, Mohamad Makhzoumi, co-director of the healthcare services and healthcare information technology (IT) investment practice at venture capital firm New Enterprise Associates (NEA) had been watching IT innovations transform radiology. "It started with the advent of teleradiology, followed by increasing subspecialization and shared radiology models," he recalled. More recently, Makhzoumi saw pressures linked to US healthcare reform spawn new uncertainties in the field, especially for the hospitals that relied on radiology groups to diagnose their patients at critical junctures in the **cycle of care**. "Insurance incentives are changing," he elaborated. "Hospitals are starting to be incented for discharging patients sooner, rather than keeping them longer. And radiology is the key to making that happen." Meanwhile, outsourcing businesses had been able to reduce costs, improve quality, and increase service levels in other hospital-based practice areas such as anesthesia, intensive care, and the emergency room. "But we hadn't yet seen anyone achieve all of those goals in radiology," Makhzoumi noted.

Sensing an opportunity, NEA venture partner and veteran healthcare services operator Rich Whitney came up with a strategy for developing a national service business that would leverage scale and technology to deliver more efficient care supplemented by value-added services. His plan was to build the practice, called Radiology Partners, by partnering with leading regional radiology groups that had a culture of physician-led quality and service. Based upon experience in other segments of healthcare services, Whitney believed that scale would offer significant competitive advantages across the dimensions of clinical quality, service to clients and referring physicians, revenue enhancements, cost improvements, and strategic positioning. "By joining a national group practice, physicians could do better for their patients, have more security, make more money, and avail themselves to leadership and career development opportunities not available in small practices," he described.

Chief among the advantages that Radiology Partners would offer to its partner practices was load balancing. "Radiology groups have to staff their practices at a level that supports the maximum volume of the hospitals that are their clients. However, that maximum volume is only realized periodically," Makhzoumi explained. "As a national group with hundreds or thousands of radiologists, we could load-balance those radiologists across providers using telemedicine technology and sophisticated workflow tools to gain tremendous efficiency and cost-savings."

A second, significant benefit to the radiology groups would be access to the newest and most advanced IT (see Figure 4.4.6). "Building a state-of-the art viewing system, supplemented by clinical decision support tools and intelligent worklists is expensive, and it's not always feasible or practical for a small or even regional

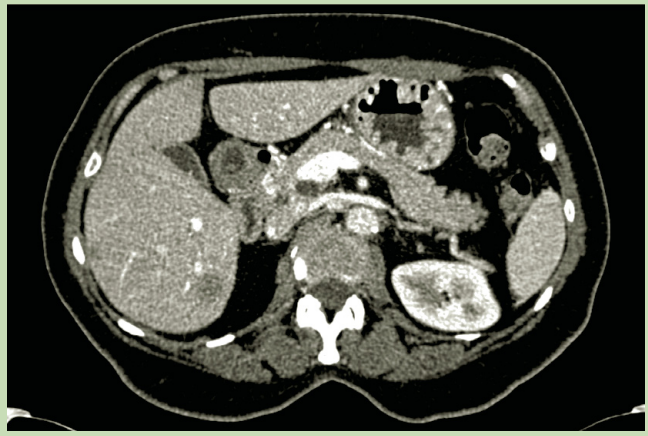

FIGURE 4.4.6
An abdominal CT scan taken with a late-generation scanner (courtesy of Professor Sandy Napel, Department of Radiology, Stanford University).

practice to make the capital investment necessary for such a system," Makhzoumi continued. "But," added Whitney, "these technologies offer the ability to manage the practice and deliver clinical excellence, service, and data in ways that smaller practices aren't capable of achieving."

Another critical leverage point was linked to reimbursement. "Radiology reimbursement rates have traditionally been pretty comfortable," said Christine Guo, an associate on the NEA team. "But with increasing reimbursement pressure in radiology exacerbated by a renewed focus on utilization, many independent radiology groups are hurting for the first time." As a large physician practice with increased negotiating power and resources to focus on revenue cycle management, Radiology Partners could achieve more attractive reimbursement rates from payers and more effectively and efficiently collect the dollars that are due.

To attract hospitals as clients, the team believed it could, first and foremost, improve the quality of care providers were used to receiving. This could be accomplished by implementing state-of-the art technology throughout its network, and giving providers access to a comprehensive range of radiology subspecialties. This benefit would be particularly valuable to regional hospitals and those in remote areas that typically did not have access to specialized expertise. "There's a huge benefit to being able to have the right radiologist read the right scan at the right time," said Guo.

Additionally, since Radiology Partners formed partnerships with local radiology practices rather than competing against them, hospitals and their referring physicians working with the national group would still be able to maintain their existing relationships and clinical interaction with trusted local radiologists.

To help deliver increased efficiency and cost savings to hospital customers, Whitney and team would implement national standards for turnaround time and other important metrics and then carefully monitor the performance of the radiology groups in their network.

Summarizing the model, Makhzoumi said, "We can go to hospitals and say, 'Radiology is a huge pain point for you. It costs you money, it's difficult to manage, and it's the biggest slow-down between getting patients admitted, diagnosed, and eventually discharged. Give us your radiology department – outsource it 100 percent to us – and we'll manage it for you. We'll do it better, more cost-effectively, and we will improve your quality and efficiency.'"

