



Insights and Lessons to Help Innovators Succeed on Their Journey from an Idea to the Implementation of a Global Health Solution

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Introduction

If you're interested in developing products or services to address global health needs, a great adventure awaits you. Most people who commit themselves to a path in global health find the work inspiring and rewarding, especially when they help bring about real, lasting impact. However, they also report that their quest can be frustrating and all-consuming, with no guarantee of a successful passage.

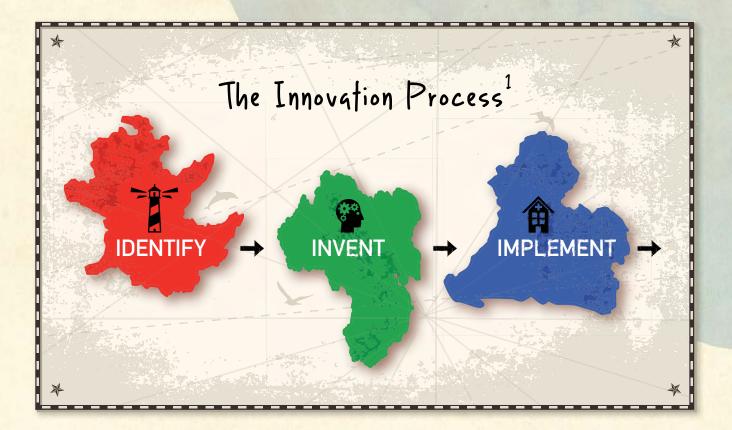
The purpose of this guidebook is to help you navigate the process of taking a global health solution from idea to implementation. The information captured here will help you capitalize on new opportunities and discoveries on your journey, as well as anticipate complexity, uncertainty, and risks along the way.

It's our belief that the fundamental process to **Identify**, **Invent**, and **Implement** a new product or service is roughly the same across industries (see diagram on page 3).

But each domain (e.g., software, automobiles, global health) has its own unique challenges and constraints that complicate the innovation process. There are plenty of books and articles that address the innovation process generally, but few of these resources are specific to global health. To help address this gap, we spent 18 months talking to global health practitioners, university teams, funders, and other stakeholders about their approach to global health innovation and, in particular, the challenges they've faced.

E By compiling their stories, we hope to shed light on what factors make global health innovation difficult and at which steps in the innovation process innovators and entrepreneurs are most likely to struggle. We also highlight creative solutions to common barriers in an effort to inspire you to be resourceful on your own global health innovation journey.

Join us as we explore the process of global health innovation!





Members of the Jaipurknee team during the early phases of their global health innovation journey

A mother and child in a Nigerian hospital

hoto: Ben Cline, courtesy of D-Rev

Background

What Is Global Health?

According to the Institutes of Medicine (IOM), global health is defined as "health problems, issues, and concerns that transcend national boundaries, may be influenced by circumstances or experiences in other countries, and are best addressed by cooperative actions and solutions."²

Some of the conditions that influence, and complicate, the innovation process for global health include:

- Multiple stakeholders, including patients, providers, and payers, with distinct yet overlapping interests
- Rigorous safety and testing requirements imposed by governments and healthcare providers
- A variety of geographies, each with different infrastructure, customs, and market dynamics
- Limited resources—financial, physical, and human—that constrain purchasing power, adoption, and collaboration.



Global Health Trends

Over the last 50 years, the health of the world's population has improved significantly. Vast strides have been made in life expectancy, infant mortality, and child health. However, progress has not been realized equally in countries across the globe. Roughly 90 percent of the world's health care resources are spent on diseases that affect 10 percent of the world's population.³ Many nations, particularly in Sub-Saharan Africa and South-East Asia, lag the rest of the world when it comes to addressing infectious and communicable diseases, as well as dealing with emerging chronic conditions.⁴ This is due, in part, to the severe resource constraints that affect many developing countries. Against this backdrop, the need for innovative products and services to address the health of people in resource-constrained settings has never been more important.



Key Players in Global Health⁵

Multilateral Organizations

Receive funding from multiple governments, which is then distributed to countries around the world. These organizations develop and collaborate on global health targets; create standards for care, treatment, and the use of related products; provide technical assistance for training, research, and program management; and support local programs with funding. The major multilateral organizations are part of the United Nations and therefore receive support from member states, in addition to contributions from private philanthropies.

Bilateral Organizations

Agencies from a single country that offer assistance to developing countries. They provide grants, loans, training, and technical assistance to improve global health and advance foreign policy priorities. While developed and developing nations support global health activities, the majority of government donations comes from the Group of Eight (G8) industrialized nations—Canada, France, Germany, Italy, Japan, Russia, the United Kingdom, and the U.S.

Nongovernmental Organizations (NGOs)

Seek to advance global health through service provision, research, advocacy, economic and social development, education, and emergency relief. NGOs include philanthropic foundations, secular private organizations, faith-based organizations, contracting organizations, and private corporations.

Local Communities and Individuals

Include health care providers, researchers, policy makers, educators, and advocates working to improve health in their local geographies. Domestic governments may provide support, but this varies widely based on income, debt, availability of external resources, and political commitment.





About the Project

To understand innovation in a global health context, we conducted interviews with aspiring and experienced global health innovators. Through these discussions, we identified six steps in the innovation process that consistently create roadblocks for innovators yet are crucial to the success of a global health project.

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These six challenge areas are:

- I. Identifying and validating needs
- 2. Understanding market/stakeholder dynamics

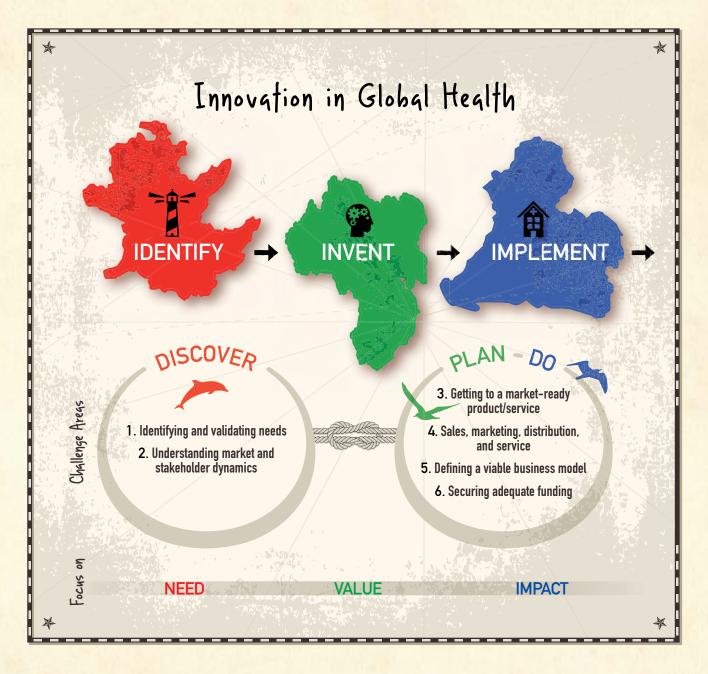
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- 3. Getting to a market-ready product/service
- 4. Sales, marketing, and distribution
- 5. Defining a viable business model
- 6. Securing adequate funding.

the NEED right. These activities are becoming better understood through university programs and courses that focus on early-stage design and prototyping. The more elusive and messy work takes place in

The steps that correspond to the **Identify** phase of the innovation process tend to be mostly about discovery and getting

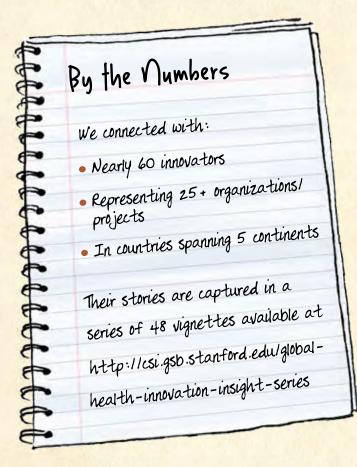
> Amy Lockwood was one of the many global health innovators who contributed to the project



steps that span the Invent and Implement phases. Activities in the **Invent** phase involve planning how the innovator will achieve VALUE for the many stakeholders affected by the new product or service. Those in the **Implement** phase focus on doing or acting so that IMPACT is achieved.

While the innovation process appears linear and these steps may seem somewhat sequential, in reality they're iterative, especially in the Invent and Implement phases where elements of planning and execution interact. Importantly, if new information is uncovered in any of these areas, it may require the innovator to revisit earlier steps and reevaluate previous decisions.

The output from our research project includes a series of short case studies—or vignettes—that focus on challenges and solutions in these six key areas. Some of the stories highlight successes, while others share failures and lessons learned. We hope you'll find both types equally instructive. The collection of vignettes, which we call the **Global Health Innovation Insight Series**, can be accessed in its entirety at http://csi.gsb.stanford. edu/global-health-innovation-insight-series.



Meet the Organizations

Anacor

Anacor Pharmaceuticals, Inc. is a for-profit biotech focused on discovering, developing, and commercializing novel small-molecule therapeutics derived from a unique boron chemistry platform. The company's Drugs for Neglected Diseases initiative leverages product development partnerships and other non-dilutive funding sources to apply Aanacor's technology to addressing neglected diseases.

AdaptAir

The AdaptAir team developed a silicone adapter for the nasal cannula that's part of the bubble CPAP equipment used in resource-constrained setting to treat children with respiratory infections.

BioVentures for Global Health

BVGH is a non-profit organization that works at the crossroads of biotechnology and global health to find the common ground between the goals of the global health community and the pragmatic needs of companies.

Consure Medical

Consure Medical devised an innovative device that enables a new standard of care for managing fecal incontinence.

Cycle Technologies

Cycle Technologies works with research institutions, government organizations, and private companies to build their businesses and bring their products or services to market. Cycle Technologies partnered with the Institute for Reproductive Health at Georgetown University to commercialize CycleBeads, a natural family planning method.

d.light

d.light Design is a for-profit social enterprise whose purpose is to create new freedoms for customers without access to reliable power so they can enjoy a brighter future. The company designs, manufactures, and distributes solar light and power products throughout the developing world.

D-Rev

D-Rev is a non-profit product development company whose mission is to improve the health and incomes of people living on less than \$4 per day. D-Rev projects include the Brilliance device for treating infant jaundice and the ReMotion prosthetic knee (originally known as the JaipurKnee).



