



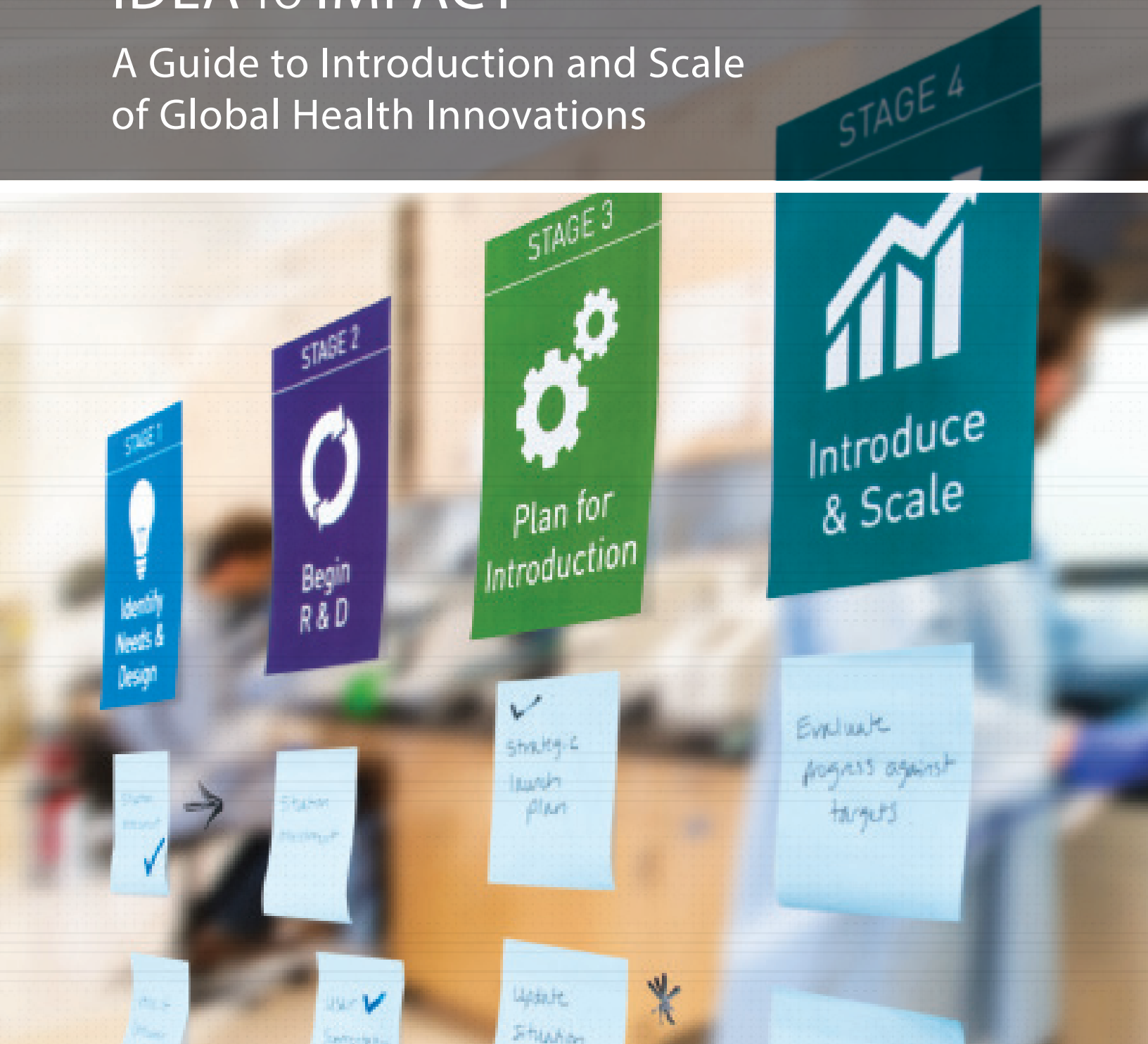
USAID
FROM THE AMERICAN PEOPLE

**CENTER FOR
INNOVATION
AND IMPACT**

USAID | Global Health

IDEA TO IMPACT

A Guide to Introduction and Scale of Global Health Innovations



From CII's IDEA to IMPACT Series

USAID's Center for Innovation and Impact (CII) applies business-minded approaches to the development, introduction, and scale-up of health interventions to accelerate impact against the world's most important health challenges. Applying these forward-looking practices to USAID's health investments, CII invests seed capital in the most promising ideas and cuts the time it takes to transform discoveries in the lab to impact on the ground.



Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations aims to support our goals by bringing together guidance and best practices from decades of public and private introduction and scale experiences. This content has been reviewed, as possible, by the organizations and companies highlighted in the case studies. USAID would like to thank our team of external advisors and reviewers for providing valuable input. We are especially thankful to PATH for their support in developing these case studies and adding their expertise to this work. Questions and comments are welcome and can be directed to the USAID lead for this Guide, David Milestone.

For contact information and to download the latest version of Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations and the companion Market Shaping Primer, please visit www.usaid.gov/cii.

Letter from USAID's Center for Innovation and Impact

Global health innovations have long been challenged by late introduction and slow scale-up. USAID founded the Center for Innovation and Impact to tackle these challenges head on, bringing business and marketplace thinking to speed the time to impact. However, whether you are in the private, public, or nonprofit sector, most of us reading this guide are acutely aware of just how difficult and complicated this task can be in any market.

As we've looked to identify best practices for scaling innovations in global health, one insight that is clear across sectors is that planning for scale must begin early and continue throughout the development process. Yet, in many cases, this is not happening. It's easy for innovators and donors to focus first on getting a product to work and leave the delivery planning for much further down the road. But innovators who fail to design their products with a clear understanding of the end market and build in delivery planning up front, often face significant challenges fully reaching their intended users at scale.

To bring added clarity to the delivery planning process—and ensure we are applying best practices to our work—we developed *Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations*. This Guide, along with its companion Toolkit and Workbook, identifies priority activities at each stage of the development continuum to help innovators and practitioners think through, plan, and execute the many activities needed to ensure successful launch and scale from bench to bedside. The Guide provides context through examples, and offers a growing set of tools that can help users put these activities into practice.

In building this Framework, we borrowed heavily from approaches used commonly in the private sector. As we met with marketing leaders from major medical device and pharmaceutical companies, what was striking from our conversations was the similarity in approaches and frameworks. The global health community also has decades of experience and critical insights from operating in developing-country markets that should be brought to bear in how we scale innovations. Through this Guide, we have worked to blend the best of these practices across both sectors.

We invite you to put this work to the test and help us learn from your experiences. Together, we can all remain on the cutting edge of best practices and successfully develop and deliver lifesaving health innovations to the poorest parts of the world.

We look forward to hearing from you.

Center for Innovation and Impact
Bureau for Global Health, USAID

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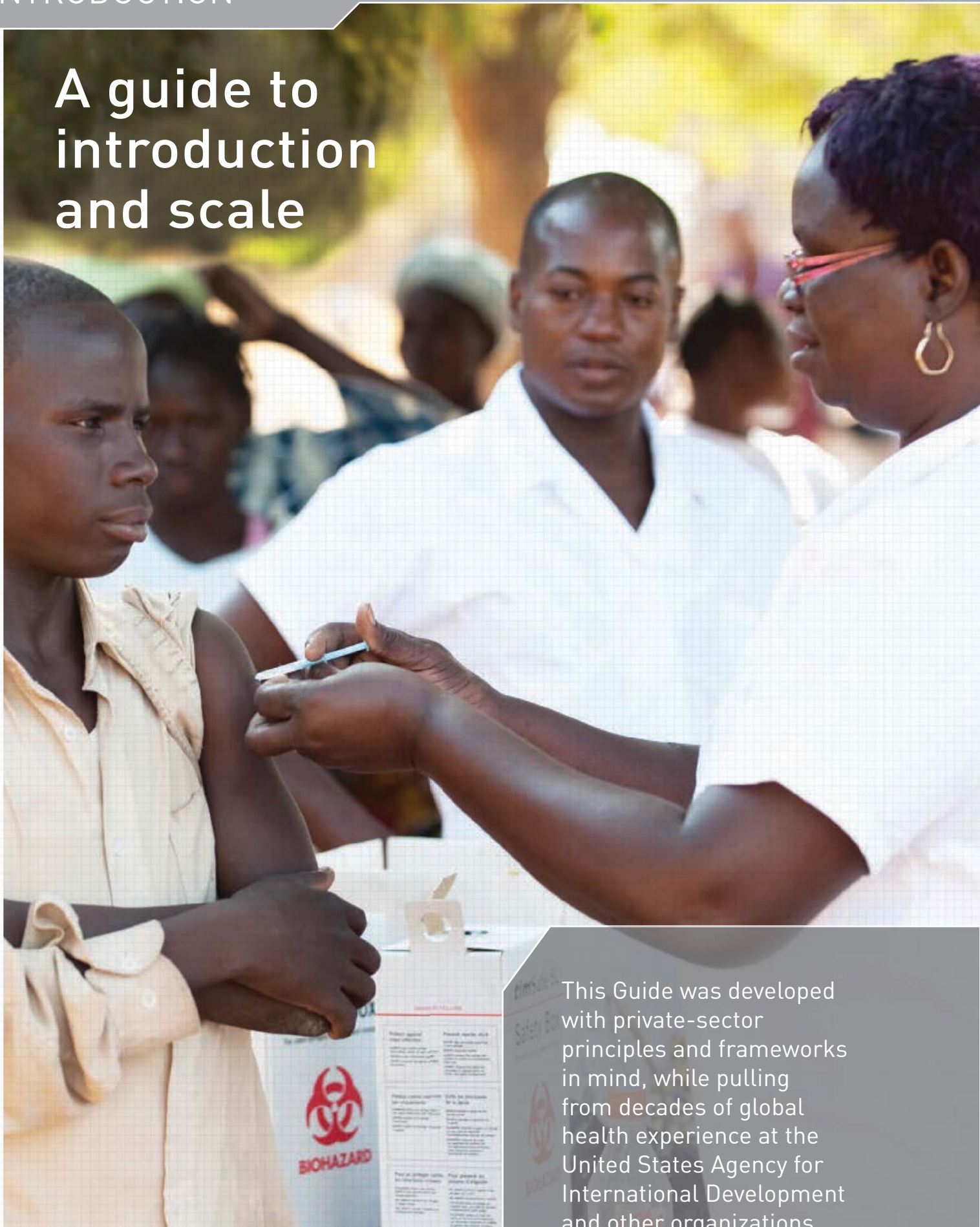
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A guide to introduction and scale



This Guide was developed with private-sector principles and frameworks in mind, while pulling from decades of global health experience at the United States Agency for International Development and other organizations.