Because the Radiology Partners business model depends on hospitals to outsource their radiology needs to the company, hospital executives are the key decision makers in entering into these integrated service contracts. However, Makhzoumi pointed out that the company actually receives **payment** for its services from the insurance companies and other payers that cover the hospital's patients. Accordingly, the company must ensure that its offering is attractive to both stakeholders for its business model to succeed. For hospitals, this means convincing them that Radiology Partners can more effectively meet their total radiology needs, as described above. For payers, it means persuading them that a national radiology model can provide higher quality care and more timely and accurate diagnoses. Whitney and the NEA team agreed that satisfying this constituent seemed more important than ever as the prospect of new payment models taking hold in healthcare likely will require that radiology practices figure out how to help hospitals and other increasingly capitated payers reduce imaging utilization. According to Whitney, "Many radiology practices in the future are likely to be faced with either delivering a highly valuable clinical, process, and technology-driven approach to reducing imaging volumes while maintaining or improving care, or have it done to them with a resulting decrease in physician incomes, not unlike what happened in the early 90s with radiology benefit managers. With an average US practice size of 16 radiologists, very few groups have the resources to make the massive investments necessary to develop and deliver these kinds of programs, and if they don't offer this value to the system, what payer is

going to agree to pay them more to offset the impact of the lower volumes?"

The success of the Radiology Partner business model also hinges on the company's ability to attract the right radiology practices and individual radiologists as partners. As Guo emphasized, one of the key challenges of building and scaling a service business (compared to a product-based business) is the fact that there is typically no proprietary technology, which makes delivering high-quality service essential. This intense focus on patient-focused clinical and service quality necessitates a rigorous screening process to ensure that the practice groups and physicians who join the network are equally committed to these goals. "Before asking a practice to partner with us, Radiology Partners meets with key physicians to make sure that they embrace the values and mission of the Radiology Partners practice. It's not about how many reads you can do in a day," Guo said. The team evaluates potential partners on the caliber and breadth of the physicians they have on staff, as well as the long-terms results they have achieved against critical performance standards and their passion to deliver the best possible service for the benefit of their patients. Those practices that make the cut are invited to become partners. Limited information is publicly available about the details of the partnership agreements, but groups in the network are given the chance to share in the profits of the national Radiology Partners consortium. In fact, a large percentage of the practice's physicians have an ownership interest in Radiology Partners.

In reflecting on other challenges associated with service models, Guo reiterated that, "Operating a service business on a national scale while maintaining consistency and quality is a lot harder than maintaining the quality of a product." Performance has to be carefully monitored and problems must be corrected swiftly before they impact customer satisfaction. And with multiple constituents using the service, keeping everyone happy can be difficult. "You have to pay attention to the underlying patients, but also to the referring physicians, hospital administration, and the health plans." Guo said. Managing these multiple relationships requires "a fully built-out infrastructure that includes layer upon layer of human capital," Makhzoumi said. "Complicating this challenge further is the need to tailor the service offering to each individual stakeholder. "It's not like selling a static device that is always going to be used in the same way," he stated. "You have to iterate, evolve, and amend your service for every customer, and that's a real challenge."

Accordingly, Whitney has recruited a top-notch team with experience in various functional disciplines, including several physicians and radiologists. Many of these individuals have a track record of leading large-scale healthcare organizations distinguished for leadership development. "In the end, developing a culture of service excellence and physician leadership will be our biggest asset," he remarked. "In fact, for Radiology Partners to achieve its full potential we'll have to, of course, be good at many things. But we must be *excellent* at attracting, retaining, and developing extraordinary physician leaders who share our passion for transforming radiology."

For innovators interested in building a healthcare service business, the members of the Radiology Partner team offered the following additional advice. First, be keenly aware of market forces and industry dynamics that yield windows of opportunity. "The timing has to be right," said Guo. "For us, the key factors included the maturation of technology to support this model and market trends converging on lower healthcare costs and increased access and quality." Second, they emphasized the need to be flexible in terms of defining a service business model in order to adapt to market realities. And finally, as with any service business, they reiterated that people are a company's greatest asset. "Seek out, identify, and recruit the best leaders you can for all levels of your new organization," Whitney encouraged.

Fee per use

A fee per use business model can be appropriate for innovations that sit squarely at the intersection of products and services. For example, laser eye surgery requires a capital expenditure to cover the cost of the equipment. However, practitioners are also charged a fee every time they perform a surgery using the machine. The event that triggers a payment to the company is nothing other than use of the machine.

Another form of the fee per use business model in the medical device field is referred to as a capitated model. With this approach, a medical provider is given a set fee per patient, regardless of treatment or equipment required. For example, a company that provides all of the disposables necessary to perform a laparoscopic gallbladder removal may charge a fixed price per patient, independent of which disposables are actually used. Similarly, a company with cardiology products may charge a fixed fee per patient for all of the stents, balloons, and catheters required to perform certain predefined procedures. This approach allows companies with broad product lines to achieve an advantage over those that offer a smaller number of related products – the bundling of products makes it more difficult for less diverse competitors to penetrate accounts.