A student showing off her dlight solar LED lantern



Health workers conducting a field trial in the Philippines

Anesthesia providers receiving training in Nigeria (above); a mother watching over the treatment of her jaundiced infant (left)

Design that Matters

DtM is a nonprofit organization that creates new products to help social enterprises in developing countries offer improved services and scale more quickly. DtM projects include the Firefly device for treating infant jaundice and the NeoNurture incubator (also referred to as the car parts incubator).

Diagnostics for the Real World

DRW is a for-profit spinout from the Diagnostics Development Unit at the University of Cambridge. The company is focused on manufacturing and commercializing technologies created at the university that can to help address the unmet diagnostic needs of patients in developing countries. DRW's first product was a reliable, low-cost Chlamydia Rapid Test (CRT).

East Meets West

East Meets West is a nonprofit organization that seeks to transform health and education in communities of disadvantaged people in Asia by building partnerships, developing opportunities, and creating sustainable solutions. EMW's Breath of Life program includes the Firefly phototherapy device, which it developed in partnership with Design that Matters.

Embrace

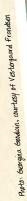
Embrace's mission is to advance maternal and child health by delivering innovative solutions to the world's most vulnerable populations. Its first product is the Embrace infant warmer. The nonprofit Embrace Global works in partnership with the for-profit Embrace Innovations.

Gradian

Gradian Health Systems equips hospitals around the world to deliver anesthesia safely and economically. The company's Universal Anaesthesia Machine (UAM) is used in Europe, Africa and Asia to deliver general anesthesia in a wide variety of environments, even in the midst of a power outage.

IDRI

The Infectious Disease Research Institute is a nonprofit seeking to advance a new approach to addressing infectious diseases. The organization combines the high-quality science of a research organization with the product development capabilities of a biotech company to create new diagnostics, drugs, and vaccines.





A family water filter in a typical Kenyan home

Impact Review

The Impact Review team created an online platform for developing-world healthcare providers that facilitates improved information sharing about affordable solutions in the maternal and infant health space.

Inspire

The Inspire Medical team developed a low-cost breathing assist device for pediatric patients in acute respiratory distress.

Institute for Reproductive Health

Through partnership with international and local organizations, IRH at Georgetown University strives to expand family planning choices to meet the needs of women and men worldwide. IRH pioneered the natural family planning approach called the Stanford Days Method and works with Cycle Technologies to commercialize CycleBeads, the simple device that supports the method.

KickStart

KickStart's mission is to lift millions of people in Africa out of poverty, quickly, cost-effectively, and sustainably. To do so, the organization designs, promotes, and mass-markets simple money-making tools that small-holder farmers buy and use to build profitable family enterprises.

Life Force Kiosks

Life Force Kiosks is a nonprofit that aims to reduce preventable waterborne diseases like typhoid, cholera, and diarrhea to save lives in the most vulnerable communities. The organization developed a new model of preventing water contamination by working with existing community water vendors to affordably purify water and clean storage containers.

LifeStraw

The LifeStraw and LifeStraw Family products are point-of-use water interventions developed by Vestergaard Frandsen, a mission-driven for-profit company. VF's Carbon for Water program, which has made more than 800,000 LifeStraw Family water filters available in the Western Province of Kenya, uses carbon financing to fund its activities.

Maternova

Maternova is an e-commerce marketplace for technologies and innovations addressing maternal and newborn health.

Project Limitations

Although we extracted many valuable insights through our interviews with global health innovators, we want to acknowledge certain limitations to our study. Our research was entirely qualitative; our approach was relatively unstructured; the sample of innovators was defined opportunistically rather than systematically; and we disproportionately gathered data from innovators connected to Stanford. As a result, the output is hardly definitive. However, we believe the themes and lesson are directionally important and can serve as a basis for conducting more rigorous studies in the future.

Mulago Foundation

The Mulago Foundation is a private foundation focused on the prospect of creating a better life for the world's poor. Concentrated in rural settings in developing countries, the foundation's work is driven by four elements that contribute to this overarching goal—livelihood, health, education, and conservation.

OneWorld Health

OneWorld Health was the first nonprofit pharmaceutical company in the U.S. The organization develops new medicines for neglected diseases around the world.



PATH

PATH is a nonprofit organization committed to delivering high-impact, low-cost solutions to global health challenges. One of PATH's projects was the Safe Water Project, which sought to evaluate how market-based approaches could help accelerate the widespread adoption and sustained use of householder water treatment and safe storage products among the world's poor.

Phoenix Medical Systems

Phoenix manufactures, distributes, and services a wide range of affordable solutions for maternal and infant care.



Young women learning how to use a female condom

PSI

Population Services International (PSI) is a nonprofit organization focused on improving maternal and child health, family planning, and the need for HIV and AIDS screening and treatment. Its projects include the development of a social franchising model and the application of commercial marketing approaches to promote the widespread adoption of products such as the female condom.

Repsira Design

This team developed a novel asthma spacer to inexpensively ensure the effective delivery of asthma medication to the lungs of pediatric patients in developing countries.

SafePoint

The SafePoint Trust is a nonprofit organization that aims to use information to solve basic healthcare problems, including the dangers of syringe reuse and unsafe injections.

3rd Stone Design

3rd Stone Design is a product design, strategy, and development company that engages in the design and development of consumer, medical, and renewable energy products. Its projects include the development and commercialization of the DoseRight syringe clip.

Using the Guidebook

The remainder of the Global Health Innovation Guidebook is organized in chapters—one for each of the six key greas in our framework. In each chapter, you'll find anecdotes and examples from the vignettes as well as lessons and themes that cut across the stories.⁶

We hope these observations and insights will help you, as current and future global health innovators, become more effective in your quests to increase access and improve quality of healthcare for people around the world.

We encourage you to leverage this resource as a:

- Roadmap to prepare you for the challenges and risks inherent in these six critical steps in the innovation process
- Source of inspiration and comfort when you encounter obstacles on your path
- Reference to aid you with problem-solving strategies and decision making
- Reminder that the learning is in the journey!

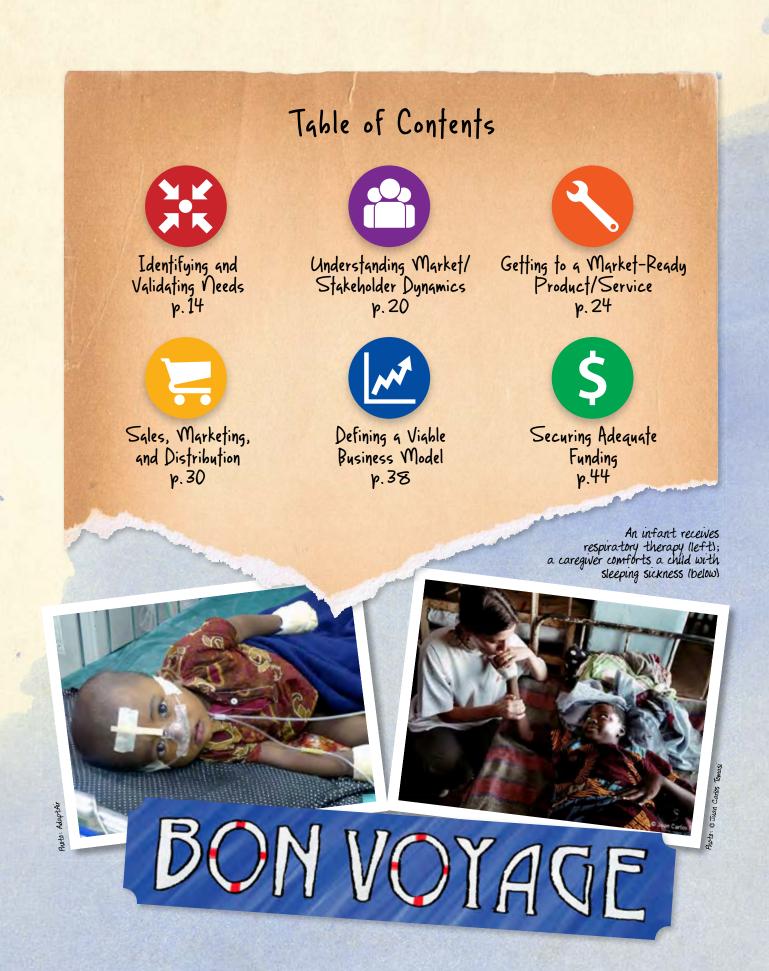


"It's not about being clever. Most people are pretty smart. It has to do with the ability to deal with failure... The ability to deal with failure in a constructive way entices you to be more creative, to be more stubborn, to be more persistent despite how difficult it is."

-Dr. Helen Lee, Diagnostics for the Real World



voto: Wellcome Trust, courtesy of DRW



Identifying and Validating Needs

Identifying and validating needs is mostly about gathering and corroborating information that will ultimately drive the creation of a product or service to meet the unique requirements of a target user group.

While needs finding has always been an implicit part of the innovation process, it is explicitly addressed in user-focused approaches. This emphasis emerged with the recognition that innovators who identify a compelling and important need have a fighting chance of reaching the market; those who get it wrong are much more likely to waste their time and effort.

At the heart of developing an effective solution is thoroughly understanding the problem it's meant to address. This can only be accomplished when the innovator immerses himself into the situation where the problem exists and develops **empathy** for those who experience it. Stories from the field reveal that this is more difficult in the health arena, where innovators may struggle to understand what it's like, for example, to suffer from a preventable illness. This challenge is compounded when innovators work in unfamiliar settings with different environmental, social, and cultural norms.

Sadness, guilt, and pity are common emotions when individuals visit resource-constrained environments and interact with people who lack access to adequate healthcare; but these emotions do not lead to empathy. True understanding of another's feelings requires innovators to figure out how to set aside their own ideas, biases, beliefs, and egos to clearly see the user's point of view. Not everyone is able to achieve this. It takes a great deal of self-awareness to be able to distinguish between one's own assumptions and the reality of the user. This challenge is especially pronounced when an innovator believes the user is either very different or very similar to himself.

"What people tell you the problem is up front is almost never the actual problem."