Photo: PATH/Gabe Biencycki

“ In many ways, launch is like rocket science. Hundreds of activities all need to happen at predefined moments to a certain standard. As uninspiring as it may sound as a starting point for excellence, organizations first need to ensure that nothing falls between the cracks.

• • Hemant Ahlawat, McKinsey & Company

The challenges of developing, introducing, and scaling global health products—whether they are medical devices, drugs, diagnostics, vaccines, or consumer products—are innumerable. Many activities are required, across many countries, and with many actors (donors, implementing partners, ministries of health, and manufacturers, to name a few), making coordination and efficient execution a tricky proposition. Perhaps more significantly, developing-country public and private markets lack the resources and health infrastructure typically seen in the developed world. As a result, it often takes years, sometimes decades, for products to reach most of their intended users.

In spite of such challenges, significant progress has been made. Child mortality has been cut in half over the past two decades, thanks in part to significant advancements in how global health products are developed, introduced, and scaled. Insecticide-treated nets, for example, scaled rapidly in African countries after they were made widely available in campaigns and integrated into routine health care programs. Their widespread use, along with other malaria control efforts, reduced malaria mortality rates in children younger than 5 years by an estimated 54 percent between 2000 and 2012 (WHO 2013). Antiretroviral treatment for HIV scaled rapidly in Africa and Asia after several global partners negotiated volume discounts and committed to deploying antiretrovirals through national health systems. By 2012, 9.7 million HIV-positive people in low- and middle-income countries were receiving treatment, an achievement that has saved an estimated 4.2 million lives and prevented 800,000 infections in children (WHO, UNICEF, and UNAIDS 2013). More recently, the Meningitis Vaccine Project orchestrated the development and introduction of a novel, low-cost group A meningococcal meningitis vaccine in Africa. The Meningitis Vaccine Project and its many partners not only developed the vaccine in record time, they deployed it quickly, reaching 100 million people within 24 months of initial regulatory approval. The vaccine has already reduced the incidence of meningitis A in the ten target countries by 95 percent.

Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations consolidates and shares best practices and lessons learned from decades of scaling global health innovations and draws on best practices from the private sector, while offering a dynamic and flexible home for new thinking and advancements still to come. Many of the insights and examples are heavily informed by the learnings and practices of private companies, non-governmental organizations, academia, USAID and other donors, and other public health experts.

With a focus on activities needed to support successful delivery, this Guide:

1. Introduces a **framework** that highlights priority introduction and scale **activities**.*
2. Demonstrates the importance of priority activities through **case studies** and **lessons learned**.
3. Provides practitioners with a growing list of **tools** and an understanding of when and how to use them.

Frameworks that offer a structured process and clear accountability are not new to the private sector. BD (Becton, Dickinson and Company), an \$8 billion medical device company, lays out years of development and launch activities in its “Global Product Development System.” Medtronic calls their process the “Patient Access Acceleration Framework.” GlaxoSmithKline applies a detailed “Marketing Framework” in preparation for all of its new product launches. In fact, while these companies may give different names to it, all major medical technology, pharmaceutical, and other product companies have defined processes with clear deliverables, timelines, and responsibility. They have learned that planning for scale must happen early, often years ahead of product approval.

While scaling products in developing-country markets presents unique challenges, the rigor and principles behind these private-sector models can offer useful structure when developing, launching, and scaling up global health products.

The audience: who can use this Guide?

This Guide was designed for the global health community, including **USAID** and **other donors** working at the global level who oversee grants and manage deliverables, and **implementing partners** who contribute to global development, introduction, and scale-up efforts of global health products. It can also inform **social entrepreneurs** and **innovators**, as well as **commercial partners**, such as **medical device** and **pharmaceutical companies** expanding into Southeast Asia and sub-Saharan Africa—home to some of the fastest growing health care markets in the world.

Generally, the principles in this Guide can be applied to any global health **product**, whether a **device, drug, diagnostic, vaccine**, or **consumer product**.

This Guide, which should be relevant to a range of practitioners from different backgrounds and with varying levels of experience, may capture some “obvious” and “not so obvious” practices depending on the reader.

* While not a focus of this Guide, additional frameworks exist to support the research and development process.

How this Guide fits together

The Guide is made up of three parts:

1

Idea to Impact



Idea to Impact can be used as a reference for global health practitioners who are interested in understanding “who should be doing what, when.” This document is not meant to describe “how” to perform a specific activity, but rather, to lay out the cadence of activities and use case studies to highlight lessons and important factors for consideration.

2

Practitioner’s Workbook



The *Practitioner’s Workbook*, which can be downloaded from CII’s website, is designed for organizations managing and coordinating activities at any stage—whether donors, implementing partners, or others playing a critical coordinating role. The workbook contains more detail on priority activities and is provided in a spreadsheet format to allow users to track partners’ progress over time, assign responsibility, and update status. Some users have already found it helpful to use the workbook’s list of priority activities in meeting agendas and as fodder for discussion topics in global working group meetings.

3

Toolkit



The supplemental *Toolkit*, also available on CII’s website, is a dynamic and ever-growing collection of tools, examples, and templates that can provide structure, inspiration, and practical guidance for many of the activities described in this Guide. For example, the Toolkit includes:

- Practitioner’s Workbook
- Situation Assessment
- Sample Target Product Profiles
- Demand Forecasting Tool
- Market Sizing Tool
- Patient Journey Tool
- User Segmentation Tool
- Bottleneck Analysis Tool
- Human-Centered Design Tool
- Competitive Product Analysis
- And others...

As this Guide is intended to be continually updated with new thinking, case studies, and tools, we encourage input or suggestions. Contact information and the latest versions of the Guide can be found at www.usaid.gov/cii.

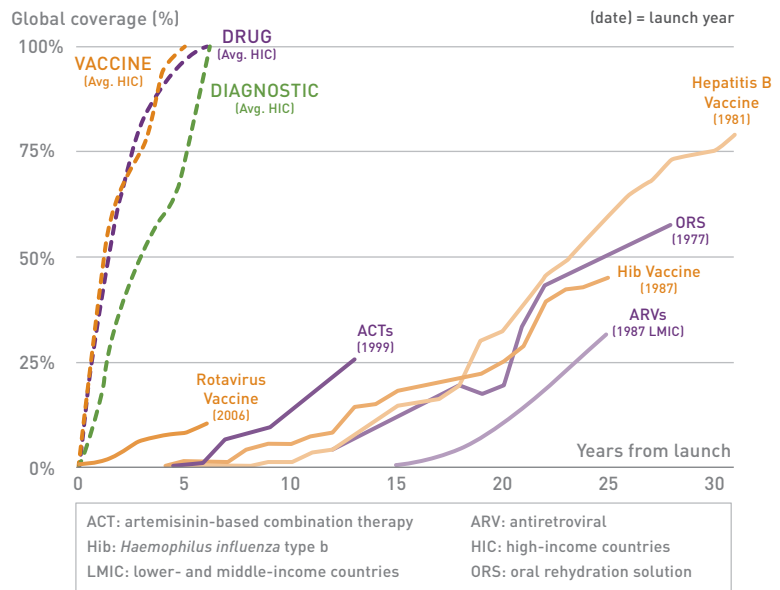
The benefits of better planning for introduction and scale

The process of introducing and scaling global health solutions can be complex, lengthy, and resource intensive. Whether incorporating user research into a compelling target product profile, executing a coordinated global clinical trial, developing an effective demand generation campaign, or convincing busy country-level advocates and regulators of the value of a new approach, there is no shortage of potential activities that must be considered, prioritized, and addressed.

Although a growing number of life-saving global health innovations have been developed in recent decades, these innovations have traditionally been slow to scale up. Protracted scale-up tends to disproportionately impact the poor. As a recent Bill & Melinda Gates Foundation, Dalberg Global Development Advisors, and Boston Consulting Group analysis shows, global health launches can sometimes take decades to reach intended users (Figure 1). This is in comparison to “typical,” or average, launches in the United States, which can reach target users in about five years. While not directly comparable given the significant complexities involved across multiple global health markets, lessons can certainly be learned from the principles by which pharmaceutical and medical technology companies coordinate and plan for market introduction and expansion well in advance of regulatory approval.

Accelerating scale-up by even one year can have a significant impact on lives saved. A Dalberg analysis recently demonstrated how accelerating a hypothetical 20-year, global health

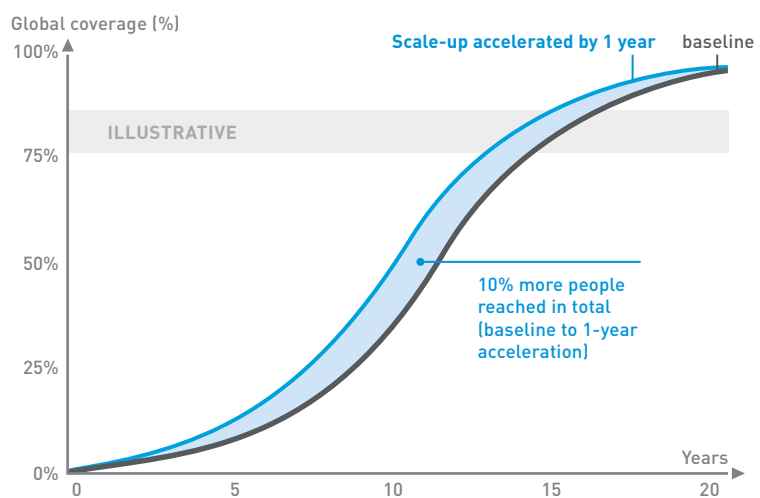
Figure 1. Years to scale-up



While drugs, diagnostics, and vaccines typically scale within the first two years of launch in developed countries, they often take decades to scale in lower- and middle-income countries.

Source: Bill & Melinda Gates Foundation

Figure 2. Benefits of accelerated uptake (hypothetical)



Accelerating scale-up by just one year can result in an increased reach of 10 percent of the target population per year.

Source: Dalberg Global Development Advisors

Better planning for introduction, well in advance of product approval, can help projects achieve success within the critical early period of launch.

scale-up by a single year can result in an increased reach of 10 percent over that period (Figure 2).

Past product launches—both successes and failures—have taught us the importance of getting launches right from the beginning. This means designing the right product early in the development process and proving efficacy and effectiveness—through clinical or field trials—to ensure rapid regulatory approval or consumer acceptance. In planning for introduction, the importance of “getting it right” becomes even more pronounced. In its white paper, *Launch Excellence IV: A New Launch Environment*, IMS Health describes a “six-month window” in which successful launches need to take shape (Figure 3) (IMS Health 2013). After this six-month window, they found that only a few launches (~20 percent) were able to recover and achieve scale.