This model can be appealing to customers seeking increased certainty in their costs since the per patient payments are fixed regardless of the complexity of the individual cases they perform (e.g., hospitals have traditionally lost money on procedures requiring the use of more than two or three drug-eluting stents in a single patient). On the downside, customers sometimes resist paying the fixed cost for cases that require few devices (e.g., one stent), which can necessitate extra time and effort from the company in defending its business model. Also, unless a business generally has a high degree of IP protection or other barriers to entry, this type of business model is often challenged by other businesses trying to compete in more traditional ways.

The VISX example below illustrates the challenges and benefits associated with a fee per use business model.

FROM THE FIELD VISX

Developing the fee per use model in the vision correction field

In the late 1980s, Charles Munnerlyn, founder and CEO of VISX, and Allen McMillan, the company's COO, were considering how to commercialize the first system for photorefractive keratectomy (PRK), the original method used for laser vision correction (see Figure 4.4.7). They knew there must be a better approach than the traditional capital equipment model. The cyclical nature of capital equipment sales would leave little money available for research and development since they would sell one model to as many customers as possible and then have to wait for years until the same customers were ready to invest in the next generation. They were also concerned that the high purchase price of capital equipment could make market penetration quite slow for a new company entering the field.

Seeking a way to realize a more consistent revenue stream and quickly build a commercial presence, Munnerlyn and McMillan conceptualized a business model that would allow the company to sell equipment and service contracts to its customers, but also charge a fee each time the system was used. "The laser vision correction industry was really the first in the medical device field, and certainly in the US, to use a true per procedure model," explained Liz Davila, CEO of VISX in the early 2000s.

In the late 1980s and early 1990s, VISX, and its main competitor, Summit Technologies, were each developing excimer lasers for eye surgery and had patents on different aspects of the technology.

FIGURE 4.4.7
A physician preparing for a laser vision correction procedure (US Navy, photo by Mass Communication Specialist 1st Class Brien Aho via Wikimedia Commons).

In order to avoid patent litigation, they combined their IP in 1992 and created a third entity, Pillar Point Partners, which licensed the combined IP. Pillar Point Partners would then sub-license the patents back to VISX, Summit, and any company that wanted to license the patents. All licensees paid Pillar Point a per procedure royalty. Pillar Point profits were then distributed to VISX and Summit. Since the licensees were paying on a per procedure basis, it was logical that they would charge their customers by procedures. The result was that the US laser vision correction industry adopted the fee per use business model.

VISX's shareholders immediately appreciated the value of the new model, but there was a period of time when the surgeons were resentful and antagonistic toward the company. VISX originally charged upward of $500,000 for the equipment, plus $250 per eye treated. The $250 charge was positioned as a licensing fee. As Mark Logan, the company's CEO (following Munnerlyn but before Davila), explained in an interview for the *Tribune Business News*, "We've spent $52 million bringing this to market, and there's no way we could sell these lasers for $500,000 and ever recoup what we've put into it. If it weren't for the $250 fee, we'd have to sell these systems for $3 million each and have a very small market, which isn't good for anyone."[13] VISX also asserted that these fees enabled the company to sustain its research and development efforts so that it could continue improving its technology to treat new indications.

The surgeons accepted the need to pay for the disposables required by the procedure because they had a utilitarian function, but they did not understand the value of the VISX keycard (which tracked equipment usage and calculated the associated licensing fees). According to Davila, "What eventually got them to quiet down was that they fairly quickly realized how much money they were making." Previously, as corneal specialists, most of the VISX surgeons performed cataract surgeries, which were primarily covered by Medicare and reimbursed at a total of about $1,600 per procedure. In contrast, Davila continued, "By expanding their practices to include vision correction surgery, the surgeons could now charge $1,500–$2,500 *per eye* and were making money as they had never made money before." Eventually, they accepted the $250 per use fee as a necessary expense associated with the more lucrative laser surgery market.

Since VISX and Summit were the first two companies to offer this technology in the US, they exercised a high level of market control (approximately 70 percent and 30 percent market share respectively). Eventually, however, other competitors began to enter the market. Several took licenses to the patents. However, a

company called Nidek refused to license the IP from Pillar Point Partners. Despite the fact that the company offered inferior technology, it was able to gain market share because it also did not charge a per procedure licensing fee. To protect itself against substantial market erosion, VISX reduced its per procedure fee from $250 to $110. Surgeons responded positively to the change, and many doctors who had switched to Nidek eventually came back to VISX because of the company's superior technology. Over time, Nidek's business declined as the company lagged technologically further and further behind. As VISX continued to improve its technology, further outdistancing its competitors, the company was able to increase its per procedure fee back to $250.

The Nidek example demonstrates that a fee per use model has the greatest likelihood of success in an industry or market where everyone is playing by the same rules. Alternatively, the company employing the model must sustain such a strong competitive advantage that customers view the license as being worth the additional cost. "When people ask me if the VISX model would work for them," said Davila, "I ask them if their technology is truly revolutionary. Because if it's not, it will be very difficult to get medical professionals to pay a per procedure fee."

Davila also underscored the importance of having IP that can be protected. Among the reasons that VISX reduced its usage fee in the face of competition from Nidek was the slowness of the patent enforcement process. VISX did sue Nidek for patent infringement, but the court process required several years and VISX decided that it was too costly to wait.