- Joel Sadler, Remotion Design



Photo: D-Rev

FIELD NOTES: Playpumps International

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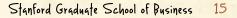
Sympathy versus Empathy

Too often, innovators develop sympathy for the target audience rather than authentic empathy. For instance, Trevor Field, who founded Roundabout Outdoor to manufacture, install, and maintain the controversial **PlayPump**, was deeply moved when he observed women and girls in rural villages of South Africa shouldering the daily burden of collecting

water. Unfortunately, his solution, a technology that was meant to serve as both a children's merry-go-round and community water pump, failed to gain widespread adoption because, among other challenges, it didn't address the real user need. His idea was that children, who lacked play equipment, would power the pumps as they had fun. However, creating mechanical energy to operate hand

pumps has not been a primary obstacle to supplying clean water in Africa. Financing, maintaining adequate water supply infrastructure, improving water quality, and water scarcity itself are all far more daunting problems, which PlayPumps didn't resolve. Moreover, the solution did not take user perspectives into account. Children found the pumps difficult to rotate and quickly lost interest, leaving women to try operating the merry-go-rounds by hand—an activity they found both inefficient and embarrassing.





According to one innovator, establishing empathy requires "immersion." When seeking to design a less expensive prosthetic knee joint for underserved patients in rural India, the U.S.-based team that developed the JaipurKnee needed a way to better understand the psychological needs of their target users before making a preliminary trip into the field. First, they spent hours talking with amputees in the U.S. Then, they acquired a specialized device that an individual could strap to a bent knee to simulate a prosthesis. By walking on this device, each engineer experienced first-hand what it felt like to

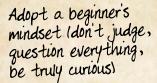
depend on an artificial limb. "It was terrifying," recalled Joel Sadler, one of the inventors. "[It helped us understand that] there was a psychological issue for these amputees when they walked on these really cheap knee joints. It boiled down to the fact that

they were really scary to use. So the problem we were trying to solve started to evolve from simply designing a cheap knee joint to helping the user reduce the fear of walking on a prosthesis and feel more confident walking."

How to Gain Empathy



Be a fly on the wall (try not to interfere)







LOOK for the duct tape (workarounds, inconsistencies) Record everything land frequently reflect on what you're learning)



Cast a wide net Italk to a variety of stakeholders in multiple geographic areas)

FIELD NOTES: Consure Medical

Experiencing Real Compassion

Amit Sharma and Nish Chasmawala of the **Consure Medical** team achieved empathy, as well as true compassion, for patients affected by fecal incontinence and their family caregivers when the mother of one of their classmates became ill and experienced this unpleasant and distressing condition. They saw their colleague become depressed by his mother's condition and

the lack of effective solutions to help her. After spending significant time learning about the problem from his point of view, they invested countless hours in the U.S. and India listening to and observing doctors, nurses, family caregivers and the patients themselves in order to understand the physical and emotional burden of the fecal incontinence, and the needs and constraints of those affected by it." In rural community hospitals in India, there are usually eight beds in a room with limited ventilation and inadequate waste

disposal systems. Family members usually try to form a human shield to do an absorbent pad change and clean the patient," Chasmawala described. Picturing their colleague and his mother in this humiliating environment, he continued," [It] created a sense of pathos in us, but also motivated us to develop a solution."



To be empathic, you have to develop a relationship with another person, to feel their pain and suffering and imagine walking in their shoes. For U.S.-based innovators, it is important to recognize that this depth of understanding is not developed quickly or over long distances. Those who are serious about addressing the needs of a population in a developing country must commit to spending significant time with those who will be using, purchasing, or servicing their solutions. In many cases, the most effective way to achieve this is to relocate to the target market to gain close, ongoing access to users. "Being in the field [is] a necessary precondition in my mind," explained Pamela Pavkov, co-inventor of the Inspire bubble CPAP device. "If you're not constantly talking to users and getting feedback, you're not going to get the learnings you need to incorporate into your design iterations."

Additionally, to be effective, innovators must adopt an approach that blends humility and perseverance. As Krista Donaldson, CEO of D-Rey—a nonprofit technology company focused on the needs of people living on less than \$4 per day—explained, "This type of work takes a lot of patience and the ability to go with the flow and recognize



Members of the JaipurKnee team get to know an above-knee amputee in India.

that you may spend a week trying to visit hospitals and get nowhere. But what you don't realize until you step back and digest the information is that you're still learning a lot." All too often, she noted, aspiring innovators are "not always very good at listening. They're too focused on getting the information they think they need," rather than hearing what people are really telling them.



Staying on the Right Path: Identifying and Validating Needs

Needs finding is an exercise in letting go...figure out how to set aside your own ideas, biases, and ego to truly understand the user's point of view

Consider the user's emotions, preferences, aspirations, limitations, capabilities, relationships, and environment

Remember that empathy building can be uncomfortable and requires a great deal of humility

Listen more than you talk

Recognize that understanding real user needs is not a long-distance activity; build relationships that allow you to develop empathy, not sympathy, for the target audience

Revisit the user need throughout the innovation process as new information is uncovered to help keep you on track

Helpful Resources

For more information about building empathy as well as methods and tooks to help you do so, check out:

"Bootcamp Bootleg," Hasso Plattner Institute of Design, Stanford University, 2010, http://dschool.stanford.edu/wp-content/ uploads/2011/03/BootcampBootleg2010v2SLIM.pdf (June 2013).

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BY AIR MAIL

Understanding Market/Stakeholder Dynamics

Problems cannot be understood in isolation. In order to effectively define a need, it's important to consider the surrounding context. Innovators must listen and observe carefully in order to comprehend the landscape, infrastructure, relationships, history, and belief systems that inform the need and surround the user experience. This can be accomplished through a detailed assessment of market and stakeholder dynamics.

Learning about these issues in global health from afar can be difficult because research reports and formal data sets rarely exist. When they do, the information can be inaccurate, dated, or misleading. Understanding how data has been collected can help an innovator assess its accuracy. In particular, many innovators noted that one must beware of broad, top-down research methods. More often than not, innovators will have to perform their own extensive research in the space where their need exists. However, there are also challenges to gathering primary data about issues of global health. Accurate, complete answers may be elusive. Intentionally or not, stakeholders apply their own lens to a situation, especially when they have a vested interest in either maintaining the status quo or altering it. We caution innovators to consider the source for all information gathered and to remember that not everyone will necessarily want to be helpful.

"They saw that there was a need. They didn't see the demand, which is completely different."

-Marc Koska, SafePoint



noto: @SafePoint

Another challenge is that users may be tempted to provide innovators with an answer that they believe they want to hear, instead of what they really think or feel. According to Jeremy Farkas, founder of Life Force Kiosks, which supplies at-the-tap water purification and container cleaning services in Kenya, "People will

tell you pretty much whatever you want to hear in order to please you. Or, if they think you're giving something away, they'll want to answer the questions correctly to be eligible for that free thing. So you have to be really careful how you frame your questions and sometimes take people's answers with a grain of salt." This is especially true if a perceived power differential exists between the person being interviewed and the person conducting the interview. One way to validate the information provided in interviews is to observe actual user behavior whenever possible. Even if no product or service exists to address a particular need, find a proxy offering against

which

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to benchmark user actions. For example, when trying to understand willingness to pay, Farkas said, "I find it far more valuable to see what people are actually buying. Look at what's really going on as opposed to what people report they would hypothetically spend their money on." John Anner, president of the East Meets West Foundation, elaborated on that point:

"Listening is tricky. Without multiple ways to verify what people really want, it can be hard to cross the barriers of language and culture to truly understand what people need and want (good or bad). This is why the best way to figure it out is to provide a range of options and let people vote with their own money."⁷

Several innovators also advised that following the purchasing process (or flow of money) for comparable offerings can be extremely informative. For one thing, the purchasing process often reveals the presence of multiple stakeholders, each with different interests and motivations. It can also point to issues or workarounds that may create resistance or roadblocks. Consider Gradian Health Systems, which equips hospitals around the

world

Identifying and Understanding Key Stakeholders

The presence of multiple stakeholders is common in the global health field and can greatly complicate the demand for solutions to certain needs. Dr. Helen Lee, who founded **Diagnostics for the Real World** (DRW), is among the innovators who have learned this lesson the hard way as she was working in the area of chlamydia. Describing the project, Lee explained, "Chlamydia has all the emotional tags to make testing an important need. It has a high prevalence and devastating consequences for women and babies born from



infected mothers. Yet the drugs are totally effective—one pill, one time and you're cured. So the problem has been how to screen the apparently healthy individuals. The asymptomatic nature of the disease is such that infected individuals will not come to the clinic. Rather, you need to go to the sexually active group, find innovative ways to screen them, and then treat them." In response to that need, Lee and her

team developed a point-of-care chlamydia rapid test (CRT) that could be reliably and inexpensively used in the field." But it turns out that it was very difficult to launch this product," she recalled. First she faced intense resistance from the central labs and manufacturers of laboratory testing equipment, which were interested in protecting their territory. The team also discovered that although chlamydia was a significant global health concern, it was not necessarily a top priority for the governments and international and



nongovernmental organizations that might provide funding or become the early, high-volume customers of the CRT. Had she more fully understood these challenges earlier in the innovation process, Lee noted, she might have started with a diagnostic test for HIV, where there was existing market demand and funding already in place. to deliver anesthesia safely and economically even in the midst of a power outage. In understanding the purchasing process for anesthesia machines, Gradian discovered that its small team would have to market and sell to four distinct but interconnected stakeholder groups: users, hospitals, Ministries of Health, and donor organizations. Additionally, they realized that the timing of anesthesia machine sales was important. "A hospital may buy one anesthesia machine this year and not purchase another for three years or more. So how do we identify and reach these folks before they make a decision?" questioned Erika Frenkel, Gradian's Director of Business Strategy. (See Field Notes: DRW for another example.)

In assessing market and stakeholder dynamics, another common challenge is deciding when you have gathered enough information to stop. While the answer varies from case to case, D-Rev's Donaldson offered this advice: "Once you start hearing the same thing over and over again, you know that you've done good research."