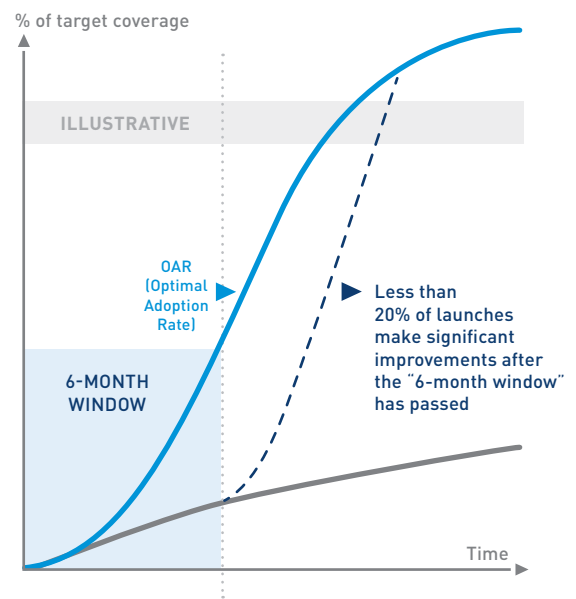
Similarly, McKinsey & Company found that 78 percent of drug launches that lagged expectations in their first year did so again in their second year (Ahlawat, Chierchia, and van Arkel 2013). While both of these analyses are based on pharmaceutical product launches in developed markets, the principle remains relevant for the global health sector that focuses on harder-to-reach populations: there is a limited window within which to succeed, after which recovering becomes much more difficult.

It is with these lessons and principles in mind that CII created *Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations*. By describing a framework and priority activities, illustrated through case studies, we hope to help global health practitioners accelerate impact through better coordination and earlier planning.

THE ROLE OF MARKET SHAPING

While not a focus of this Guide, it is important to acknowledge the role market shaping can play in accelerating introduction and scale. Market shaping interventions can vary in form, but they generally aim to reduce transaction costs, improve access to market information, and/or distribute risk more evenly to create product markets with healthy characteristics: affordability, global and local availability, appropriate design, assured quality, and awareness of health need and product by providers and end-users. For more information on market shaping, please reference CII’s *Market Shaping Primer* at www.usaid.gov/cii.

Figure 3. The first six months after launch tends to set the growth rate in high-income markets



An IMS Health analysis of pharmaceutical products in high-income markets shows the “majority of launches do not improve on the trajectory they establish within the first six months on the market.”

Source: IMS Health

Origins of the Framework

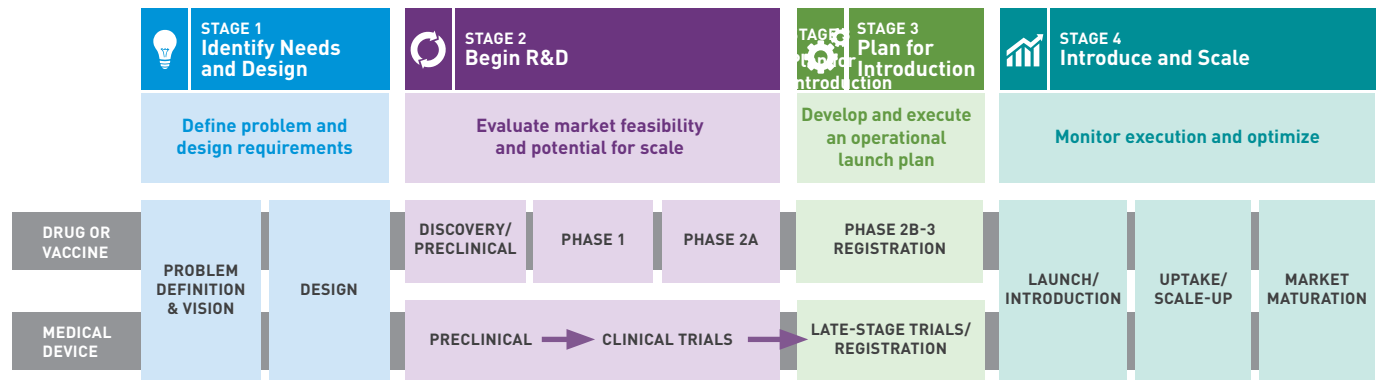
Frameworks abound across all industries and sectors, especially health care. Stanford Biodesign, for example, has “The Process of Innovating Medical Technologies,” Marie Stopes International shares a “Scaling Up Management Framework,” and USAID applies its own high-level “Research to Use” model to some of its health work. Without exception, all major medical device and pharmaceutical companies rigorously follow their own detailed plans as a part of everyday business. All of these approaches share the same simple goal: provide structure and order to a complex set of interconnected activities.

The Framework described in this Guide builds off of these existing bodies of work, including private-sector models and a recent collaboration between Dalberg and the Bill & Melinda Gates Foundation. Blending these models with decades of global health experiences, this Framework focuses on practical, activity-level detail across four-stages: (1) Identify Needs and Design, (2) Begin Research and Development (R&D), (3) Plan for Introduction, and (4) Introduce and Scale (see Figure 4).



Photo: PATH/Patrick McKern

Figure 4. The components of the Framework



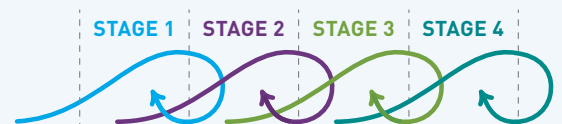
Because product development, introduction, and scale-up is, by nature, complex, we have streamlined the traditional and detailed process into four stages: (1) Identify Needs and Design, (2) Begin R&D, (3) Plan for Introduction, and (4) Introduce and Scale.

Who does what?

A team comprised of people with diverse skills and expertise is necessary to execute the wide range of activities required for successful introduction and scale-up. We have all seen good examples when specialized skills are applied to the right activities. For many reasons, often due to budget limitations, we have also seen sub par examples when teams attempt technical work outside their area of expertise. The priority activities described in this Guide often require staff or consultants with specialized expertise and training to ensure the best output. Along the left side of the Framework on the next page, priority activities are organized by four major areas of focus:

- Market and user understanding
- Manufacturing and distribution
- Policy and advocacy
- Clinical and regulatory



While illustrated as a linear process for presentation and simplicity, the execution of priority activities is more often nonlinear and highly iterative. In fact, many activities across stages will happen simultaneously and should be revisited and refreshed many times.



Rapid experimentation is also encouraged throughout the four stages. “Failing fast, better, and forward” (i.e., quickly iterating and applying learnings) can help practitioners more quickly get to the “right” product and introduction and scale plan.

Priority activities

The delivery Framework outlined below highlights priority activities to undertake across four stages.

	 STAGE 1 Identify Needs and Design	 STAGE 2 Begin R&D
DELIVERY FOCUS	Define problem and design requirements	Evaluate market feasibility and potential for scale
MARKET AND USER UNDERSTANDING	<ul style="list-style-type: none"> • Conduct situation assessment • Develop value proposition • Understand end-user needs through market research and/or human-centered design 	<ul style="list-style-type: none"> • Update situation assessment • Conduct bottleneck analysis • Develop user segmentation • Update and strengthen end-user needs through market research and/or human-centered design
MANUFACTURING AND DISTRIBUTION	<ul style="list-style-type: none"> • Perform manufacturability assessment and landscape • Conduct intellectual property evaluation 	<ul style="list-style-type: none"> • Develop manufacturing strategy • Develop distribution strategy • Identify partnership opportunities • Develop, test, and refine prototypes (if applicable) • Conduct COGS analysis • Conduct demand forecast • Develop business plan (ROI) for partners
POLICY AND ADVOCACY	<ul style="list-style-type: none"> • Evaluate global policy considerations 	<ul style="list-style-type: none"> • Develop communications, advocacy, and KOL engagement strategy • Conduct cost-effectiveness analysis of TPP
CLINICAL AND REGULATORY	<ul style="list-style-type: none"> • Define the TPP 	<ul style="list-style-type: none"> • Develop and execute clinical plan with clearly defined endpoints • Conduct regulatory landscape

ACRONYMS: COGS: cost of goods sold EML: essential medicines list KOL: key opinion leader
R&D: research and development ROI: return on investment TPP: target product profile

The Framework only includes the priority activities that—when done well and at the right time—can significantly influence and enhance “deliverability.” Only a few clinical and regulatory activities are listed that are most closely linked to a successful delivery. Similar comprehensive R&D frameworks should also be used to support the development of innovations (product development).

 STAGE 3 Plan for Introduction <small>(Complete R&D)</small>	 STAGE 4 Introduce and Scale
Develop and execute an operational launch plan	Monitor execution and optimize
<ul style="list-style-type: none"> • Update situation assessment • Develop strategic launch plan with uptake targets • Update bottleneck analysis • Update end-user needs assessment • Develop pricing strategy • Develop demand generation strategies and create marketing material 	<ul style="list-style-type: none"> • Evaluate strategic launch plan progress and achievement of uptake targets • Evaluate progress against prioritized barriers and update bottleneck analysis • Introduce into new markets and to new user segments • Expand demand generation campaigns for new markets and user segments
<ul style="list-style-type: none"> • Establish manufacturing strategy • Establish distribution strategy • Identify partnership opportunities • Finalize product and packaging designs • Update COGS analysis • Update demand forecast • Update business plan (ROI) for partners 	<ul style="list-style-type: none"> • Evaluate manufacturing and distribution footprint and adjust as necessary • Redesign and optimize product and/or packaging (if necessary)
<ul style="list-style-type: none"> • Support inclusion in treatment guidelines and on country-level EMLs • Execute communications, advocacy, and KOL engagement strategy • Update cost-effectiveness analysis 	<ul style="list-style-type: none"> • Continue to support inclusion in treatment guidelines and on country-level EMLs for new markets • Validate impact and cost-effectiveness analysis
<ul style="list-style-type: none"> • Complete clinical trials • Obtain national regulatory authority approval(s) 	<ul style="list-style-type: none"> • Continue with national regulatory authority approval(s) for new markets • Conduct post-market surveillance

Description of stages



STAGE 1: Identify Needs and Design

Define problem and design requirements

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Most product development efforts begin with a problem that needs to be solved. Some people call this stage the “fuzzy front end” of product development because problems can be complex and solutions can emerge from hunches, observations, and spontaneous connections. Over time, through keen observations, probing conversations, and discussions with many different actors, particularly the end-users, the picture becomes clearer and a concept is born.

In this stage, product designers refine and shape the concept, seeking input from users and manufacturing partners to test ideas. To manage the activities to come, project managers should begin to develop a high-level project timeline and project plan. Business and marketing experts should examine the market to determine the commercial viability of the product and the price the market can bear.