Finally, she pointed out that eye surgery is an elective procedure that is not reimbursed through Medicare and infrequently covered by private insurance providers. The fact that VISX did not have to take third-party payers into account simplified its decision to pursue an alternative business model. The company only had to convince providers and patients that the value provided by its offering would outweigh any non-traditional costs – a somewhat easier hurdle to clear than the cost-effectiveness requirements increasingly imposed by payers.

VISX was acquired by Advanced Medical Optics (AMO) in 2005, and AMO was in turn purchased by Abbott in 2009.

Subscriptions

Subscription models require a customer to pay a fixed price to gain access to a product or service for a defined period of time. The model was pioneered in the publishing field and has now been popularized across industries, including healthcare. The access granted through a subscription can be limited to a certain amount or configuration of a given product or service, or it can be unlimited. Usage can also be given to an individual or group in a transferrable or non-transferrable fashion. These are all variables innovators must consider and define when evaluating a subscription business model. The most important factor is to ensure that there is a clear and accurate way to differentiate subscribers from non-subscribers as they seek to interact with the product or service, especially if some basic portion of the offering will be given away for free.

One example of a subscription-based offering is Welltok, a consumer engagement platform that helps health plans, large self-insured employers, and other population managers connect with their members and reward them for healthy behavior. These population managers subscribe to Welltok's CafeWell on behalf of their individual members. In turn, these consumers gain access to the "social health management platform," which includes health information, competitive wellness and fitness challenges, incentive programs for healthier lifestyle changes, support for chronic conditions from peers and professionals, and anonymous social networking. In exchange for subscription fees, the population managers receive de-identified metrics on member wellness and participation.[14] Rather than targeting consumers to generate income from its offering, Welltok intentionally went after payers. As Chairman and CEO

Jeff Margolis explained, "The insurance companies are at the top of the food chain, in terms of how the dollars flow."[15]

Another example of the subscription model in healthcare can be found in direct primary care offerings. Two of the most common approaches are concierge medicine and direct primary care, through which subscription-based healthcare practices charge patients anywhere from $60 to $30,000 per year to deliver a defined range of health-related services. Patients that sign-up with direct primary care provider like One Medical pay roughly $150–$200 per year for same-day appointments, online prescriptions, and personal email access to doctors. Many patients retain their health insurance to cover acute conditions and emergencies, but pay **out-of-pocket** for the better access and increased convenience that the direct-pay subscription model provides. In parallel, the physicians that belong to these practices maintain a steady income stream without the pressure to see more and more patients each day as they would in traditional medical practices. They also report that they can spend more time coaching patients on wellness and prevention.[16]

On the plus side, subscription businesses have the benefit of being an annuity once a customer-product relationship is established. Growth is driven by maintaining customer satisfaction with the offering and expanding the reach of the business to other customers. On the downside, subscription business models can be put at risk by other models that provide the same or a similar offering for free by leveraging a broad customer base to derive income from advertising or another type of information exchange.

Over-the-counter products

An over-the-counter (**OTC**) business model depends on patients' ability to choose a treatment path and then acquire the product(s) for themselves. OTC products are more typically seen with drugs (e.g., Motrin®, Benadryl®), but can also include devices (e.g., steam machine for treating sinus congestion, home blood-pressure cuff devices, glucose monitors, or the vast array of emerging "quantified self" technologies). OTC products can, at times, be combined with services. For example, companies selling at-home blood pressure monitoring devices may offer data analysis and feedback services to users who upload their blood pressure readings via a computer.

Because physicians often are not involved in recommending OTC treatments, they must be relatively simple and easy to use. Advertising is usually targeted directly to consumers, and generic retail outlets (e.g., Walgreens) can be used to support sales. On the upside, OTC products rarely require an expensive direct sales force. On the other hand, they require sizable marketing budgets to promote brand recognition, which can be a significant barrier to overcome. In this model, the goal is to make the consumer aware of the product and how it works through conventional advertising channels (e.g., television, magazine, radio). Within this construct, companies at times find it challenging to differentiate their products since consumers spend less time than physicians understanding the clinical benefits of one product over another.

Models that require doctors to specify an OTC product to their patients can be even more challenging. In general, the smaller and more specific a physician population is, the easier it is for a company to reach. However, physician-specified OTC products tend to rely on the recommendations of general practitioners – a vast market that is nearly impossible for any single company to reach effectively with a reasonable investment of time, money, and resources.

Prescription products

Prescription drugs provide a classic example of prescription-based medical products. However, prescriptions can also be used for devices and combined with services (e.g., physical therapy), disposables (e.g., blood glucose monitoring testing strips, drug cartridges to a delivery system), and hardware (e.g., nerve stimulator pain control units, certain inhalers). With this type of business model, the physician selects the treatment and directs the patient toward it, but the patient is still required to act on the physician's instructions.

Prescription products often require more specialized training to understand than OTC alternatives and the process of selling them is more complicated since the

physician is directly involved in selecting the treatment. However, a more clinically oriented sales approach can be used to differentiate products, usually through a direct sales force. The size of the sales force is typically proportional to the number of physicians the company is trying to reach. For example, a sales force focused on primary care physicians would be the largest, whereas a smaller, but still significant sales force would be required to support specialty products, such as anti-nausea medications used for patients receiving chemotherapy. To support these requirements, the products must command high enough margins, as is the case with most prescription medications and devices. Direct-to-consumer advertising is sometimes used in parallel with the physician-focused sales effort, because physicians are expected by many patients to respond to their desires and requests.