Staying on the Right Path: Understanding Market/ Stakeholder Dynamics

Just because you identify a need doesn't mean there will be demand for a solution...demand is complicated, especially when the patient, provider, purchaser, and funder can all be different stakeholders with different perspectives and motivations

Watch out for biases in what users tell you as they seek to maintain or promote their own interests

Study comparable products/ services in the market for a more objective view of stakeholder behavior More often than not, you will be required to make assumptions about the state of the market — use the best available information you can gather in combination with your own critical judgment

PRIORYTET PRIORITAIRE

Corruption exists everywhere; in low-resource settings it mostly involves informal payments...whether you decide to resist or go along with these different financial norms, you must be aware that they exist and account for them in your plans

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Getting to a Market-Ready Product/Service

Developing a market-ready product requires that a prototype be turned into something that meets required regulations and industry standards and can be manufactured and delivered at scale, at a cost that will allow a return to be realized. The ability to take an idea or prototype and transform it into a marketable offering is an essential step in the innovation process, yet innovators are often unprepared for the time- and resource-intensive nature of these activities.

As Robert Miros, CEO of product design, strategy, and development consultancy 3rd Stone Design, stated, "That's not to say the idea is the easy part, but there are a lot of needs and a lot of potential ideas. The challenge becomes how do you take that initial idea, scale it up, and make it into a real product?"

Typically, this phase of the process is described as being the least glamorous. Funders—either grant making organizations or commercial investors—tend to be more interested in underwriting ideation, which is an energetic phase of work that moves more quickly by comparison; or in supporting scalable implementation, where significant impact is achieved. Moving from prototype to product is time consuming, costly, and often fraught with unexpected risks. According to D-Rev's Donald-

son, "People love prototyping and the really

cool 'silver bullet' science and technology that go into solving a problem. But at the end of the day, we need to find people who are also willing to support good old-fashioned engineering. That's not the sexy part to fund." Jayanth Chakravarthy, product manager for D-Rev's Brilliance infant jaundice solution, added, "You can deliver a prototype and a really nice story in about a year. But to make a real product, you need to invest two years at least. It's a lot of work and there's no immediate gratification. You have to wait for it." Some innovators believe that the process of developing medical technologies takes even longer. Based on her own experiences, Pavkov, a member of the Inspire team who now works as an investor, reported, "[It] takes 5 to 10 years—and that's in the for-profit world. Developing a device for emerging markets or in a non-profit setting adds additional layers of complexity."

In order to build a for-profit or nonprofit organization, innovators invariably need a strategy to cross the "chasm" between prototype and product. Increasingly, even those individuals or teams who would rather hand-off their innovations (through licensing or acquisition) need to overcome these hurdles. More often than not, organizations that purchase or license technologies want offerings

> "To get a factory set up, to have the right sort of drawings and guality documents and inspection criteria...there's



a lot of hard work that goes into making something consistent and high quality at a low cost."

-Robert Miros, 3rd Stone Design

that are market-ready. They prefer to focus on the commercialization aspects of the innovation process and are rarely interested in early-stage ideas that require the heavy investment of resources. Alejandro Palandjoglou, co-inventor of the AdaptAir nasal interface, which was designed to increase the effectiveness of a treatment for infants with respiratory infections, experienced this challenge first hand when he approached a major medical

device manufacturer about licensing his product. "They were really interested in selling the [AdaptAir] device along with their CPAP machines. The thing is, they want me to give them the market-ready device with their packaging and they'll take care of the sales. I would have to take the product through clinical testing and regulatory approvals, which is time consuming and expensive to do." Palandjoglou proposed turning over the technology to the manufacturer in its current state of development, but his contacts implied that it would likely get lost inside such a large organization with competing priorities. "And [they said] it would be better if I took it forward and sold it to them when it was ready to go," he noted. Unfortunately, without access to the funding or the expertise to move forward through clinical trials and regulatory approvals, progress on AdaptAir has stalled.

One strategy to help innovators make the leap from prototype to product is to partner with experienced individuals and organizations that can help overcome important hurdles. As Ned Tozun, co-founder of d.light, maker of low-cost, high-quality solar lamps, put it, "There's a real value to experience." Some people believe that a single team or entity can execute all of the required steps in the innovation process. In reality, it is more common for many players to be involved and for the team to evolve over time through growth or collaboration to meet the organization's changing needs.



Whether collaborations are achieved through strategic hires, contractors, consultants, joint ventures, or outsourcing, the key is for innovators to be brutally honest about what they're good at and how/where they can benefit from greater expertise. For example, many student teams coming out of universities can successfully design and produce small numbers of prototypes for testing under controlled circumstances, but they lack the expertise to design for mass production and create products that perform as in-



DoseRight comes in 10 different sizes that are color-coded by dosage volume

A nurse fills a syringe fitted with the DoseRight clip (left), the DoseRight syringe clip after final manufacturing (above)

tended when implemented outside a lab or study environment. "They are coming from a largely theoretical training so the basics of manufacturing are often not top of mind," Miros explained. He has partnered on several projects with the Beyond Traditional Borders program at Rice University to help students developing global health technologies, such as the DoseRight syringe clip, transition out of the laboratory environment and into mass production. Bringing in experience can be costly, but so can the rework associated with making mistakes or pursuing unproductive paths.

Another challenge that frequently derails global health innovators on their way to market is the added burden of regulatory requirements and clinical testing that is unique to the healthcare industry. Teams seeking to aid the world's poor through the development of better irrigation pumps, cook stoves, or other non-health innovations can test their innovations with users and rarely need safety or effectiveness data and government authorization to make them publicly available. In contrast, those working in healthcare have a legal and ethical obligation to ensure that their products and services are safe and efficacious. This requirement can add millions of dollars and years to the innovation process.

FIELD NOTES: Respira Design

Complex Requirements for a Simple Solution

Respira Design developed an asthma spacer for use in resource-constrained settings, produced from a single sheet of paper. It could ship and store flat, and then be transformed into a usable spacer through a series

of cuts and folds. Despite the simplicity of the design, because

it was a medical device, it was necessary to test the extent to which it impacted the delivery of medication, and how many uses each device could sustain. The team also needed to study the circumstances in which the device would perform successfully, including whether the spacer would function as intended in situations of emergency or distress." This was a medical device that would potentially be used for someone who was having an asthma attack," said Barry Wohl, one of the co-founders." We couldn't

put it in the hands of a mother to treat a child without a detailed understanding of how effective the device was in transferring aerosolized particles from the inhaler to the lungs. That was the minimum amount of clinical data we needed to be able to sleep at night." Collecting this data was also necessary if the device was to receive approval from regulatory board, such as the FDA, which would impact where it could be sold.

To conduct the necessary tests, Respira needed substantial funding. Unfortunately, the team quickly discovered that potential donors and investors wanted to see clinical data showing that the device worked before making a sizable financial commitment. Ultimately, this quandary was one of the factors that halted development of the solution." Cost was on our radar from the beginning, in terms of materials and distribution," said Eric Green, another Respira co-founder." But we didn't realize how expensive testing would be." The team cautioned other medical device innovators to plan carefully for the time and expense associated with gathering user data in a safe and ethical manner.



10to: Respira Desui



Amit Sharma and Nish Chasmawala in the lab, preparing for product testing (left), Sharma and Chasmawala submitting their first-in-human clinical study protocols to the hospital ethics committee (right), the Consure device (far right)

One benefit of gathering evidence that demonstrates the safety and efficacy of a health-related offering is that it can be used to convince users of the offering's value in the sales and marketing process (see next section). Some innovators report concerns that if a medical product is specifically developed in or for a low-resource environment then users may believe it is second rate. The Consure Medical team, for example, intended to use

the results of its rigorous clinical trials to debunk the view that cost-saving products from emerging countries were either knock-offs or inherently inferior. "Our product serves an unmet need in both emerging and developed markets by improving clinical outcomes and reducing costs," Chasmawala said of his fecal incontinence device. "For Consure to realize its global potential, we [have] to overcome any perceptions of substandard quality."

Helpful Resources

For additional information about developing medical technologies and preparing to bring them to market, check out the following resources:

Stefanos Zenios, Josh Makower, and Paul Yock, et al., Biodesign: The Process of Innovating Medical Technologies (Cambridge University Press, 2010).

Supplemental materials to the Biodesign textbook are now available that focus on topics such as regulatory, reimbursement, and intellectual property in Singapore, India, China, and Japan. Visit ebiodesign.org and search "global chapters" to access the information.

Rebecca Richards-Kortum, Biomedical Engineering for Global Health (Cambridge University Press, 2010).

Peter J. Hoetz, Forgotten People, Forgotten Diseases (AMS Press, 2013).





Staying on the Right Path: Getting to a Market-Ready Product or Service

It's difficult to find companies to license early-stage ideas, so getting to a prototype often isn't enough... you may be required to delve into product development, regulatory, legal, manufacturing, export, etc. even if your end goal is to create an exit rather than build a company

AIR MAIL

PAR AVION

Funder interest in supporting this phase of work is low compared to ideation and dissemination...be prepared to spend significant time and effort raising the money needed to get from a functional prototype to a market-ready product

There's no substitute for experience... but experience isn't cheap; be realistic about how much it will cost to get the talent you need

Sales, Marketing,

In parallel with transforming a prototype into a market-ready product or service, innovators must determine how the offering will reach the user and be adopted. In global health, the local context dictates what sales and distribution channels are available, how much marketing will be necessary to stimulate adoption, and what sort of after-sales service will be required.

All too often, new U.S.-based innovators try to apply Western approaches to these challenges only to discover that they're infeasible, ineffective, and/ or culturally inappropriate. For example, while companies in the U.S. invest considerable time and energy in generating referral sales, this strategy can backfire in other geographies. KickStart, which manufactures an affordable line of "Money-Maker" irrigation pumps, discovered that cultural norms in some parts of East Africa prevent the use of word-of-mouth sales and "viral marketing," as people in these areas are traditionally modest. Practical considerations also discourage sharing news about success. "If you're very, very poor, you actually don't even tell your family that you made a lot of money, because, if you do, your extended family will come and beg from you. You certainly don't tell your neighbors. They will be jealous of you, and they will also beg from you.

And so there's almost no word-of-mouth about the good news of making money in Africa," explained Martin Fisher, one of KickStart's founders.