STAGE 2: Begin Research and Development (R&D)

Evaluate market feasibility and potential for scale

p. 23

Once a target product profile is defined and the market is assessed as promising, more significant investments can be directed to research and development. For a drug or vaccine, this means defining a regulatory pathway and beginning clinical trials. For less intensely regulated products, this stage involves developing early prototypes and testing them with users, identifying potential bottlenecks to supply and demand, exploring manufacturing and distribution strategies, and forecasting demand. The goal is to test the efficacy, effectiveness (in real-life situations), and safety of a product and to better understand the costs, policies, procedures, and partners that might be involved in bringing the product to market.



STAGE 3: Plan for Introduction

Develop and execute an operational launch plan

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With product development shifting to its later phases, the delivery focus turns to preparing for launch, attending to everything that needs to be finalized, approved, and arranged before a product is introduced. Marketing and advocacy teams begin developing demand generation campaigns, training programs, and advocacy strategies. Manufacturing and distribution professionals should revisit and update assumptions about demand, cost of goods sold, distribution strategies, and pricing. Regulatory experts navigate approvals and updates to treatment guidelines or essential medicines lists, and “Uptake Coordinators” develop a strategic introduction plan for each target country or region. When feasible, early pilot introductions may take place during this stage to better predict the market’s reaction and make necessary changes to demand, training, and introduction strategies so the launch goes smoothly. At this stage, market authorization holders or commercialization partners should be sought.



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STAGE 4: Introduce and Scale

Monitor execution and optimize

When the product is both available and manufactured, it is ready for launch. Launches can be significant turning points when the entire engine of an organization shifts into action. The build-up to a launch is palpable and time sensitive, as the success or failure of a product will be determined soon after launch.

Although launches represent a new stream of activities to track and manage product introductions, supply chain issues, customer interactions, repairs and recalls, and all the details of maintaining a product in the marketplace, many activities from Stage 3 are repeated for the next launch in the next geographic region. New regulatory approvals may be required, new staff must be hired and trained, new procedures and policies understood and negotiated. This simultaneous investment in Stages 3 and 4 may continue until the product has launched and scaled in all target countries.

Stage 4 requires a long-term and sustained investment of time and resources to achieve global scale and maximized health impact. While all the planning and activities leading up to the launch will increase the likelihood of early success, it is persistence and focus over the long term that will allow these global health innovations to realize their full impact at scale.



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The Uptake Coordinator

Given the inherent complexity of managing work across all four stages, this Guide describes the concept of an “Uptake Coordinator” as an emerging idea among global health donors and implementing partners. An Uptake Coordinator, also called a “Market Manager” or “Project Manager” depending on the setting, could play a project management role by troubleshooting issues that arise, liaising with and coordinating work across all stakeholders, maintaining a project timeline, and helping to prioritize decisions that need to be made and work that needs to be done. Given these responsibilities, the Uptake Coordinator should have the leadership authority to convene stakeholders, delegate tasks, and hold partners accountable for addressing problems or delays. This role could be supported by an individual or, more likely, an organization working at the global level. The Uptake Coordinator role could shift to different organizations or individuals throughout the stages.

Identify Needs and Design

Define problem and design requirements

The formative stage of product design and development sets the foundation for the increasingly complex and costly later stages. The case studies in this section illustrate how project teams reveal unmet needs, translate those needs into design requirements, describe potential markets, explore manufacturability, and investigate regulatory and intellectual property considerations.

Photo: PATH



Priority activities

MARKET AND USER UNDERSTANDING

- **Conduct situation assessment**

A situation assessment paints a picture of the market prospects and challenges facing a possible solution (e.g., device, drug, diagnostic). Situation, or “market,” assessments describe the problem or need, the overall competitor landscape (i.e., existing products, products in development elsewhere), the estimated size of the market (both globally and for specific markets/countries), reimbursement and payment considerations, intellectual property considerations, overall trends, and other relevant market characteristics. Completing a situation assessment grounds all stakeholders and the development effort in a clear and consistent understanding of the overall opportunity.

- **Develop value proposition**

A value proposition is a description of the perceived value or importance of a product from the perspective of the user and other target audiences (e.g., purchaser, payer, provider, advocate). It explains specifically how the product solves a problem or makes life better and why the product is a superior choice to alternative products or behavior. A value proposition is usually developed for each stakeholder based on perceptions of the benefits and costs (including both economic and social risk) associated with the product.

- **Understand end-user needs through market research and/or human-centered design**

Many techniques are used to understand the context, needs, and constraints of different users and customers, including surveys, human-centered design, direct observation, voice of the customer analysis, co-design workshops, and other forms of user-focused research. This work should be performed early and in the target communities to provide the full and realistic context for how the product would meet the needs of all the stakeholders involved. At this stage, an early needs assessment can inform the target product profile.

MANUFACTURING AND DISTRIBUTION

- **Perform manufacturability assessment and landscape**

An early manufacturability assessment describes the type of expertise required to make a product and explores which suppliers have that expertise. This early and rough assessment should also consider how to achieve economies of scale by leveraging capacity with multiple suppliers versus a single global supplier or locating a supplier in a certain geographic area. Efficient manufacturing is a cornerstone of most successful development and scale-up initiatives, so manufacturability must be considered throughout the project.

- **Conduct intellectual property evaluation**

An intellectual property evaluation is an opportunity to review the relevant existing and potential future patent landscape affecting a new product. This work will help determine whether existing patent rights may block commercialization and/or whether new patent rights can be generated by the developers.

POLICY AND ADVOCACY

- **Evaluate global policy considerations**

Policy considerations for a product may include current protocols, laws, and/or standards related to targeted diseases or conditions, and treatment procedures. Policy considerations can also inform priority activities in earlier stages, such as product design and bottleneck analysis.

CLINICAL AND REGULATORY

- **Define target product profile**

The target product profile is based on market and human-centered design research and can include intended usage, target user, technical criteria, and key value drivers.

HUMAN-CENTERED DESIGN (HCD)

See IDEO’s “HCD Toolkit” for more context on human-centered design. While it can be initiated in Stage 1 and strengthened in later stages, the timing of human-centered design can vary by product or issue being addressed. For example, some products (e.g., consumer directed, high behavior change issues) may require more human-centered design research than others.



“ Just because it works in the lab, doesn't mean it will work in the field. There is a lot of variability in people's homes.

•• *Erik Simanis, Center for Sustainable Global Enterprise at Cornell University*

“ Human-centered design is about meeting people where they are and learning from their behavior. Nothing can be more humbling or empowering. Once you see how their needs fit into the larger picture, you are much better prepared to design solutions that are truly relevant, engaging and empowering.

•• *Robert Fabricant, Co-Founder & Principal, Design Impact Group, Dalberg Global Development Advisors*

“ Make sure your initiative is commercially viable from the beginning.

•• *JW Raistrick, Stryker*

TIPS FROM EXPERTS

- Human-centered design research can demand considerable time during the design and prototyping phase of project initiation. Ample time should be allocated to working with the end-users while designing the solution.
- Because end-users are not the only stakeholders involved in a product's success, designers need to consider the entire ecosystem of stakeholders when identifying needs. This ecosystem can include manufacturers (concerned about profitability and risk), donors (concerned about politics and impact), ministries of health or public-sector programs (working within a bureaucracy and often adverse to risk), and others.
- Market segmentation can help define a product's initial customers. While it can be tempting to cast a wide net, it is more productive to identify a specific market segment for a given product.
- Consumers in low-resource settings do not necessarily have a reference point for many of the questions asked in typical market research. In these cases, it is important to look at how a new product or service will affect users' experiences of time, place, relationships, or social identity.
- Determining a cost threshold can help project teams set parameters for design. However, willingness to pay studies often overestimate what people are willing to pay for a given product or service.
- From the beginning and with global scale in mind, project managers should set a clear goal for the health impact the solution can and should achieve. This goal should be revisited and updated over time and the success or failure of the project should be measured against this goal.



“ It’s not are we solving the problem with the right solution, but are we even solving the right problem?”

•• Augusta Meill, Vice President, Continuum Design

Stage 1: Activities in action

Good design requires a deep understanding of end-users. Their unique needs and constraints, hopes and aspirations, can be the driving force behind inspiring innovations that improve quality of life for lower-income households.

However, in addition to satisfying end-users, practitioners also need to consider market, regulatory, and manufacturing issues that may impact a product’s success. **Design that Matters** learned this lesson when it developed what designers thought was the perfect, low-cost infant incubator. While the incubator satisfied the needs and desires of doctors, nurses, and mothers, it did not meet the needs of administrators, manufacturers, and purchasers. The incubator never reached the market, but the company learned a valuable lesson. The company’s next product, the Firefly phototherapy device, was developed with significant input from users, manufacturers, and purchasers and a better understanding of the market.

Innovative ideas can also flounder when incorrect assumptions are made about users or the market itself. Some companies have lost considerable time and money chasing the wrong idea. **Deere & Company** was set back a few years when it introduced a large, high-powered tractor in India based on the assumption that the Indian market would evolve in a similar direction as the U.S. market.

Those entities that can balance market knowledge with user needs are best positioned for success. **Godrej & Boyce**, a major appliance manufacturer in India, already understood the appliance market and was interested in reaching lower-income consumers. Their story of co-designing a refrigerator with low-income users shows how user input paired with competent engineers and marketing professionals can lead to truly novel solutions.



CASE STUDY 1.01
Design that Matters



19
CASE STUDY 1.02
Deere & Company



21
CASE STUDY 1.03
Godrej & Boyce





Photo: Design that Matters

Designing a medical device for use in rural clinics

Why Design that Matters began viewing end-users as part of a larger ecosystem of stakeholders

SITUATION

Design that Matters, a nonprofit design firm in Boston, Massachusetts, wanted to design a health product that made a difference in the world. Their first product, an infant incubator, was designed to help the nearly 2 million babies, mostly in developing countries, who die from lack of warmth during their first weeks of life. Design that Matters invested months interviewing and observing low-income families and rural doctors and nurses. They developed and tested dozens of prototypes with these users, sought input from local repair technicians, and proudly revealed the final product: the NeoNurture infant incubator. The product won many design awards and was featured in numerous magazines. However, it was difficult to

manufacture and the actual sales prospects in the competitive hospital equipment marketplace were unclear. Design that Matters was unable to convince a manufacturer to take the risk of scaling up production without strong sales prospects, so the product never became commercially available.

While they spent considerable time with users, Design that Matters neglected to understand the needs of the broader customer ecosystem, including manufacturers, distributors, hospital administrators, regulators, ministers of health, and foreign donors—all of whom play critical roles in the ultimate success (or failure) of global health products.