Given the strength of the advanced marketing expertise amassed by large companies over the last couple of decades, prescription markets can be difficult to penetrate for small start-ups. Companies are often advised to enter the prescription business only if their product is clearly differentiated from the competition and/or if they can enter into a co-development partnership with a large pharmaceutical company that has an established sales force. "Me too" products have little chance of success without the marketing "muscle" and deep pockets of a major partner.

Physician-sell products

Physician-sell products are those treatments that are sold directly through physicians. With this business model, the physician essentially becomes a retailer for the product and usually receives some direct incentive for helping to promote and provide the treatment. Common examples include BOTOX® injections, teeth whitening products, and hearing aids. Physicians can also sell disposables or OTC products, such as contact lenses or solutions.

Typically, physician-sell products are offered on an outpatient basis and are often paid for by the patients (rather than by insurance). Once again, the margins for products sold through this channel must be high enough to cover not only the compensation to the company, but also to the physician for being a distributor. While some physician-sell products can be quite profitable, the primary downside to this model is the potential for ethical conflict. Anytime a physician receives a direct incentive to steer a patient toward a particular treatment, questions may arise about whether the physician is truly keeping the patient's best interests in mind. For this reason, physician-sell products tend to be limited to non-essential, elective treatments that patients may desire but are not necessarily purely medically indicated. Although there are some settings – such as in dermatology or dentistry – where physician-sell models are completely legal and appropriate, recent laws have changed the scope of the products physicians can sell in their offices for a profit. As a result, it is important to consult these regulations prior to utilizing this type of model.

A note on mobile health

Mobile health (**mHealth**) and health information technology (HIT) are rapidly becoming important segments of the medtech industry. New IT-based applications, devices, and services are being launched at a rapid rate, all with the goal of more effectively facilitating the flow of information between patients, healthcare providers, and other stakeholders in the healthcare ecosystem.

mHealth applications and devices, along with their related service offerings, are quickly proliferating in two broad categories: technologies targeted at consumers and those aimed at physicians and institutions (hospitals, employers, insurance companies, etc.). Estimates of the patient/consumer market for remote monitoring devices alone range from $7.7 billion to $43 billion, with 40 percent of consumers surveyed indicating that they would pay for remote monitoring devices and a monthly service fee to send data automatically to their doctors.[17] Within the physician community, doctors surveyed by the Health Research Institute reported that they would like to use mobile health to enable them to remotely access electronic health records, prescribe medications, monitor patients in and outside of the hospital, and better communicate with patients. A full 56 percent believed that mobile health could help them expedite decision making, 39 percent said it would decrease time spent on administrative tasks, 36 percent it had the potential to increase collaboration among physicians, and 26 percent anticipated the ability to spend more time with patients.[18]

Mobile technologies have the potential to create value in multiple ways, including the ability to help deliver less expensive solutions, enable new ways of managing care, and facilitate better health outcomes. The challenge is how to monetize these technologies in the healthcare space. When these technologies first began to emerge, the traditional fee-for-service reimbursement model, which rewards physicians for the volume of patient office visits they conduct, was firmly in place. The Health Research Institute's physician survey revealed that some phone consultations related to chronic disease management were being reimbursed, but insurance payments for remote transactions related to patient wellness and prevention was lagging.[19] As public and private health insurers make the shift toward paying for outcomes as the implementation of US healthcare reform and payment reform efforts accelerate, many more mHealth and HIT solutions will be better positioned to achieve reimbursement. For example, within new **pay-for-performance** healthcare models like Accountable Care Organizations (**ACOs**) and patient-centered medical homes, physicians and the organizations they work for will have direct incentives to improve health outcomes for a defined population. Mobile technologies that enable remote monitoring and provide patients with rapid access to medical staff when questions arise or when changes in the patient's health status are detected are expected to play a key role in enabling these organizations to succeed.[20] In the near term, however, these approaches are being experimented with on a relatively small scale in the US. Other countries are somewhat further along. In the United Kingdom, for example, a telehealth trial conducted by the National Health Service (NHS) yielded a 15 percent reduction in doctor's office visits, a 20 percent reduction in emergency admissions, a 14 percent reduction in the need for planned admissions, and a 45 percent reduction in mortality rates.[21] In February 2012, the NHS, which is run by the government and acts as both payer and provider, began encouraging physicians to prescribe smartphone applications to their patients in an effort to improve monitoring between visits to reduce unnecessary appointments when patients are stable and proactively intervene if they take a turn for the worse.[22]

As they wait for the reimbursement landscape to shift for mobile health applications and online health services, many companies are attempting to have patients pay for their technologies directly through an over-the-counter business model. Numerous health-related consumer products have emerged that depend on an up-front sale of a reusable piece of hardware and/or software, supported by online services made available at no charge. For instance, for approximately $100, the FitBit daily activity tracker allows individuals to automatically record their steps taken, calories burned, and stairs climbed with the purpose of motivating improved fitness and well-being. For roughly $200, AliveCor offers a heart monitoring application and sensors that work with an iPhone to deliver a clinical-quality electrocardiogram. Thousands of other health-related smartphone apps are available online, with worldwide consumers downloading 44 million of them in 2012.[23]