There are many different approaches to encourage product adoption, and innovators must be thoughtful about which route they choose, especially initially. For instance, when the Minister of Health in Mali asked University of Georgetown's Institute for Reproductive Health (IRH) and Cycle Technologies to roll out CycleBeads, their natural family planning product, the team had some reservations but decided to press ahead with a large-scale launch. Unfortunately, they quickly learned that they were underprepared. "We didn't lay the needed groundwork, and we tried to do too much too quickly," recalled Victoria Jennings, a researcher at IRH. In particular, fostering buy-in among health workers and expanding their capacity to offer the method was more difficult than the team imagined. Raising public awareness about the availability of the new method and how it worked was another challenge. In addition, IRH had trouble establishing an effective delivery and support model for the product. "If you're trying to do all of those things across the country without having tested them in pilots, you're going to make mistakes," Jennings emphasized. For the adoption of a new health technology to be sustainable, innovators must identify the key stakeholders affected by the innovation and put plans in place to engender their support on an ongoing basis. (See Field Notes: SafePoint for another example.)

Building awareness of the problem and the solution, as well as establishing a trusted brand, are

essential in the adoption process. However, the importance of marketing is often underestimated in developing countries. As Tozun explained about d.light's solar lamps, "We felt like if we could get the product right, at the right price, then we could just sell gazillions of them. At the time, we didn't fully understand how complex marketing and distribution can be." One of d.light's challenges was that the market was littered with low-quality, solar-based

lighting products. "People are used to getting screwed by bad products," Tozun said. "Even if we could find a way to make the product available in hard-to-reach rural areas, which is hard enough, no one would actually buy them. This is a new technology and people are inherently risk adverse." Although people had been more than willing to help test the products, getting large numbers of consumers to buy them was another matter. Despite its relatively low cost, any d.light solution was a sizable investment for most low-income families. d.light ultimately relied on demonstrations via road shows, mobile sales vans, and other approaches that enabled potential customers to interact with the products.

"All of this stuff takes time. You need to have the right team in place. You need to have the right marketing and the right brand support, the right product portfolio, the right pricing set, the right scale capability. All of the pieces have to be there, and you really have to claw your way up."

-Ned Tozun, d.light



roto: d.light design

d.light Founders Sam Goldman and Ned Tozun

Two Rollout Strategies Achieve Different Results

Marc Koska, inventor of the K-1 auto-disable (AD) syringe, established a nonprofit, The SafePoint Trust, to raise awareness about the dangers of unsafe injections. SafePoint's

FIELD NOTES: SafePoint first order of business was planning and executing a massive public awareness campaign in India." My overall goal was to get a mandate for the use of auto-disable syringesnot mine, anybody's—in all the public clinics and hospitals, which were a travesty in terms of delivery of unsafe injections," Koska said. In the span of a week, the campaign reached 509 million people through thousands of public service announcements about the perils of syringe reuse, delivered via television, cinema, and radio, press conferences, and newspaper articles. In response to the public outcry that followed the campaign, the Minister of Health issued a mandate for all of India's states to use AD syringes in government hospitals and health centers, and 11 out of 26 states converted. Unfortunately,

the change didn't stick. Several states reverted back to their old practices when multi-use syringe manufacturers, concerned about losing malan and and and and their foothold, flooded the market with free product and sought to discredit SafePoint's messages about the



noto: @ SafePoin

risks of unsafe injections.

Realizing that he needed a more comprehensive adoption strategy, Koska used a more thoughtful, measured approach when he took SafePoint and his AD syringe to Tanzania. There, rather than push from the outside, he identified six key stakeholder groups that had to be aligned from the inside to make a lasting change. He worked closely with the Ministry of Health, Tanzania's standard agency, syringe manufacturers, donors, health workers, and the public to create a mutually beneficial

ecosystem around the adoption of AD syringes, with support cascading from one group to the next to ensure they were all on board. SafePoint also piloted the approach in several facilities before rolling it out across the country." It worked beautifully. It's a fantastic system," Koska reported, and it generated more sustainable results.

To convince customers that the lights would last, d.light also experimented with loaning lights to students in target communities during exam season. "It's something that gets awareness in a community without positioning the product as a handout," Tozun explained. d.light structured the program to allow students to use a solar light to study at night for roughly one month. "After the month was up," Tozun said, "we found that 70 to 80 percent of the families would buy the

light. Plus, study time doubled in the evening for students and grades went up dramatically." Trials like this helped d.light earn trust throughout the community as the lights proved to be reliable during the trial period and beyond. (See Field Notes: PSI for another example.)

In addition to marketing and branding activities, innovators also need to build a sales strategy. Sales channels in health care can be long and complicated, with multiple stakeholders. This characteristic is often more pronounced in countries with less organized market mechanisms. It's important to ensure that each player in the value chain has an appropriate incentive and the right knowledge/ training to promote the offering, otherwise little will get done.

Tapping into established power structures and directly engaging with key opinion leaders, such as village leaders and other local government officials, is also worth considering, as representatives from the nonprofit PATH discovered on the organization's Safe Water Project. According to PATH consultant Ben Mandell, "Outsiders tend to invent things from scratch. But just because you're in [a new geography] doesn't mean there's not some sort of power network in place." When PATH first tried disseminating safe water products in rural areas without involving key opinion leaders, it found that its sales results were low. "We realized that we weren't being sensitive to the existing influencer relationships that existed in the villages," said Mandell. PATH then modified its approach to proactively meet with the key opinion leaders in every village before initiating sales. "We discussed what we're doing and tried to get them onboard. We explained the merits of our program, the health benefits, and the uniqueness of how consumers can get clean water through

our program. Usually, when they're onboard and supportive our sales are much better," he noted.

Another important lesson is that after-sales service can become a source of competitive advantage. Too often, goods targeted at low-income populations are donated and then left to languish because no one was trained or equipped to maintain or repair them. In addition to helping bolster correct and consistent use, after-sales service can be an invaluable source of sales leads, as well as a channel for collecting customer data to inform product improvements and new product development. Because it involves educating/training local residents and employing them (which, in turn, contributes to the local economy), after-sales service can also improve public perception of the innovation or organization. (See Field Notes: Phoenix Medical Systems for an example.)

One additional challenge worth mentioning is the fragmented nature of many health markets in developing countries. Clinics in remote, rural areas are especially difficult to reach. Moreover, resource-constrained facilities typically want products in small volumes to address their immediate needs, which can make it challenging to achieve economies of scale. As a result, some innovators have begun experimenting with the idea of aggregating demand. For instance, ReMotion was trying to catalyze the development

Linking Branding to Stakeholder Analysis

FIELD NOTES:

Population Services International (PSI), a nonprofit focused on delivering global health products to those in need, has spent a great deal of time thinking about how to use branding and social marketing to drive positive health behaviors." It's important that when you have a new product you think carefully about how to position the product, not just around the functional benefit but also around the emotional benefits, " said Brian Pedersen, a PSI technical services advisor." Pedersen led a campaign to stimulate female condom use in Lesotho among

women aged 18-29. He first conducted market research in the target age group to understand perceptions of the female condom, which he found were overwhelmingly negative. Based on these findings, he developed a comprehensive campaign to rebrand a next-generation female condom, positioning it as the preferred choice for women who are sophisticated, independent, and able to take charge of their lives rather than focusing on improvements to the product itself. Through the involvement of peer educators, events, media, and a distribution strategy that made the female condom available where young women were most likely to need it (in toilets and dormitories at five universities in Lesotho), PSI successfully changed women's opinions about the female condom.

However, the results of the program were hampered by a miscalculation regarding the relative power of stakeholders in contraception decisions. The campaign was narrowly focused on marketing to female consumers. But in Lesotho, even if a woman is comfortable bringing a female condom into a relationship, the man is culturally the one who decides whether or not to use it. "The feedback we got from women was," You need to talk to our husbands and our boyfriends about this. You need to tell the men why they should accept it," Pedersen stated. Accordingly, PSI's next campaign would be targeted at men. "We're going to see if we can convince men to accept having their female partners use the female condom, or at least encourage them to find out about it, by marketing it as the alternative for the man that wants to feel like they're having condomless, natural sex again."

Defining an Integrated Sales and Service Strategy

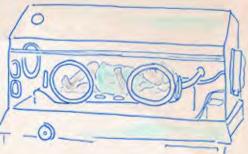


V. Sashi Kumar, the founder of Phoenix Medical Systems, figured out an optimal sales and service

strategy through trial and error. When Kumar tried selling his first lowcost incubator, he went through the few medical equipment distributors that existed in India at the time. Relative to the simple medical products these companies were used to representing, such as blood pressure cuffs, the incubator was technically complex. "They were willing to sell the product, but they didn't make an effort to understand how it worked. So when they went to a hospital, they couldn't present the incubator very well." This deterred many sales reps from making a concerted effort to sell it.

Kumar recognized that he needed a sales team that better understood the technology, and that could anticipate and thoroughly address questions from doctors. To accomplish this, he hired three sales representatives of his own." I trained them very well on the product and then put them on the job," he said." Naturally, since they were able to talk about the product pretty well and impress upon the doctors that it was the right product, sales started picking up."

Kumar had another key insight related to the role that after-sales service could play in fueling sales. Phoenix initially had a single service technician. However, he noted," Most of the medical device manufacturers in India failed because they couldn't provide good after-sales service. I knew that was the case, but



I didn't think about it until later on. When I gave good service, the customers kept coming back." Kumar significantly increased Phoenix's service technician staff. Again, he carefully trained these employees and coached them to help build relationships with the customers. Metrics were established to ensure that each customer received timely, thorough service and that customer satisfaction was maintained at high levels. Because of the support they received, customers developed a strong sense of loyalty to Phoenix. In addition, "The technicians became a channel for us to bring in information about hospitals and customers who might be interested in the product," Kumar said. Phoenix passed these leads to its sales reps who then followed up to close a deal. of networks among small clinics that fit 20 to 30 knee prostheses per year, enabling them to share resources and make joint purchasing decisions. "One of the things we've heard time and time again in developing countries is that it's really hard for people to procure parts," Donaldson said of D-Rev's experience in the field. If clusters of small clinics would make joint purchasing decisions, they could improve their assurance of supply for prosthetic knees as well as other devices. At the same time, it would be more manageable for ReMotion to meet the needs of these smaller entities.