PRIORITY ACTIVITIES HIGHLIGHTED

- Develop value proposition
- Understand end-user needs through market research and/or human-centered design
- Perform manufacturability assessment and landscape

SOURCES (full citations pg. 71)

Design that Matters 2012
Prestero 2012



ACTIONS TAKEN

Timothy Prestero, CEO of Design that Matters, began anew by building relationships with a manufacturer of medical equipment and a successful medical product distributor, both of which had operations in Vietnam. He asked them for their insights into the needs and opportunities in their marketplace, and they suggested newborn jaundice. Technologically, newborn jaundice is easy to treat by shining a bright blue light on the infant for a certain period of time. Existing equipment was not designed for resource-constrained environments and was often misused or abandoned for lack of spare parts. Applying their formidable design expertise, Design that Matters met with manufacturers, distributors, hospital administrators, donors, users, and ministries of health, and developed a product that balanced the needs and constraints of all of these stakeholders.

In field studies, mothers, who were worried that their newborns were not warm enough, often placed blankets on their infants receiving phototherapy, effectively preventing the light from reaching the newborn. Design that Matters designed around this practice by placing lights above and below the infant, rather than trying to change the habits of mothers.

RESULTS

Design that Matters' Firefly phototherapy device is highly effective—requiring 40 percent less treatment time than competing devices. It is also cost-effective—as low as \$1.50 per infant. The double-sided lighting, compact size, high-tech aesthetic, and lack of moving parts, meets the needs of infants, mothers, doctors, nurses, and repair technicians alike.

While still early in its introduction, Design that Matters and partners, Medical Technology Transfer and Services (MTTS) and the East Meets West Foundation, have installed Firefly and treated more than 5,000 newborns in ten developing countries across Southeast Asia, sub-Saharan Africa, and the Caribbean. The company expects to sell an additional 1,000 devices in the coming years and aims to reach 500,000 newborns with effective phototherapy.

LESSONS LEARNED

- Good design must consider the needs of a large number of stakeholders, including but not limited to users. Stakeholders also include manufacturers, distributors, administrators, government officials, regulators, foreign donors, maintenance workers, nurses, and patients.
- Hypothetical use is no substitute for actual use. Design that Matters took prototypes to Vietnam and watched users interact with the device. Observations from these field visits led to significant design alterations that made the device more effective in real-life scenarios.
- An innovative product that cannot be efficiently manufactured will not succeed in saving lives. Design that Matters worked with MTTS to identify areas of competency and potential growth, which enabled MTTS to expand their capabilities and manufacture a better Firefly. By expanding a local manufacturer's capabilities, Design that Matters was able to keep costs low and avoid manufacturing setbacks.
- Manufacturers can be unwilling to take risks in new markets, so it is important to engage a willing and committed manufacturing partner from the beginning of the design process to foster commitment to the product vision. Usually, a manufacturer will radically change a product in order to make it less expensive and easier to make. However, in this case, MTTS was involved from the early stages of the design process, which brought the co-designed product vision to life.



Photo: Design that Matters

Finding the keys to the market by listening to and observing users

How Deere & Company was misled by market assumptions

SITUATION

Deere & Company had established itself as a powerful equipment brand within the agricultural sector in much of the developed world. Their share of the market in India, however, was initially fairly small. To increase sales in India, the company sent a team from its Iowa headquarters to study the Indian market. The team concluded that the agricultural market in India looked much like the U.S. market a few decades ago, and developed a plan to introduce larger tractors that would enable Indian farmers to rapidly increase production—a strategy that had worked well in the United States.

However, after setting up a large Indian manufacturing plant and marketing the new, high-powered tractors, Deere & Company failed to capture any meaningful share of the robust Indian tractor market. They had fallen into a common trap: concluding that a new market would behave like one they already knew well.



Photo: PATH/Arvind Chengi

PRIORITY ACTIVITIES HIGHLIGHTED

- Conduct situation assessment
- Develop value proposition
- Understand end-user needs through market research and/or human-centered design

SOURCES (full citations pg. 71)

Govindarajan and Thrimble 2012



Photo: PATH/Arvind Chengi

ACTIONS TAKEN

Deere & Company realized they did not understand the true needs and desires of the Indian market. Over a span of two years, with the help of local market researchers and marketers, Deere conducted a thorough study in India both of how tractors were being used by farmers and what their competitors' products and service offerings were. A team of engineering, marketing, sales, finance, supply chain, and manufacturing staff convened in a hands-on workshop where they fully disassembled the tractors of six competitors to discover which parts added value, which design elements decreased production costs, and how Deere could differentiate itself.

The company also learned that its Indian target customers were not yearning for high-powered, large tractors, but instead were looking for a tractor that was "no bigger than was necessary for the job," had a short turning radius, could operate from sun-up to sun-down, and could occasionally serve as the family vehicle. An attractive value proposition for an Indian farmer (compact size, ultra reliable, nimble) was far different than that of an American farmer (high power, maximum capacity).

LESSONS LEARNED

- Market characteristics and trends can differ dramatically from one country to the next. It is dangerous to make assumptions about what consumers want without first understanding each market and identifying what really matters to users and consumers.
- Competitor research can provide clues about the target market, which needs are being met, and (most importantly) which ones are not.
- "Saving" money by skimping on early-stage user and market research is often short sighted, especially in new markets. Findings from early-stage research should always be tested in small pilots and improved before rolling out on a large scale.

RESULTS

Deere developed the 35-horsepower Krish tractor, a much smaller and less powerful version than their initial offering in India, and launched it in July 2010. Nearly 700 tractors were sold in advance of the launch and total sales over the first four months surpassed 2,500 units, beating the company stretch goal of 2,350 units sold.

“Your value proposition needs to be in the language of the customer. It should join the conversation that is already going on in the customer's mind. In order to do that you need to know the language your customers use to describe your offering and how they benefit from it.

•• Peep Laja, *Conversations XL blog*

Abandoning assumptions in user research

How Godrej & Boyce co-designed the ChotuKool refrigerator with end-users

SITUATION

In 2009, Godrej & Boyce, a \$4.1 billion Indian company, challenged itself to introduce a refrigerator targeting lower-income households earning 5,000 to 8,000 rupees (\$125 to \$200) per month. Their initial plan was to remove the expensive features from one of their existing refrigerator/freezer models and sell the scaled-down model at a lower price point.

However, extensive user research revealed that lower-income consumers did not use refrigerators the same way that higher-income consumers did. Low-income households tended to have unreliable access to electricity; they moved often; and they did not consider it important or possible to freeze ice or food. They tended to keep only a few items cool and only for about 24 hours at a time. It became clear to Godrej & Boyce that they could not serve the needs of this new market segment by adapting their existing models—they needed to design a new product from the ground up.



The ChotuKool refrigerator was designed for low-income consumers whose needs are vastly different from the mainstream refrigerator market.

Photo: Godrej & Boyce Manufacturing

PRIORITY ACTIVITIES HIGHLIGHTED

- Develop value proposition
- Understand end-user needs through market research and/or human-centered design
- Define target product profile

SOURCES (full citations pg. 71)

Eyring 2011
Innosight 2014



“ Figure out the needs of the customer.

The answer is not the cheapest solution;

it is the right solution.

•• Hari Nair, Global Managing Director, Kimberly Clark Innovation Center

ACTIONS TAKEN

The company developed a fundamentally new product for the lower-income market. The product has only 20 parts, including an electric cooling chip and a small fan that can be operated during power outages using a battery. Its first prototypes were tested by more than 600 women in workshops where they discussed each design element, including the interior arrangement, the lid, and even the color. Project engineers were initially resistant to consumer input, especially the suggestion to eliminate the freezer component, but they came to appreciate and understand user desires after testing the prototypes.



Photo: Godrej & Boyce Manufacturing

LESSONS LEARNED

- Direct, in-depth interactions with end-users are invaluable and, in most cases, irreplaceable. Expert opinion or product developer speculation on what users need or want can be well intentioned, but can also be wrong.
- Focus groups and surveys may not be enough. Sometimes direct observation of the behaviors of end-users in their relevant operating environment (i.e., the household for consumers, the primary health care clinic for health care workers) is necessary to really understand the problems end-users face and solutions that might address those problems.
- Convincing engineers and designers to develop the right product, rather than what they think would be the best product, can be a challenge. In the ChotuKool example, the project leader faced, but ultimately overcame, his own engineers' resistance to removing the freezer function from the design.
- Consumers can be invaluable participants in design. Involving them in the design process can lead to new discoveries and insights, resolve design questions, and prime the market with early adopters.

RESULTS

The ChotuKool (“little cool” in Hindi) refrigerator is a cherry red, top-opening, portable, 1.5 x 2 foot cooling unit with enough capacity to keep a few items fresh for a day or two. The unit uses half the energy of mainstream refrigerators and, at \$69, is half the price.

Since launching the product in 2011, Godrej & Boyce has developed innovative ways to distribute the ChotuKool refrigerator to lower-income households, using both the postal system and microfinance institutions to reach rural areas. The company has also discovered new markets for the product, including as a portable or backup refrigerator or workplace/beverage refrigerator. Customers can now personalize their refrigerator exterior with their own artwork and order the product online or through brick and mortar retailers.

A close-up photograph of a man wearing sunglasses and a light-colored shirt, drinking water from a blue water filter device. The device is a clear plastic cup with a blue base and a blue filter inside. Water is being poured into the cup from a source above. The man's hands are holding the device. The background is a blurred outdoor setting with green hills and a blue sky.

Begin Research and Development (R&D)

Evaluate market feasibility and potential for scale

Once a potential solution and target market is identified and articulated in a target product profile, work can begin to design and develop that product to the point of prototyping and demonstrating proof of concept based on user feedback and/or initial preclinical and clinical trials. In this stage, more stakeholders are involved in the project and clearer pathways are defined to bring initially fuzzy concepts to more clarity.

Photo: PATH/Jesse Schubert



Priority activities

MARKET AND USER UNDERSTANDING

- **Update situation assessment**
As the solution becomes more clearly defined and more data become available, the situation assessment can be updated to match the evolving product definition. Updates may be needed for one or several parts of the initial situation assessment.
- **Conduct bottleneck analysis**
A supply and demand bottleneck analysis assesses potential uptake challenges along the value chain early enough in the process to take action. In this analysis, a series of questions related to the value chain (manufacturing, distribution, procurement, service delivery, and user adoption) are evaluated in a desk review to highlight challenges and critical bottlenecks and identify interconnections between demand- and supply-side factors. This analysis also guides the decision-making process for how to best address the critical bottlenecks through a prioritization framework.
- **Develop user segmentation**
A user segment is a subset of a larger target market, made up of people with one or more characteristics that cause them to demand similar products or services based on qualities such as price or function. Segmenting potential users into discrete groups, and quantifying these segments, helps designers prioritize the needs of target customers and optimize distribution channels and marketing strategies.
- **Update and strengthen end-user needs through market research and/or human-centered design**
With the target product profile better defined, project teams can develop a more robust understanding of end-user needs. In addition to traditional market research (interviews and surveys or secondary desk research, for example), there are many techniques used to understand the context, needs, and constraints of different users and customers, including human-centered design, direct observation, co-design workshops, and other forms of user-focused research. This work has to be performed early and on the ground to provide full and realistic context for how the product would meet the needs of all the stakeholders involved.