Fee per use and subscription models are also common in mHealth. For example, HealthTap offers a free online knowledgebase of medical information and the ability to get general health questions addressed by practicing physicians in a discussion forum format. However, for about $10 per inquiry, patients can get their more detailed, specific questions answered through a private, one-on-one interaction with a doctor in the appropriate specialty (with follow-up questions charged at $5 each). This approach to acquiring customers by offering basic services at no charge and then trying to monetize their interactions as they seek more premium services is sometime referred to as a "freemium" model.[24] In mid-2013, HealthTap was devising additional ways to charge patients for premium services, like connecting with a specific physician or getting faster responses. HealthTap was reportedly considering additional fee-for-service offerings as well as subscription models.[25]

Some subscription models target physicians, not just consumers. ZocDoc charges doctors a flat monthly fee in exchange for referring patients to them through their online site. This kind of subscription-based model for sourcing leads is also used by companies such as 1-800-DENTIST.

Other mHealth and online health offerings rely on advertising models to support their businesses.

WebMD, a health information knowledgebase, got its start selling ads to pharmaceutical firms and other health-related companies (more recently it has expanded its revenue streams to include selling private health-portal services to employers).[26] Practice Fusion, which offers a free electronic health record system for individual practitioners and small- to mid-sized physician groups, earns the bulk of its revenue from ad sales. However, it too is trying to diversify into other models.[27] One factor driving companies away from advertising is the sensitivity to the economic swings that can dramatically affect advertisers. Another issue is that the traditional display ads that dominate the Internet do not translate well to smartphones and other smaller, more portable devices that are proliferating globally.[28]

On the whole, the mHealth space is changing rapidly. Although many interesting approaches are being developed and tested in the segment, the most effective strategies have yet to be proven. The following example about remote monitoring company Cardiocom and its acquisition by Medtronic illustrates how large and small companies alike are experimenting with business models in the mHealth space.

FROM THE FIELD CARDIOCOM

Business model evolution in mHealth

Cardiocom, based in Chanhassen, Minnesota, entered the telehealth space in 1999 with the introduction of its Telescale, a remote monitoring device designed to help reduce acute care hospital admissions for heart failure patients. Individuals using the device stepped on to the scale and responded to simple "yes/no" questions to provide information about how they felt, and also about their diet, medications, and exercise. This data was then transmitted to the patient's healthcare provider and Cardiocom via a phone line. The company used data analysis software to proactively detect and act on risk factors that could potentially signal a change in health. For instance, an increase in weight could mean that a heart failure patient was retaining water, a dangerous symptom of the disease. As risk factors were identified, a registered nurse in the Cardiocom call center would telephone the patient to check in and devise an appropriate course of action, from patient education to scheduling a doctor's appointment for prompt and thorough diagnosis.[29]

Over time, Cardiocom expanded from heart failure into other long-term health problems, including chronic obstructive pulmonary disease, asthma, diabetes, hypertension, and obesity. Each of its hardware- and software-based products (along with their related services) was designed to identify symptomatic patients in these disease areas and intervene early to keep them out of the hospital.[30] The Commander Flex was one of the company's core products (see Figure 4.4.8). This device was a table-top display that posed questions to patients about their health. As patients responded, the system used branching clinical logic to provide additional inquiries based on their answers. The device also connected to ancillary vital sign monitoring devices

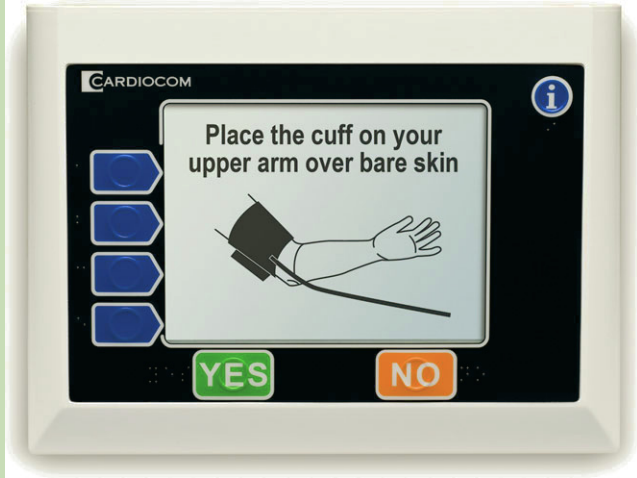

FIGURE 4.4.8
The Commander Flex telehealth system (courtesy of Medtronic).

manufactured by Cardiocom (such as a weight scale, pulse oximeter, etc.) to gather and transmit relevant physiological data to Cardiocom so that nurses in the call center could understand patients' specific symptoms and their severity.