FIELD NOTES:

Maternova

Bringing Together Buyers and Sellers

Maternova, an online knowledge platform in the field of maternal health, was experimenting with demand aggregation as it sought to build a marketplace for maternal health supplies. With this strategy, the organization hoped to grow its downstream sales volume at the same time it addressed an upstream manufacturing challenge." One of the problems we found is that manufacturers will only produce products in runs of 5,000 or 10,000. But there are very few customers who want to buy 5,000 before they've ever tried something," said Meg Wirth, Maternova's founder. While a handful of international agencies might place an order of this size, most health clinics and hospitals wanted much smaller quantities." What we're doing is pulling together NGOs and other smaller organizations who want to buy something. If it's something new that nobody has ever tried before, we combine their orders to unlock the minimum quantity. And I'm pretty excited about that because I think that's where a lot of innovators get stuck. They have this great idea that they've tested using prototypes they've made themselves. But then, when it's time to start manufacturing the product, nobody can actually try it because manufacturers won't produce less than 5,000 units." Maternova intended to leverage its network of contacts and its online platform as a mechanism for overcoming this barrier." One group may need 100 units, and another one

needs 30, and another one needs 500. When you put them all together, you're getting closer to the minimums," Wirth said." And one of these groups might write to someone else and say 'Do you want some too? If we can get the rest of the people, then we can make it happen." Maternova's marketplace model was just getting off the ground, but Wirth and her team were encouraged by their early results.



Staying on the Right Path: Sales, Marketing, and Distribution

Sales and distribution are often the greatest challenges innovators face...it's the most local aspect of business and Western models often don't apply

Effective adoption strategies must align the interests and financial incentives of all key stakeholders in the value chain

Just because you figure out marketing, sales, distribution, and support in one country does not necessarily mean that the same model will translate to other geographies...typically, these issues must be figured out one market at a time Be careful not to reinvent the wheel when establishing sales, distribution, and support...be really clear about what channels already exist and do detailed due diligence to assess whether they can effectively meet your needs before you decide to build your own

It's often necessary to build demand and/or educate multiple stakeholders to sustain adoption...figure out what each group needs to know and craft a plan to effectively and efficiently get that information to them

➢ If you have a big need but a small, fragmented market, consider aggregating demand to address upstream and downstream demand-related challenges

Helpful Resources

For an interesting report on marketing to base of the pyramid consumers, see:

"Marketing Innovative Devices for the Base of the Pyramid," Hystra, March 2013, http://www.hystra.com/opensource/Full_report_Maketing_for_the_BOP.pdf (June 2013).



Defining a Viable Business Model

A sound business model integrates decisions about developing and producing an offering and plans for marketing, sales, distribution, and service, with a strategy for how the product will generate value. Accordingly, defining a business model should never be done in isolation of the other steps in the innovation process or without thorough research.

For example, part of creating a viable model involves determining how to price the offering so that the end user can access and afford it. Yet, pricing cannot be set until manufacturing, sales-related, and distribution costs have been determined, as each of the parties involved in these activities will demand an incremental margin. In an effort to appeal to potential funders, innovators will frequently identify a price for their product or service based on cursory knowledge of the costs or the price requirements, without doing enough research to build an accurate model. Changing the price later in the development process can undermine the authority of the innovator and shake funders' confidence. "I feel like our space is littered with good intentions and great ideas that aren't sustainable because so many people overlook the business model," D-Rev's Donaldson noted.

To design an effective business model, innovators require a combination of legal, financial, and business acumen. They also need a keen understanding of the geography in which they're working. Each market is distinct. While there may be similarities, it is important to understand the unique characteristics and nuances of each country, state, and region and the customers they include. The breadth of skills and depth of un-

"The challenge is that when you want to serve the poorest of the poor, there's only so much you can do in terms of cost recovery."

-Jeremy Farkas, Life Force Kiosks



derstanding that's needed to define a viable business model contributes to the high likelihood that partnerships with those more experienced in different subject areas and with knowledge and personal relationships in the markets where the innovator seeks to work will be helpful.

One early decision that global health innovators struggle with is whether to become a nonprofit or a for-profit entity with a social mission. Here's how one article summarized fundamental differences between these alternatives:⁸

For-profit businesses have as their primary objective the pursuit of profit for the benefit of their owners. The directors and managers of a for-profit business have a fiduciary duty to maximize shareholder return, and if pursuit of a social mission interferes with that primary duty, the directors and officers can face legal jeopardy.

Nonprofits, on the other hand, have as their primary objective the accomplishment of a social or public mission. Nonprofit directors and managers must run the enterprise to further public rather than private interests. If they confer private benefits on individuals (other than reasonable compensation for services rendered, itself a touchy subject), they may face legal liability. And they generally cannot engage in profit-sharing arrangements with private investors or businesses. To put it another way, businesses and nonprofits are fundamentally single-purpose entities.

In the global health field, it's increasingly common to see innovators try to stretch these two models toward each other. For example, nonprofit organizations are pursuing greater sustainability (and lesser dependence on grants and donations) by generating earned income that can be reinvested back into the business. Gradian, for instance, is a wholly-owned subsidiary of the nonprofit Nick Simons Foundation. However, the organization uses market mechanisms to help it achieve its mission of making appropriate and afford-

able anesthesia equipment available to the widest possible audience. "Previous thinking suggested that to be a nonprofit 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 the organization. We felt strongly that a nonprofit could incorporate traditional business strategies," Frenkel stated. Gradian's business model is to sell its product to nonprofit organizations and governments at roughly its manufacturing cost so it has a revenue stream to reinvest in expanding the business. "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 requires," Frenkel described. Additional philanthropic funding from the Nick Simons Foundation is used to support other aspects of getting the business off the ground during its first few years in operation, such as user training and after-sales support.

Mission-driven for-profit companies (also called social enterprises) are similarly borrowing from nonprofit models in an effort to achieve financial returns as well as social impact. Diagnostics for the Real World is one such organization. "DRW is a for-profit company, but not only for profit," Lee stated. "The founders voluntarily agreed to cap our profits at 15 percent," she noted. In doing so, DRW's goals are to keep the price of its products low for customers in resource-limited settings while making just enough of a return to be self-sustaining. The advantage of this strategy is that it helps DRW achieve its mission; the downside is that it limits the type of funders willing to invest in the organization (see see next section). One criticism of applying commercial methods to global health is that this approach is most successful in reaching middle-income customers and only the upper tiers of low-income users. To effectively reach users at the base of the socioeconomic pyramid, some assert that it's necessary to provide products and services to this target audience at no charge. Many studies have been performed in the field to understand the effects of giveaways on user demand, as well as the perceived value of an offering. To date, the outcomes are mixed, although many of the innovators we spoke with have developed their own opinions on the subject.

d.light's Tozun summarized the main argument we heard about the problems created by nonprofit subsidies: "I've been to many villages where you see [products] that have been given away. Almost 100 percent of the time, they're no longer functioning because there's no infrastructure that's been developed to support them." Vin Narayan, Co-founder of ReMotion Design, which was commercializing the JaipurKnee, explained that the users' perception of value is also important: "The decision to sell devices rather than donate them was fundamental to our philosophy on social impact. People will almost always accept a donated product even if it does not work for them, but they will not continue to purchase your product unless it provides them with value. It's very difficult to find out if you are actually solving the problem when you give things away for free."

Over the last several years, "hybrid" business models, that formally blend elements of nonprofit and for-profit legal structures, have emerged. According to the article referenced previously, ⁷ hybrids are "based on the principle that a single entity cannot by itself do everything that a social venture needs to do. Instead, the hybrid uses a series of contracts and agreements to combine one or more



independent businesses and nonprofits into a flexible structure that allows them to conduct a wide range of activities and generate synergies that cannot be done with a single legal entity. The two (or more) entities that generally make up a hybrid are distinct for legal purposes, and each is responsible for compliance with the laws and regulations that govern it, but when properly structured, the legally distinct entities can behave much like a single entity. For these reasons, a hybrid is often



a better solution than a single legal entity that tries to incorporate a wide range of activities."

These models can be complicated and challenging to define, given the lack of proven examples, but they can offer innovators the benefits of being able to tap multiple sources of funding and employ the best of both philanthropic and business-based strategies. For instance, the Infectious Disease Research Institute (IDRI) has devised a model to create for-profit spinouts from its nonprofit arm. As IDRI conducts neglected disease research, it periodically identifies technologies with first-world applications that may provide significant profit. The nonprofit licenses these technologies to a for-profit arm, which then raises private funding to accelerate and enhance research and development for commercial applications. When the for-profit company licenses the resulting products to large pharmaceutical companies or achieves other forms of commercial success, IDRI's portion of those royalties can be used by the nonprofit to further its efforts in developing global health solutions. In some cases, IDRI receives equity ownership in the company as well, so that if the company is successful IDRI can direct the proceeds from its equity stake back into its mission-centric programs. While the financial benefits of this arrangement are clear, IDRI's CEO Stewart Parker acknowledged the administrative burden as well as a potential "tensions" between the two entities. "Your [for-profit] partner always wants you to make sure it's the first priority all the time, and that's probably not going to be the case given our mission-centric programs."



Defining a Hybrid Structure

One organization that recently adopted a hybrid model is Embrace, maker of a low cost infant warmer. Embrace

was originally founded as a nonprofit. However, according to CEO Jane Chen, the team underestimated the resources required to develop and commercialize its product. "Little did we know the time and capital it would require for us to get from a concept to a manufactured and clinically tested product—not to mention what it would take to build a distribution channel to sell our product. Nor did we realize the amount of management time it would require for us to raise this capital as a non-profit organization; precious time that would be taken away from building the product and the infrastructure needed to deliver the product, and to make impact at the scale we had envisioned."⁹ At the peak, Chen estimated that she was devoting upwards of 80 percent of her time to fundraising.

Taking these factors into account, along with advice from lawyers and other advisors, the leaders ultimately decided that they would benefit from having a hybrid structure: a for-profit and a nonprofit organization working in conjunction. The nonprofit owns the intellectual property for the infant warmer and licenses it to the for-profit organization, which pays a royalty for each unit it sells. In terms of funding, the nonprofit, Embrace Global, accepts philanthropic contributions so it can purchase warmers and donate them to NGO partners to reach the poorest communities and develop educational programs to promote newborn health. The for-profit, Embrace Innovations, raises its funding from venture capitalists and impact investors to fund research and development, manufacturing, clinical testing, and establishing the sales and distribution infrastructure to sell the product to customers who can afford to pay for it.