MANUFACTURING AND DISTRIBUTION

- **Develop manufacturing strategy**
It is important at this early stage to evaluate potential manufacturing options, considering geography (global

versus regional versus local), channel (e.g., public, private, social marketing), and existing programs that may be able to manufacture the product at consistent, high-quality, sufficient volumes and at an acceptable cost. Longer-term scale-up volumes should be considered as well.

- **Develop distribution strategy**
Although still early in the development lifecycle, it is important at this stage to evaluate potential distribution options, considering geography (global versus regional versus local), channel (e.g., public, private, social marketing), and partners who may be able to distribute your product to target consumers efficiently and effectively.
- **Identify partnership opportunities**
Partnerships with local manufacturers, distributors, and non-governmental organizations can help make the introduction of a new health product successful. At this stage, appropriate partnership opportunities should be identified and developed.
- **Develop, test, and refine prototypes**
When applicable, prototypes can be developed to test with users, manufacturers, and other stakeholders. Prototypes allow project teams to more closely match the target product profile given manufacturing requirements, user needs, and price targets.
- **Conduct cost of goods sold (COGS) analysis**
Depending on the solution, a COGS analysis calculates the total cost of the product in terms of the parts, raw materials, supplies, labor, and other applicable overhead associated with the product. A COGS analysis must also account for profit incentives for private-sector distributors and retailers, where applicable. This information can be used to determine whether the solution, as initially designed, can meet the pricing targets identified in the target product profile.
- **Conduct demand forecast**
Demand forecasting is an analytical process of estimating the *actual* quantities of a product or service that would be purchased and used under varying scenarios of uptake, usually over a one- to five-year time frame. This is different from the potential need or total market size described in the situation assessment. At early stages, strategic demand forecasting involves desk research to create rough estimates and provide “directionally correct” estimates to planners.

- **Develop business plan (return on investment) for partners**

A business plan incorporates data from the COGS analysis, pricing strategy, and demand forecasting to highlight the return on investment that potential manufacturers, distributors, and other partners could see.

POLICY AND ADVOCACY

- **Develop communications, advocacy, and key opinion leader engagement strategy**

A clearly defined communications and engagement strategy should describe key audiences, messages, and tactics needed to keep stakeholders well informed about the development and launch progress. Early identification and engagement with key opinion leaders is important.

- **Conduct cost-effectiveness analysis of target product profile**

An initial cost-effectiveness analysis of the target product profile can help to directionally understand the value-for-money improvement over existing

products or standards of care. Donors, who can help finance these early stages of development, often factor the cost-effectiveness potential into their investment decisions.

CLINICAL AND REGULATORY

- **Develop and execute clinical plan with clearly defined endpoints**

A strategic clinical plan is an informed outline of the content and sequencing of the clinical studies necessary to achieve regulatory approval for a new drug, vaccine, or medical device, complete with initial performance targets to serve as go/no-go criteria. Any product that requires clinical trials will need a clinical plan that includes estimated timelines, major milestones, and clearly defined endpoints. An ill-conceived or incomplete plan can waste resources on expensive clinical studies that fail to answer the right questions or satisfy regulatory authorities.

- **Conduct regulatory landscape**

A regulatory landscape identifies applicable regulations and evaluates the potential impact on development and launch—globally and at country level. At this stage, project teams can begin building relationships with the appropriate actors in regulatory bodies so that regulations and changes to the regulatory environment can be addressed.

“Remember, you cannot create your success alone. Think about which partners can help you and what’s in it for them.

• • *Ole Kjerkegaard Nielsen, Novo Nordisk*

TIPS FROM EXPERTS

- Despite information gaps at this stage, it is important to make estimates for cost of goods sold, manufacturing, user segmentation, etc., to inform planning—and then revisit and refine the estimates as more information becomes available.
- Potential uptake bottlenecks along the value chain should be examined carefully, both to recognize interconnections between demand- and supply-side factors and to prioritize and address critical bottlenecks early.
- It is important to start planning for manufacturing and distribution as early as possible, as either can derail a project.
- In some cases, clinical trials may focus purely on clinical outcomes, while ignoring the broader usability lessons and opportunities for feedback. As such, trial designs should have implementation or manufacturing representatives involved in the design and write-up.
- Country-level implementers (e.g., ministry of health, regulators) are the ultimate decision makers. Early consultations with these key stakeholders in support of resource planning and costing studies should begin in Stage 2.



“ Get prototypes out quickly, because you’ll be doing lots of iteration. Don’t waste 3 to 4 years to get it exactly right—because it won’t be.

• • Erik Simanis, Center for Sustainable Global Enterprise at Cornell University

Stage 2: Activities in action

For many health products, the focus during Stage 2 is on developing and iterating on a prototype, initiating clinical or field trials, and moving forward along the road to regulatory approval. Solutions that require regulatory approval can learn from the **Meningitis Vaccine Project**, which navigated the clinical trial and regulatory landscape by hiring expert staff and consultants with experience in their target environments and emerged with an effective product that scaled quickly in Africa.

Not all development efforts start as smoothly. **HPV vaccine** was initially offered at a price out of range for developing countries and their donors. However, this case study shows how careful market evaluation, including cost of goods sold analysis and demand forecasting, can become levers for price negotiations.

Other important activities in this stage focus on identifying the major supply- and demand-related bottlenecks and prioritizing which activities require action, by whom, and at what stage. The UN Commission on Life-Saving Commodities has been working to improve access to 13 commodities, including injectable antibiotics. **UN Commission on Life-Saving Commodities** completed bottleneck analyses in several African countries and has used the output to support unifying plans that both national and global partners can now follow to address priority barriers to access.

The example from the **Drugs for Neglected Diseases initiative** shows the importance of finding partners who understand the regulatory environment and can develop a realistic strategy so that regulatory needs are understood well ahead of launch, as the product (in this case, a fixed-dose malaria drug) is being developed.



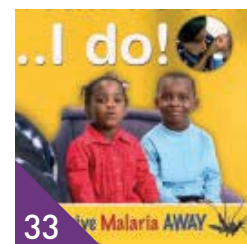
27
CASE STUDY 2.01
**Meningitis
Vaccine Project**



29
CASE STUDY 2.02
HPV vaccine



31
CASE STUDY 2.03
**UN Commission
on Life-Saving
Commodities**



33
CASE STUDY 2.04
**Drugs for Neglected
Disease initiative**



Setting up clinical trials for success

How the Meningitis Vaccine Project accelerated vaccine launch



Photo: PATH/Gabe Biencycki

SITUATION

In 1996 and 1997, 25,000 people died as the largest meningitis epidemic in African history swept across sub-Saharan Africa. Responding to this serious global health issue, in 2001, the Bill & Melinda Gates Foundation provided a ten-year, \$70 million grant to establish the Meningitis Vaccine Project (MVP), a partnership between PATH and WHO with the goal of catalyzing the development, testing, licensure, and widespread introduction of a conjugate vaccine with the promise of protecting millions of lives from group A meningococcal meningitis. To ensure the vaccine would be available in the ten most vulnerable countries located in the “meningitis belt” of Africa, the team would need to conduct simultaneous clinical trials in countries with very little regulatory or clinical trial experience.

ACTIONS TAKEN

As a first step, MVP formed an early project advisory group comprising senior African public health officials and researchers to advise on the choice of African clinical trial sites and trial design. The project also hired staff and consultants with significant vaccine clinical trial and regulatory expertise, including on-the-ground expertise with some of the proposed clinical trial sites. Drawing on the knowledge of staff and consultants, MVP developed a clinical plan and timeline using project management software to identify the critical path for regulatory approval and potential delays.

By 2005, MVP was ready to launch a Phase 1 clinical trial to evaluate the vaccine in humans in India. This trial showed the vaccine’s safety and immunogenicity. In 2006, as a new epidemic wave

PRIORITY ACTIVITIES HIGHLIGHTED

- Identify partnership opportunities
- Develop communications, advocacy, and key opinion leader engagement strategy
- Develop and execute clinical plan with clearly defined endpoints
- Conduct regulatory landscape

SOURCES (full citations on page 71)

Marchetti 2012
PATH (1) 2014
PATH (2) 2014



swept over the African meningitis belt from Senegal to Ethiopia, MVP launched a more intensive Phase 2 trial in Mali to evaluate the vaccine among a younger age group. This pivotal study confirmed that the conjugate vaccine was safe and demonstrated that it produced antibody levels almost 20 times higher than those obtained with the existing polysaccharide vaccine. These encouraging results cleared the way for more Phase 2, Phase 2/3, and Phase 3 studies among age groups and populations in India and Mali as well as the Gambia, Ghana, and Senegal.

During these trials, the project developed and maintained open communication channels with the community and encouraged teamwork between the sponsors, clinical study site staff, local study monitors, clinical collaborators, and consultants. To mitigate anticipated supply chain problems, sponsors sent mock vaccine shipments to each trial site. These mock shipments allowed partners to test importation, storage, and transport procedures and evaluate refrigeration and temperature recording equipment before actual vaccines were shipped. The exercise ensured that all partners were ready to receive the vaccines and prevented unnecessary loss of equipment and vaccine.

RESULTS

By 2009, four years after its first Phase 1 trial, Serum Institute of India, the manufacturer of MenAfriVac®, had enough clinical and product data to submit a dossier for regulatory approval of the vaccine. The Indian regulatory authorities granted marketing authorization (often referred to as regulatory approval) for export in December 2009, and in June 2010, the vaccine was prequalified by WHO. Within 24 months, the vaccine was approved in ten countries in the meningitis belt and had been administered to 100 million people.

LESSONS LEARNED

- It is critical to have clinical trial expertise available from the beginning. Staff, consultants, and/or advisory groups can be leveraged to create a sound clinical development plan and timeline.
- Clinical plans should be developed with the end-goal (regulatory approval) in sight. This helps illuminate the shortest and most economical path through the process.
- A strong project management tool can be helpful to identify the critical path and actively track and manage all activities across multiple sites.
- Data integrity of the clinical trials can be protected by conducting frequent co-monitoring visits and independent audits and creating an open flow of communication among all partners.
- MVP discussed the research and consulted with the communities in the study area before, during, and after study completion. Providing an open and accessible channel for communication built trust and diffused concerns before they became issues.
- Local logistical support and procedures should be carefully selected and tested while the study is being set up to ensure that issues relating to importation, temperature-controlled shipments, and delivery and maintenance of equipment are addressed as expediently as possible.

Mock shipments allowed partners to test importation, storage, and transport procedures, while evaluating refrigeration and temperature recording equipment, before actual vaccines were shipped.