Because reimbursement for remote monitoring services was not available under the fee-for-service paradigm, Cardiocom decided to build its business model around selling to insurance companies interested in reducing the cost of caring for patients with chronic conditions. They also targeted home care agencies that would potentially adopt the technologies as a way to make their services more competitive.[31] The company devised a "per member per month" (PMPM) subscription model for generating revenue. Cardiocom retained ownership of the equipment and charged its customers approximately $100 PMPM for its use. For example, a home health agency with an average of 100 complex, high-risk patients under its care at any given time would purchase 100 subscriptions from Cardiocom (the typical service agreement was 3 years in length). The agency would provide its high-risk patients with the Cardiocom communication hub and appropriate plug-ins for a defined period of time (e.g., someone experiencing heart failure might use the system for 30 days after being discharged from the hospital to help prevent readmission during this critical period). Once the patient stabilized, s/he returned the equipment to the agency, which refurbished it and then redeployed it to the next patient. "This model is attractive," commented Brett Knappe, Executive Director, Strategy & Corporate Accounts, US Region for Medtronic, "because it enables patients to enjoy the benefits of daily monitoring and support, and at the same time helps providers distribute their resources across a population of patients more cost-effectively."

Using this approach, Cardiocom grew its business to $10–15 million in sales by 2010.[32] Then two important events transpired. First, the Affordable Care Act (**ACA**) was signed into law in the United States, which stimulated greater demand for remote monitoring technologies. Specifically, the ACA's Readmission Reduction Program established penalties for hospital readmission of patients with acute myocardial infarction, congestive heart failure, or pneumonia within 30 days of discharge.[33] Along the same lines, the law also led to the formation of Accountable Care Organizations (ACOs) through which consortiums of hospitals, physician groups, and private payers could share in savings realized from reducing the overall cost of care for a defined population of Medicare recipients.[34] Second, Cardiocom was one of six companies awarded $225 million in health monitoring service contracts by the US Department of Veteran's Affairs (VA) in 2011.[35]

Roughly in parallel with these important changes, another Minnesota-based company, medical device manufacturer Medtronic, appointed a new CEO. Upon assuming his new position, Omar Ishrak, who joined the company from GE Healthcare Systems, outlined a handful of strategic themes for Medtronic, including globalization, an increased emphasis on economic value, and an expansion into healthcare services. "That's where Cardiocom fits in," said Knappe. Medtronic had a strong presence in heart failure, offering a number of implants such as pacemakers, cardiac resynchronization therapy (CRT) devices, and implantable cardioverter defibrillators (ICDs). But it was looking to broaden its footprint in this disease area, and remote monitoring seemed like a good way to do it. "By getting involved longitudinally across the continuum of care and providing services not just devices, Medtronic can be more relevant to a variety of healthcare stakeholders," Knappe noted. "It allows us to have more impact on patient outcomes, not just in the acute setting. And we can also be involved in improving long-term outcomes and reducing costs for healthcare systems." To expand into healthcare services, Medtronic needed to make a strategic acquisition in telehealth; one that would give the company critical mass from which it could continue to build.

Cardiocom surfaced as a strong acquisition candidate, in part, because it was an independent entity. Knappe elaborated: "If you look at the leader board, you'll find remote monitoring offerings tucked under Bosch and Philips and Honeywell – big industrial companies that leverage a position in security, or another connection to

the home, to get involved in patient monitoring. As a rare example of a pure play, Cardiocom was an attractive company to pursue." At the time, Cardiocom had been growing at 80+ percent annually for several years and had a run rate of approximately $50 million in annual revenue, making it relatively insignificant compared to Medtronic's $16 billion in net sales in 2012.[36] However, the remote monitoring category was forecast to experience double-digit growth for the next several years.[37] "And Cardiocom was growing even more rapidly," said Knappe. This was quite a contrast to Medtronic's own, single-digit growth rate. "We were also drawn to their commercial success," Knappe said, referencing Cardiocom's VA contract and the fact that the company "was performing very well for this and other blue-chip customers." After a period of due diligence, Medtronic acquired Cardiocom in August 2013 for $200 million.[38]

According to Knappe, who was managing the post-acquisition integration activities, Cardiocom would retain its PMPM subscription business model in the nearterm. But, over time, it would play an important role in Medtronic's strategy to transform its own business model. "It used to be about selling device features to physicians," he explained, "and sometimes these physicians didn't have a vested interest in the financial performance of the institution. That was the old model that the medical device industry grew up with. It depended on relationship-based selling with sales reps who were deeply embedded in the hospital and with the docs." Medtronic's vision for the future was to shift from selling implants through this traditional approach to offering a holistic suite of products and services that help decrease variability of outcomes and reduce risk for its customers. "This new strategy will enable us to engage with payers, integrated payer-providers, ACOs, and even hospitals who are at risk of incurring readmission penalties in new ways that are not based just on the features and functionality of our devices," Knappe said. "We can go to a [healthcare alliance] or a hospital system and say, 'We know you're at risk and we can align ourselves better because we believe that we've got the solutions to improve patient outcomes. And if we get better than expected results, we're both going to profit from it. If we struggle, we're both going to struggle.'" He continued, "In a sense, the ability to reduce risk becomes part of the product and is a new way that we can help physicians and healthcare providers succeed."

Linking this idea back to Cardiocom, Knappe stated, "For heart failure patients, we have a set of implants that communicate data to our CareLink system. The CareLink system produces reports that are available to electrophysiologists and can be shared with the heart failure docs. The problem is that only 8–10 percent of heart failure patients are indicated for this kind of implant therapy, and only a portion of them use Medtronic devices. So, in the scheme of things, we're saying to the hospital or to the payer, 'We've got really great solutions for some small percentage of your patients with heart failure.' And their response is, 'Thank you, but ho-hum, because it's the rest of the patients that we're having trouble managing.' So with Cardiocom, we now have something that can benefit the vast majority of heart failure patients, who need to have their medications managed but are not indicated for an implantable device." By more closely managing these patients, Medtronic intended to reduce their cost of care. "We can make sure that any complications are treated through scheduled clinic visits, which is a far more cost effective approach than treating them in the emergency room."