This hybrid structure was still being proven, but Chen believed it was the right decision for her organization." Hybrid structures have become sexy in the social





enterprise Space. When people come to me asking about whether they should take this approach, I tell them to think really hard about whether it makes sense. If they can figure out a structure that works within a single entity, it's a lot less work. But the most important thing is to start with your mission and then adopt a structure that allows you to achieve it." As these models continue to emerge, innovators are beginning to develop more well-defined approaches for effectively managing the complexity inherent in any hybrid organization structure. Having a clearly defined and articulated the division of labor between the two organizations seems critical to success.

Regardless of what legal structure is chosen, the key to defining a viable business model seems to be figuring out how key stakeholders in the value chain-from the company to end users and all the players in between—receive appropriate value from the offering. For the organization, this means how it realizes impact and the desired return on its

FELD NOTES:

Brilliance

investment of time, money, and other resources in the space. For the customer, it means receiving a product or service at a price that is affordable and also commensurate with the value the offering delivers. For other value chain participants, this means earning "market rates" for the role they play. Even nonprofits need to compensate their partners at a competitive level if they want to create a lasting solution, and every agreement needs to be carefully constructed so that roles and expectations as well as incentives are well-understood. "Negotiations related to any kind of deal like this consume a huge amount of time and resources, especially for a small team," said Donaldson. But, she emphasized, they are critically important.

Motivating Desired Behavior Through a Creative Licensing Agreement

As a central aspect of its business model for the Brilliance infant jaundice solution, Donaldson and the D-Rev team used a partnership agreement to address manufacturing, sales, and distribution. Phoenix Medical Systems licenses the technology from D-Rev in exchange for licensing fees and royalties. In terms of incentives, D-Rev felt strongly about making sure the deal represented fair but competitive rates for Phoenix so the company would be committed to the project. To help motivate the Phoenix sales team to devote time and energy to selling to public and



district hospitals in India, D-Rev got creative with how it structured its royalty stream. Customers across all market segments would be offered the same price, but D-Rev would take a lower royalty on sales to healthcare providers in public and district hospitals." If you sell to a public hospital, you get a bigger cut. If you sell to a private hospital that serves higher-income patients, you don't get as much back," the team clarified. By making sales to the target market more lucrative, D-Rev believed the sales reps would be more focused on reaching this audience.

The idea of pursuing dual markets is another strategy that innovators are experimenting with to make their business models viable. This involves making a product available at the lowest possible price to a low-income target market while simultaneously selling it at a higher price to those who can afford it. For example, while the Institute for Reproductive Health makes CycleBeads available at cost through government agencies and NGOs, Cycle Technologies attempts to achieve economies of scale (in manufacturing, etc.) by selling the product at a profit to consumers in developed markets. This approach also reinforces the credibility of the product. "If I'm living in Benin and I feel like I'm receiving this product because you think it's culturally appropriate for me, but someone in the U.S. would never use it, then I'm going to feel like there's some sort of credibility gap," explained Leslie Heyer, CEO of Cycle Technologies.

While dual markets can be attractive, innovators must be thoughtful about how and when to pursue them. Particularly with medical devices, the added burden of clinical and regulatory requirements in multiple environments can place a financial strain on a fledgling organization. The demands of tackling multiple markets at once also can be dangerously distracting. As with any business model, you must carefully and realistically consider the pros and cons before making a commitment.

Staying on the Right Path: Defining a Viable Business Model

Without an effective business model it's nearly impossible to achieve scale, regardless of the strength of your product or access to funding...a sound plan is needed whether you intend to create a company or achieve an exit.

When choosing a legal structure, consider the importance of your mission and the best way to preserve and achieve it...for-profits with equity investors often have to give up some control over their missions in the interest of maximizing shareholder returns, while nonprofits may be influenced by the missions of their donor organizations. Hybrid (for-profit/nonprofit) structures are helping some innovators protect their mission while at the same time giving them access to a great variety of funding sources...but hybrid models are inherently more complex and resource-intensive to manage.

For-profits, nonprofits, and hybrids all must create business models that meet the needs of key value chain participants li.e., the model must incentivize desired behaviors).

AIR MAIL

Securing Adequate Funding

Raising substantial financial support to develop and disseminate a global health solution can be another difficult challenge. This is largely because traditional funding sources like venture capital (VC), which is routinely available to entrepreneurs in other sectors, are out of alignment with opportunities in the global health space.

As Miros of 3rd Stone Design summarized, "The VC funding window of expectation is usually too short or too grandiose for global health applications." DRW's Lee concurred, commenting that in most cases VC firms, which are notoriously driven by financial returns, "are not interested in products for the developing world. By definition, you are working for a market that has no money." \$1,000 to \$250,000. While producing the entries can be time-consuming, the contests offer benefits that extend beyond just the money raised. Innovators pointed out that they can help teams think deeply about their business models and approach to the market, strengthen their "pitch," generate publicity/interest in the project, and lead to relationships with mentors and other connections

As noted, funding can be easier or harder to raise at different points in a project. Many find it relatively simple to secure small amount of funding when they're first getting started with ideation and prototype development. One widely-used approach is to enter business plan competitions, which often include awards that range from



"If you don't have the big bucks, then it's going to take time."

-Geno de Hostos, Oneworld Health

that can be invaluable over time. "I wouldn't necessarily recommend this approach for everyone, but it was a really good stepping stone to help us get ready to involve real investors," said Tozun of d.light's experience with business plan competitions. Just be aware, cautioned Chen from Embrace, "You can devote a lot of time to these competitions,

but only one or two organizations win. If you enter, make sure you're far enough along that you have a cohesive, compelling story."

As projects progress and increasingly large sums of capital are needed, fundraising can become more challenging. But an innovator's ability to overcome these hurdles is a critical success factor. "I've learned that you have to really identify the funding realistically and thoroughly. Other-

wise a good idea and a lot of enthusiasm and idealism will not get you anywhere concrete," Lee said. To help address the void created by the absence of VC firms in the space, grant funding is playing an increasingly important role in financing global health needs for nonprofits and for-profits alike. As Gradian's Frenkel described, "Working with a foundation and philanthropic money has been an immense asset to us. As project-related invest-

ments are becoming more common with some foundations, looking to these organizations for seed funding, investment, or other forms of support is an incredibly powerful option for innovators who may be developing products that aren't inherently profitable." In addition to providing capital, many foundations also contribute important know-how, useful contacts, and other resources to their beneficiaries based on the experience they've amassed working with organizations at various stages of development.

Anacor Pharmaceuticals provides an example of how for-profit organizations are finding creative ways to take advantage of foundation and government funding to support their global health initiatives. Anacor has a boron-based chemistry platform that showed activity against the causative agents of several neglected bacterial and parasitic diseases during the company's early research period. Although CEO David Perry felt a responsibility to apply this technology to the neglected disease space, the company was venture-backed and pre-revenue. As a result, devoting time and money to the pursuit of new therapies for complex, unprofitable global health markets would create a conflict with the objectives

of its investors. However, Perry and Eric Easom, Anacor's Program Leader for Neglected Diseases, developed a plan to leverage foundation and government grants as well as Product **Development Part**nership agreements to support its global health R&D efforts on a cash-neutral basis. "We felt like if we could do it by raising money, rather than spending shareholder money, then we should do it," said Easom.

However, foundation and government funding can have certain limitations. Notably, many grants are designated for a particular development program and have specific underlying rules and timeframes governing their use. That means they cannot be used to develop infrastructure or to explore new projects that might enhance different research platforms. D-Rev experienced this with its Brilliance product. After realizing that financing from larger funders would be restricted in such a way that it could limit D-Rev's ability to respond to unexpected challenges and opportunities when getting the product to market, the organization decided to focus on a series of unrestricted grants from smaller, more agile foundations rather than pursue contributions from major foundations.



Photos: Mulago Foundation

The team found that these smaller funders were able to make funding decisions more quickly, and were often more flexible in terms of how their grants could be used. D-Rev also appreciated that smaller funders were more open to supporting innovative approaches to addressing global health needs, while larger organizations tended to limit themselves to more traditional models for international development. Laura Hattendorf and Kevin Starr of the Mulago Foundation (back row, to the right of center) with the staff of a health center in Hatiya, Nepal; a doctor and patient interact in India (below)

As innovators wrestle with challenges like these, other creative funding solutions are emerging in the global health field. "I always like to look at how resourceful people have been," stated Laura Hattendorf, portfolio director of the Mulago Foundation, in describing some of the factors she considers when making an investment. (See Field Notes: DRW and Field Notes: LifeStraw Carbon for Water for examples.)





Crafting a Blended Funding Strategy

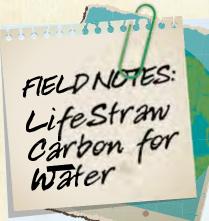
One emerging strategy, employed by organizations with hybrid structures, is to capitalize on blended funding strategies. For instance, **Diagnostics for the Real**

World (DRW) was set up as a for-profit entity in the U.S., with a whollyowned for-profit subsidiary in England. In addition, Lee still had her nonprofit academic entity at the University of Cambridge. In part by design and in part by luck, each of these three different entities was able to access different funding streams. In the U.S., DRW applied for funding from the National Institutes of Health (NIH) and the Small Business Innovation Research (SBIR) program. The SBIR program gives grants for domestic small businesses to engage in research and development opportunities for technologies with the potential for commercialization. Meanwhile, DRW's U.K. subsidiary applied for grants from the Technology Strategy Board, a public body in England that promotes, supports, and invests in technology research, development, and commercialization. The Diagnostic Development Unit at Cambridge was able to expand its nonprofit funding by applying for different types of grants from various foundations. "By having multiple sources of funding through multiple organizations, but all working towards one goal, we have managed to raise the funds we need," Lee said.

However, Lee admitted that managing a mélange of funding sources was burdensome. Because the relative dollar amount of each individual grant was not always substantial, the organization had to apply for funding repeatedly. More problematic was the team's lack of control over how the funds could be spent



and when they were received. With the timing of application deadlines, decisions, and awards completely in the hands of the funders, there was no direct link to the cash flow needs of the organization. As a result, "[The funds] sort of show up at the time they show up," Lee said, which limited the organization's ability to optimize its plans.