Illuminating the possible

How stakeholders used cost of goods sold and demand forecasting to increase access to human papillomavirus vaccine

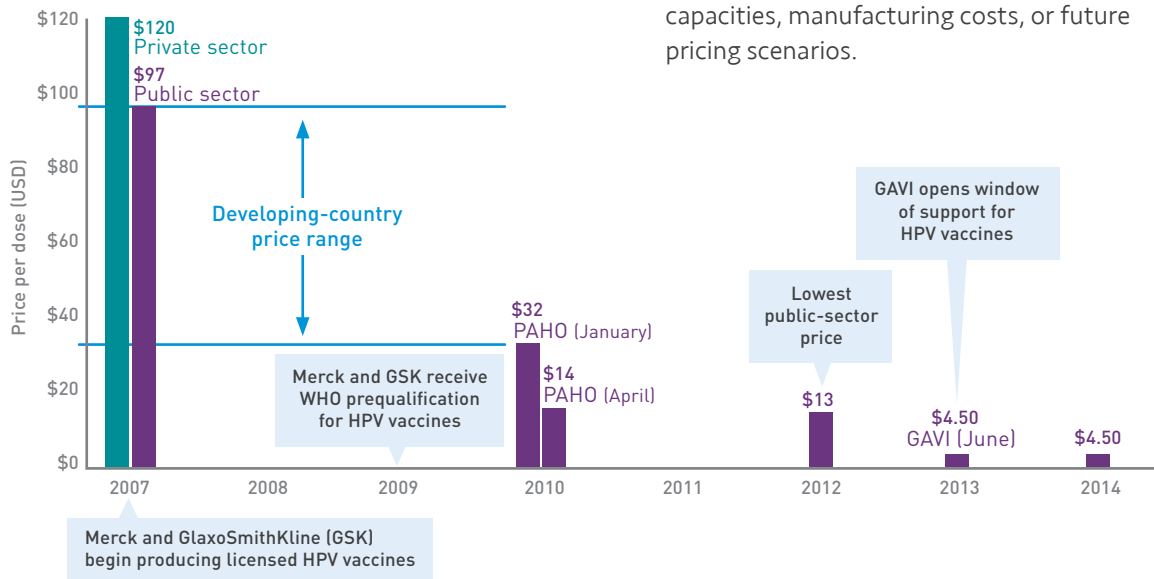
SITUATION

In the late 1990s, both Merck and GlaxoSmithKline (GSK), two of the world’s major vaccine producers, began developing vaccines to prevent infections by key strains of human papillomavirus (HPV). These strains were identified as causing the majority of cervical cancer cases—a costly disease in developed countries and a deadly disease in developing countries. Merck received United States Food and Drug Administration approval of its vaccine, Gardasil®, in June 2006. GSK received European

approval of Cervarix® in September 2007. Both companies announced pricing of around \$120 per dose—more than \$350 for the full three-dose course, which at the time was the highest-priced course of vaccine in the world.

Many global health experts declared that these vaccines would never be affordable for widespread use in developing countries, and questioned the wisdom of such an initiative being supported by the Bill & Melinda Gates Foundation to conduct pilot introductions. While both companies were supportive of the initiative and donated a significant number of HPV vaccine doses for the pilot introductions, neither company was willing to share information on their production capacities, manufacturing costs, or future pricing scenarios.

HPV vaccine prices (2007-2014)



PRIORITY ACTIVITIES HIGHLIGHTED

- Conduct cost of goods sold analysis
- Conduct demand forecast
- Develop business plan (return on investment) for partners
- Conduct cost-effectiveness analysis of target product profile

SOURCES (full citations pg. 71)

- IAVI and PATH 2007
- Nguyen 2011
- Politi and Kaddar 2009
- Sekhri 2007
- Vicari 2011



ACTIONS TAKEN

In response, the Bill & Melinda Gates Foundation commissioned (1) a detailed, independent analysis of both the production capacities and cost of goods sold (COGS) for the HPV vaccines from Merck, GSK, and a Chinese vaccine producer with an HPV vaccine candidate; and (2) an HPV vaccine demand forecasting tool which could estimate various long-term uptake scenarios across all developing countries.

These analyses, considered together, provided surprising and useful insights. Merck and GSK had built sufficient bulk HPV vaccine production capacity to supply the majority of both developed- and developing-world demand even in optimistic uptake scenarios. More importantly, the production process and COGS analyses showed that the new vaccines had very favorable economies of scale and relatively low long-term variable costs of production. Unlike with both pneumococcal and rotavirus vaccines, where the complexity and low yields of the production process led to both capacity constraints and relatively high variable cost, analysis suggested that both HPV vaccine producers would have strong incentives to increase production volume (and therefore overall profit) by offering lower-tiered pricing for developing-country use.



Schoolgirls in Peru after receiving the HPV vaccine.

Photo: PATH

LESSONS LEARNED

- An initial high price for a new product is not necessarily a deal breaker for global health investment. Credible, detailed analyses of COGS and demand scenarios can illuminate a potential pathway forward to lower prices and increased access.
- While not all COGS and demand forecasting efforts need to be as detailed and costly as the work done for HPV vaccines, analyses should be rigorous enough to be credible to outside stakeholders.
- Even a back-of-the-envelope analysis can be helpful to understand the interplay between fixed and variable costs. Such information can help decision makers understand the importance of reaching scale, especially when fixed costs are high.

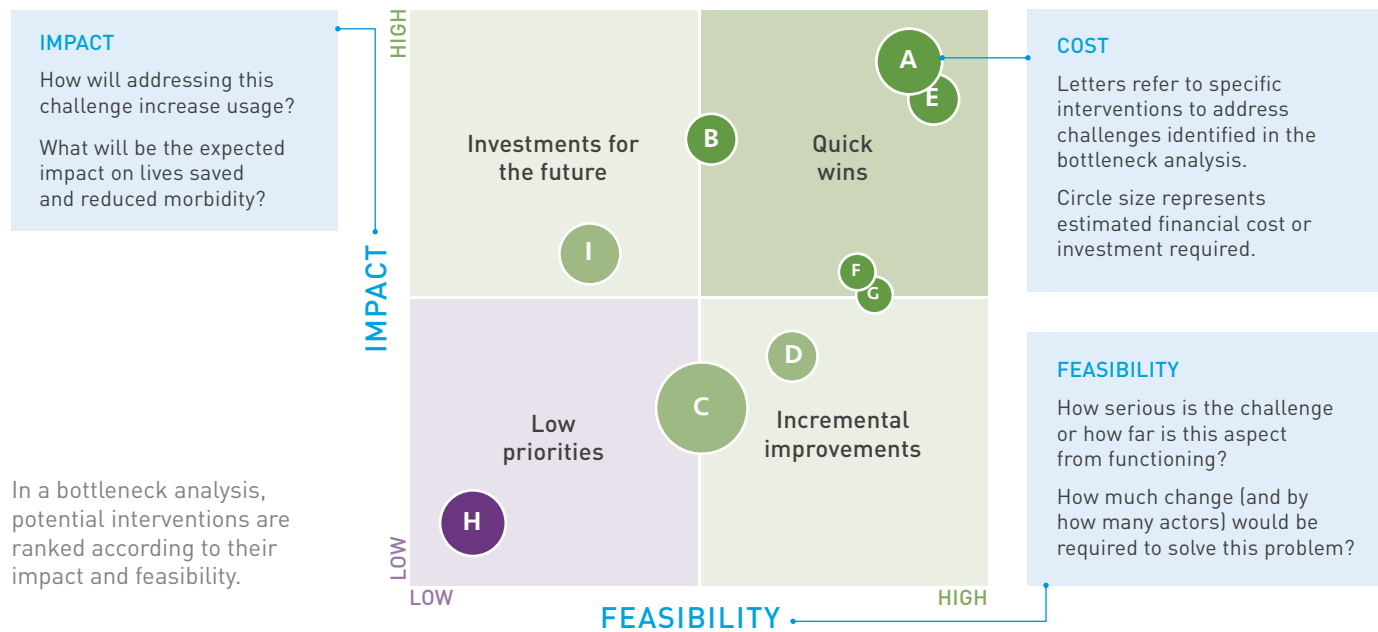
RESULTS

By sharing the COGS and demand forecasting scenario analyses in various global immunization fora, partners began to counter the prevailing attitude that HPV vaccines would never be affordable for developing-country use. The analysis alone was only the first step in a complex set of interactions that have come together over the past six years to bring HPV vaccines into the portfolio of the GAVI Alliance-supported programs for developing countries. By around 2010, UNICEF was able to negotiate HPV vaccine prices down to \$13/dose for developing countries. In 2013, a further reduction to \$4.50/dose was achieved (less than 4 percent of the initial developed-country price), with manufacturer commitments to lowering prices further if purchase volumes increased.

Turning knowledge into action

How a bottleneck analysis helped prioritize initiatives for improved access to injectable antibiotics

Prioritization table (illustrative)



SITUATION

Injectable antibiotics are one of a group of 13 health commodities identified by the UN Commission on Life-Saving Commodities that stands to dramatically improve the health of women and children—if barriers to access and use can be removed. In 2013, a global technical reference team was formed to focus on injectable antibiotics for treating possible severe bacterial infections and create a plan for addressing access issues. The team brought together information

and expertise on the challenges related to supply, regulatory issues, and awareness. The team convened international consultations and discussed the complex, interrelated problems of access, debating which solutions required their focused attention and when. The context was further complicated by uncertainties around the recommended regimen, since promising trials were underway to test a simplified, easier-to-adopt regimen.

PRIORITY ACTIVITIES HIGHLIGHTED

- Update situation assessment
- Conduct bottleneck analysis



See Toolkit for CII's Bottleneck Analysis Tool at www.usaid.gov/cii.



ACTIONS TAKEN

Narrowing the focus of the work to first examine global issues and then explore challenges in six countries, the team decided to apply a bottleneck analysis to both contexts. This analysis uses a “value chain” structure with a list of potential bottlenecks related to manufacturing, distribution, procurement, service delivery, and user adoption. Each issue is analyzed and rated according to whether it is an advantage to access (e.g., formulations are clearly specified on essential medicines lists and in treatment guidelines), a neutral/mixed issue (e.g., payments by purchasers are reliable, but almost always delayed), a challenge (e.g., product stockouts are not tracked), a critical bottleneck (e.g., severe shortage of providers with adequate training), or unknown (e.g., lack of data on awareness of the severe bacterial infection symptoms). Most of the research questions were initially answered in a desk review, with vetting underway or planned for the country-specific analyses by in-country stakeholders.

“The group already had a lot of expertise on the challenges—by assembling and structuring this information, we were better able to agree on what to do and why.