While this aligned incentives model remained to be proven, Knappe was optimistic. "To responsibly take risks, you need to have control of the factors that create the risk. We may need to add additional technologies and services to get us to the point where we have our arms around improving outcomes for a broad population of patients. And then we can start reducing risk for payers, integrated delivery networks, and ACOs," he said. Summing up his thoughts, Knappe added, "What we're trying to do is improve outcomes for any patient diagnosed with heart failure, and for the healthcare system in general. And Cardiocom is a great start."

The strategy of bundling multiple offerings to more holistically address a customer's needs in a disease area is becoming increasingly popular as companies seek new ways to increase the value of their products and services. For more information about this approach, see 5.9 Competitive Advantage and Business Strategy.

Validating a business model

From the array of business model choices, one or two will usually seem most immediately viable for a given concept. However, innovators are encouraged to evaluate all available alternatives before making a decision so that opportunities and risks are not overlooked. In the current healthcare environment, where external factors such as reimbursement hurdles are rapidly changing and cost sensitivity is becoming particularly acute, it can be difficult to predict which model will have the greatest likelihood of success. The one that seems to deliver the greatest value to the customer (decision maker) in terms that are meaningful to that audience is a good place to start.

Ultimately, innovators will depend on the strength of their own research and judgment to match a concept to a business model. But they will be well-served to validate the choice by seeking input from other innovators, entrepreneurs, and business advisors. A few important questions to ask include the following:

- Can the technology or therapy be delivered via a different business model?
- If so, and if this was to be done by a competitor, would it be a threat to the business model or is the chosen model still sound?
- If the other business model could be a threat, are there significant barriers to allowing customers or other businesses from executing that business model against the one the innovator has chosen?

If the business model selected by the innovator is the most appropriate and sustainable one available, it should rise to the top regardless of the competitive scenarios outlined above. Because it is so important not to choose a business model in a vacuum, it should be tested with potential purchasers of the solution before a final decision is made. Additionally, the innovators should consider the primary risks associated with the model and develop specific plans for managing them. A framework such as Michael Porter's Five Forces can be helpful when evaluating business models within the medtech industry (see 2.4 Market Analysis).

Operationalizing a business model

Fundamentally, the steps in the biodesign innovation process that come after a business model has been chosen are focused on helping innovators operationalize the business model they selected. As soon as a business model is chosen, it is important to begin thinking about what kind of expertise will be required to implement it. Ideally, a young company will identify a potential hire who has previously built the kind of business it is pursuing. For example, if a disposable model has been chosen, it might be time to augment the engineering team with someone who has successfully pioneered disposable products in the past.

There are many different ways to align a company's expertise with its business model. One approach, of course, is to directly hire individuals with the right experience. Depending on the stage of the company's development, however, consultants can also be leveraged. Another approach is to seek this expertise in the form of advisors who might sit on the company's board of directors. When considering what type of expertise is required, it is important to consider technical and business competencies, both of which will play a critical role in successfully operationalizing a company's business model.

Sometimes, as a company grows, a new product is considered that requires a different model than what is used for the other products in the portfolio. The first and most important step is to recognize this fact before proceeding with development. Typically, for instance, companies that are organized around large capital equipment devices with service contracts have a hard time transforming themselves to act as a disposable company, and vice versa. While there are some notable exceptions, such as Intuitive Surgical which has executed well on both capital equipment and reusable models, the list of companies able to master dual-business models is short. Unless the managers of a business are uniquely prepared

for the challenge of executing multiple models, the best choice, at least initially, is to "keep it simple" and focus on one model at a time, based on an evaluation of the company's total overall opportunity.

A final note: using business models to screen and eliminate concepts

Using business models as a concept screen differs substantially from IP, regulatory, and reimbursement. While these other factors require significant, increasingly in-depth research to enable innovators to assess the risks associated with each concept, business model screening is more of a thought experiment. By working through the questions outlined in this chapter, innovators are able to determine the most appropriate business model for a concept. Accordingly, this screen can be applied to every idea under consideration without undue time or effort. If a concept falls squarely into a business model category and there are examples of companies successfully using that model for comparable technologies within or outside the medtech sector, then this idea should move up on the prioritized list of concepts (and will perform well on the risk scoring matrix described in 4.6 Final Concept Selection). On the other hand, if a concept seems out of alignment with typical medtech business models or there are few examples of companies successfully employing the chosen business model for similar offerings, then innovators may be well served to consider how to modify the concept or model. Alternatively, if the business model appears to be particularly difficult or infeasible, they might treat this as a killer risk and set aside that concept, particularly if it is not a top performer relative to the other concept screens.

Online Resources

Visit www.ebiodesign.org/4.3 for more content, including:

Activities and links for "Getting Started"
- Understand characteristics of different business models
- Choose a business model
- Validate the preferred business model and identify risks
- Determine what new expertise will be required to operationalize the model

Videos on business models

An appendix that outlines rules of thumb for choosing a business model

CREDITS

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NOTES

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