Using Carbon Credits to Fund a Public Health Intervention

Vestergaard Frandsen (VF), a for-profit company that operates under what it dubbed a humanitarian entrepreneurship business model, considered seeking donor funding to subsidize the cost of its LifeStraw Family water filter. However, the company had repeatedly

observed the fickle nature of philanthropic funding for point-of-use safe water programs." The funding would support a solution for a small area over a period of three to five years, and then move on to another project or be discontinued," related Alison Hill, VF's Managing Director, Climate." But access to safe drinking water is a long-term investment that a community needs. And in the short run, we didn't feel like these populations could wait." VF eventually came up with the idea of linking carbon finance to providing safe water at the household level. VF gives away LifeStraw Family water filters and provides training/support to families in homes without access to municipal water sources. In exchange, the company earns carbon credits based on the premise that the filters make it unnecessary for recipients to boil their water for safety, thereby preventing current and future

carbon emissions. Admittedly, the undertaking, called the LifeStraw Carbon for Water program, pushed the limits of existing carbon finance projects and was somewhat controversial in development circles. Yet, it underscored how innovators were becoming increasingly creative in devising sustainable funding strategies.





A mother and child with their LifeStraw Family water filter in Kenya's Western Province; a woman washes sugar cane

with purified water

An additional issue to consider when developing a funding strategy is the importance of being able to demonstrate impact. Savvy commercial, philanthropic, and impact investors are increasingly requiring their prospective portfolio companies to provide data that shows their intervention truly makes a difference. As the Mulago Foundation puts it on their website, "We measure impact because it's the only way we know whether our money is doing any good. In fact, we don't invest in organizations that don't measure impactthey're flying blind and we would be too. Those organizations that do measure impact perform better and evolve faster, and discussions around measuring impact almost always lead to new ideas about effectiveness and efficiency.¹⁰" The Mulago team advocates for an approach that's rigorous enough to be believable, but simple enough to be doable for a lean, growing organization.

This involves:

• Figuring out what you're trying to accomplish the real mission (e.g., prevent HIV infection in Brazil).

- Picking the single best indicator to demonstrate that you've accomplished you mission. (e.g., decrease in HIV infection rates).
- Getting real numbers—this means establishing a baseline, measuring again at the right interval, and sampling enough of the right subjects in the right way.
- Making the case for attribution showing that your intervention/ efforts caused the change.
- Calculating bang-for-the-buck figuring out how much it cost to achieve the impact you demonstrated.

None of this is easy but, as the Mulago Foundation points out, "Everyone benefits from a brighter look at impact: the doers, the funders, the social sector itself, and most importantly, those who are hoping for a brighter day ahead."

Measuring Impact to Demonstrate Results

In its efforts to raise funding, KickStart International realized that it needed to be able to demonstrate to donors that its low-cost MoneyMaker irrigation pumps were having a positive impact on

the lives of the African subsistence farmers that made up the organization's target market. However, the number of pumps it sold did not indicate whether the organization was successfully meeting its mission to help lift people out of poverty." So as we were building the model for KickStart, we built our monitoring efforts," said co-founder Martin Fisher. Specifically, the organization wanted to understand how much money users of its pumps were making. To uncover this information, the team developed a systematic and replicable methodology. Every Money Maker pump that was sold through a retailer came with a guarantee form. The purchaser used the form to provide basic identifying information to KickStart. Each year, the company selected a randomized, statistically valid cohort of individuals (usually around 50-60) who had recently purchased Money Maker pumps. Two KickStart staff members then visited and interviewed each pump owner at three different intervals. The first visit, which occurred within one month of purchase, provided baseline data. The second and third visits took place 18 months and three years later, and were designed to enable KickStart to assess what changes in income and living standards were being realized over time. KickStart used the

information it gathered from the interviews to quantify the effects of MoneyMaker pumps on farm activities and quality of life. This impact-monitoring program required a sizable ongoing investment by the company. However, according to the company's website, "This is how we can offer our impact numbers with confidence."



FIELD NOTES:

KickStart

Staying on the Right Path: Securing Adequate Funding

Traditional venture funding is almost never available for solutions targeted at low-resource settings, and the growth of impact investing is not keeping pace with expansion in the global health field...this means you must get creative!

Your legal structure and physical location will dictate what funding is available to you...keep in mind that you may need to combine multiple types and sources of financing to meet your needs



Nonprofit/foundation funding is playing an increasingly important role in addressing global health needs... however, this type of funding still tends to come in smaller increments than entrepreneurial global health organizations want/need to achieve scale relatively guickly

To secure/sustain funding, you must be able to demonstrate impact

Consider the requirements of funding and the timing of its availability to assess its real value...some funding sources have implicit "costs" that make them less attractive

Helpful Resources

Students at Stanford can access an internal listing of business plan competitions at https://docs.google.com/a/stanford.edu/ spreadsheet/ccc?key=OAobB_IU61Dn4dFpVQmU5V21xaDU3T2V aTkdONkZrN3c#gid=O.

For a directory of impact investors, see "Money and Impact Investing Directory," Talgra LLC, http://impactinvestingdirectory.com/impact-directory (June 2013).

For case studies that demonstrate how six pioneering companies in the biotech space have accessed donor funding and partnered with disease experts to apply their knowledge to global health , see "Global Health Innovators: A Collection of Case Studies," BIO Ventures for Global Health, 2009, http://www bvgh.org/Biopharmaceutical-Solutions/Data-Center/Case-Studies/Case-Study-Insights.aspx (June 2013).

The Road Ahead

The six steps explored in the sections of this guidebook certainly don't reflect all of the challenges you may face as you seek to develop and commercialize global health products or services. Similarly, the lessons captured here don't necessarily represent circumstances and solutions applicable to all global health projects.

That said, we hope that this information illusvation is pressing. And, as an innovator with the trates the nature of the risks you may face and the desire to make a difference, you have the opportumagnitude of the hard work you should expect nity to change the lives of hundreds, thousands, or as you progress through the innovation process. even millions of people. The journey will test your By drawing attention to the roadblocks other ingenuity, resourcefulness, resilience, and innovators have encountered, our intent is determination as you navigate its unpreto get you thinking earlier about creative dictable twists and turns. But we hope solutions and effective strategies for you find the experience inspirational and rewarding. Good luck overcoming them. on the adventure The need for globthat awaits you! al health inno-

Why global health innovators do what they do...

"Developing novel health solutions for the underprivileged masses of our generation is excruciatingly hard but also a moral imperative. Leadership is often about being the first one to lead — putting your hand up when it matters most...All of the pain, agony, and frustrations will be worth it the moment your novel medical device benefits at least one patient in these underserved markets."

-Nish Chasmawala, Consure Medical



The co-inventors of the Consure technology: Nish Chasmawala, Dr. Sandeep Singh, and Amit Sharma (from left)



Easom is Vice President, Neglected Diseases at Anacor Pharmaceuticals

"To the child, the same age as my 7-year-old son, saved by our visceral leishmaniasis drug, I'd say 'sorry it took us so long."

-Eric Easom, Anacor

"I get to do something that actually might impact positive change in the world. What could be better than that? The problems are real, but they aren't insurmountable. They just require a little inspiration and a lot of thought, focus, and hard work. I'm lucky to have the opportunity to be a part of it." -Leslie Heyer, Cycle Technologies



Leslie Heyer is founder and President of Cycle Technologies



Gradian's Erica Frenkel meets the Director General of the Butare University Teaching Hospital

noto: gradianhealth.org

"My drive to work in global health innovation is the same drive people might have to innovate anywhere — the thrill of contributing something new to the universe is just a human thrill. The ability to have that contribution work to end some seemingly intractable problems only exponentially increases that thrill."

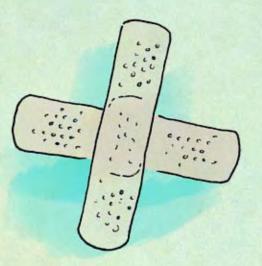
-Erica Frenkel, Gradian Health Systems

"It's a field with unmet needs that are huge in terms of the size of the population they affect and the suffering they cause." -Eric Green, Respira Design



Photo: Respira Design

Green in the Field



"It challenges our abilities as designers, provides an opportunity to make a difference in the world and the lives of those who live on the planet, and gives us the chance to meet people from many different backgrounds who share similar intents and motivations. Simply put, we believe that life is too short to put one's efforts into frivolous exercises and instead prefer to focus on projects that will challenge us and help our customers."

-Robert Miros, 3rd Stone Design

"Investing time, resources, and human capital to create and innovate simple solutions that could impact millions of lives at a time is what blows my mind. As a medical doctor, I could have impact on many more patients I this ways than from a lifetime in private practice. That is exciting." -Santiago Ocejo, Respira Design



Photo: AdaptAir

Co-inventors of AdaptAir: Dr. David Janka, Dr. Md Jobayer Chisti, and Alejandro Palandjoglou

"I worked on AdaptAir because I got personally, deeply involved with the doctors/nurses who are doing their best to save babies. Seeing my device in use was an amazing experience that energized me. I enjoy getting to know the people and hear about their problems. I get inspired by their stories..."

- Alejandro Palandjoglou, AdaptAir

"I feel bound by a sense of injustice in the world. Millions of women all over the world have no choice about how to nurture and protect their newborns. If not for the random stroke of luck that allowed my family to immigrate to the U.S., I could have been in the same predicament. I, therefore, consider it to be my responsibility to give back however I can."

-Pamela Pavkov, Inspire



Pavkov speaking with a mother at a hospital in Bangladesh

Endnotes

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- Center for Innovation in Global Health
- Program in Healthcare Innovation
- SPARK Drug & Diagnostic Discovery Program
- Stanford Biodesign
- Design for Extreme Affordability
- Stanford Health Policy
- The Program on Liberation Technology

As part of this multi-disciplinary effort, Stanford Graduate School of Business initiated the qualitative research study that resulted in the creation of the guidebook, as well as the series of case studies upon which it is based. Lyn Denend led the project. Stefanos Zenios was the faculty sponsor.

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