•• Amy Lin, USAID

LESSONS LEARNED

- Project managers and developers are constantly challenged to identify potential supply and demand issues as well as means of addressing them early so that they do not add significant delays. A bottleneck analysis provides a snapshot of access challenges to prioritize activities and direct resources toward those issues that are most likely to delay, hamper, or prevent introduction.
- A larger pool of expertise allowed the team to access better, more comprehensive data, and to paint a more complete picture of the global and in-country injectable antibiotics landscape.
- A large and diverse working group can raise many issues that need to be discussed and prioritized—but it can also result in a better end-product.

RESULTS

Desk review-based bottleneck analyses have been completed for the global context and for Ethiopia, Nigeria, and Uganda. In these three countries, results are being reviewed by in-country stakeholders. The analyses summarize bottlenecks along the value chain and highlight which issues are limiting progress (i.e., critical bottlenecks), which fall outside the group’s scope and should be referred elsewhere, and which need to be investigated further. For example, the analyses highlight the potential to support country pilots of the simplified regimen, emphasize the need to coordinate with the UN Commission on Life-Saving Commodities supply chain working group, and reveal the lack of critical data around product usage. Potential interventions to address the critical bottlenecks have been ranked according to their impact and feasibility (see prioritization table on opposite page). These analyses have made it much easier to chart a pathway to scale and agree as a global group on where to focus limited resources and take action.

Developing a tailored regulatory strategy



How a public-private partnership navigated regulatory obstacles to introduce a fixed-dose combination malaria drug in Africa

This advertisement for ASAQ was created by the Ghana Sustainable Change Project, implemented by USAID.

Photo: Academy for Educational Development

SITUATION

In the early 2000s, malaria-endemic countries in Africa found themselves in urgent need of a new antimalarial drug. Resistance to existing drugs was rising, and, although a fixed-dose artemisinin-based combination treatment (ACT) from Novartis was in the final stages of prequalification, access to ACTs was limited (Novartis' ACT, Coartem, received approval through the WHO Prequalification Programme in 2004).

To increase access to treatment options, scientists began working on a fixed-dose combination therapy for malaria combining two well-established active pharmaceutical ingredients, artesunate (AS) and amodiaquine (AQ). The fixed-dose combination, ASAQ, was simple to use, appropriate for all age groups, effective, and affordable. In 2005, when the Drugs for Neglected Diseases *initiative* (DNDi) and Sanofi Aventis came together to help implement ASAQ in malaria-endemic countries, they began working on their regulatory strategy.

PRIORITY ACTIVITIES HIGHLIGHTED

- Identify partnership opportunities
- Conduct regulatory landscape

SOURCES (full citations pg. 71)

- DNDi 2014
- Moran 2010



Their initial regulatory strategy was to file for approval in France or the United Kingdom (U.K.), which would establish international quality and facilitate follow-on African approvals. However, a preliminary meeting with the U.K. regulatory agency revealed that amodiaquine was no longer listed in the U.K. pharmacopoeia and the agency would not register the ASAQ combination unless it was intended for U.K. citizens traveling to endemic countries as tourists. Another option was to seek a scientific assessment of the ASAQ regulatory dossier by the European Medicines Agency (EMA) under Article 58, a fairly new (at the time) process designed for products used outside of the European Union. However, DNDi learned that the EMA and the United States Food and Drug Administration (USFDA) considered artesunate a New Chemical Entity because it had never been approved in either jurisdiction despite its common use in the rest of the world and documented support by WHO. The EMA approach would substantially lengthen either agency's review process, so DNDi looked to other regulatory pathways.

To date, ASAQ has been registered and is available in 34 malaria-endemic countries.

ACTIONS TAKEN

Ultimately, DNDi and Sanofi elected to register the drug first in Morocco where Sanofi planned to manufacture ASAQ, and to apply for WHO prequalification for the international endorsement to facilitate rapid registration in target countries. To meet WHO's stringent standards, Sanofi submitted a complete dossier that included results from a series of safety, pharmacology, repeat-dose toxicity, genotoxicity, reproductive, and development toxicity studies on both active ingredients separately and in combination.

LESSONS LEARNED

- By initiating discussions with potential regulators early in the project, DNDi and Sanofi were able to shift their regulatory approach from one focused on European and U.S. regulators to WHO prequalification, saving valuable time and money in the process.
- The strategy for registering ASAQ was to prioritize access in malaria-endemic countries without compromising international quality standards. Articulating these principles clearly and early in the project helped partners make difficult decisions about how, where, and when to seek registration.
- Obtaining the first registration in the country of manufacture (often required by other countries before they will review a new drug for approval), combined with WHO prequalification, enabled rapid registration in 30+ additional countries.
- While the USFDA and EMA will not formally approve drugs that will not be sold in the United States or Europe, they do offer technical evaluation processes widely respected by developing-country authorities. However, with the emergence of drugs designed specifically for developing-world use, USFDA or EMA first strategies should be weighed against alternatives that may enable more rapid introduction in target countries.

RESULTS

The drug regulatory authority of Morocco granted marketing approval for ASAQ in February 2007. WHO granted prequalification status to the ASAQ combination treatment in October 2008. To date, Sanofi's fixed-dose combination ASAQ product has been registered and is available in 34 malaria-endemic countries and more than 280 million treatments have been distributed.

Plan for Introduction



Develop and execute an operational launch plan

In this stage, product development and testing are well underway and the delivery focus shifts toward preparing for launch. Priority activities include gaining necessary regulatory approvals, developing manufacturing capabilities, establishing distribution channels, organizing demand generation strategies, providing training, and preparing other elements needed for introduction. During this stage, all the work completed in previous stages is continually revisited, updated, amended, and improved as more information becomes available. At the end of this stage, the product is ready for introduction in its target countries based on a strategic launch plan.

Photo: PATH/Gabe Biencycki



Priority activities

MARKET AND USER UNDERSTANDING

- **Update situation assessment**
As the product becomes more clearly defined, the situation assessment can be updated again to match the evolving product definition. Updates may be needed for one or several parts of the initial situation assessment.
- **Develop strategic launch plan with uptake targets**
A strategic launch plan describes the rationale, activities, and timeline for launch and scale-up. The plan should consider disease burden, clinical trial location, country readiness, interest from the ministry of health, and strategic priorities. It should specify uptake targets (global and country-specific) to which the team should be held accountable in each new market.
- **Update bottleneck analysis**
At this stage, the bottleneck analysis can be updated to account for progress and pinpoint demand- and supply-side barriers to introduction and scale-up for target countries. This analysis helps project teams prioritize which bottlenecks to address at what time and identify potential approaches.
- **Update end-user needs assessment**
An updated end-user needs assessment should analyze key influencers/gatekeepers and complement the updated situation assessment and manufacturability discussions to inform any changes before finalizing product and packaging design. The results of this assessment can be used to refine the user segmentation, willingness to pay analysis, and demand generation strategy.
- **Develop pricing strategy**
Based on the refined situation assessment, end-user needs analysis, user segmentation, and willingness to pay analysis, a pricing strategy gathers input from likely purchasers and key stakeholders to establish product prices for specific user segments and by channel (e.g., public, private, social marketing).
- **Develop demand generation strategies and create marketing material**
A demand generation strategy describes the primary and secondary audiences or key influencers that might be involved in the decision to purchase, recommend, or use the product. The strategy includes messages that have been tested with each target audience as well as

appropriate channels for delivering those messages (including training for doctors, health workers, pharmacists, and sales staff).

MANUFACTURING AND DISTRIBUTION

- **Establish manufacturing strategy**
A manufacturing strategy identifies the manufacturer(s) that will be used to produce the final product and packaging. It can be informed by the end-user needs analysis, demand generation strategy, distribution strategy, and regulatory requirements.
- **Establish distribution strategy**
The distribution strategy specifies which channels (e.g., public, private, social marketing) will be used to reach the target customer. The strategy must align with manufacturing and demand generation strategies and should leverage existing networks when possible.
- **Identify partnership opportunities**
Partnerships with local manufacturers, distributors, and non-governmental organizations can help make the introduction of a new health solution successful. As the design and launch plan are finalized, partnership opportunities should continue to be identified and developed.
- **Finalize product and packaging designs**
Final product and packaging designs reflect all testing and user input while conveying any key messages and instructions for use. All designs should be tested with users before finalization and meet all regulatory requirements.
- **Update cost of goods sold (COGS) analysis**
An updated COGS analysis identifies required raw materials and supplies, labor, and any applicable overhead. At this time, opportunities can be explored to reduce the COGS to maximize affordability. Increased accuracy of COGS and demand estimates can help determine pricing strategies and calculate profit margins for manufacturing and distribution partners.
- **Update demand forecast**
Updated demand forecasts should cover years 1 through 5 (actual usage, not total market size) and should account for both public and private channels in all target markets. More rigorous and accurate demand forecasts can also be used to influence donors, manufacturers, purchasers, and other partners who have a stake in production or the product pricing strategy.

- **Update business plan (return on investment) for partners**

An updated business plan that includes a more accurate demand forecast, COGS analysis, and pricing strategy can be used to estimate the return on investment that existing and potential manufacturers and distributors could expect.

- **Update cost-effectiveness analysis**

A compelling and reliable cost-effectiveness analysis can be used to secure financing from donors and support from local and global policy stakeholders. Practitioners should refine and confirm the cost-effectiveness analysis of the final design across various rollout scenarios, highlighting the most sensitive variables and using input from likely purchasers and other stakeholders. The analysis should consider how the new product would fit into existing health programming.

POLICY AND ADVOCACY

- **Support inclusion in treatment guidelines and on country-level essential medicines lists**

Some products cannot be recommended for use in the public sector until they are included on country-level essential medicines lists (EMLs) and/or the WHO Model List. Clinical trial data and cost-effectiveness analyses should be submitted for consideration by global- and country-level regulators that make recommendations for the EML listings.

- **Execute communications, advocacy, and key opinion leader engagement strategy**

Executing the communications, advocacy, and key opinion leader engagement strategy ensures that appropriate parties are well informed about the development and launch progress.

CLINICAL AND REGULATORY

- **Complete clinical trials**

If required, clinical trials should be completed to demonstrate efficacy and safety (and any side effects should be documented) so regulatory approvals can be secured.

- **Obtain national regulatory authority approval(s)**

Approvals from relevant national regulatory authorities are often required to launch a new drug or device. Earlier regulatory landscape analysis should inform which approvals are necessary, the timing required, and how to obtain them.

TIPS FROM EXPERTS

- Although the timeline for regulatory approval can be difficult to gauge, products need to be ready to launch at the time of approval, so no time is lost between regulatory approval and product launch.
- At this stage, multiple stakeholders are often working in parallel on a large number of activities, and their efforts can sometimes overlap, resulting in duplicative or redundant streams of work. Uptake Coordinators (see page 59) should look for ways to minimize duplication and create synergies across the many stakeholders and activities required in this stage.
- As soon as target countries are identified, project teams should start looking for ways to transfer responsibilities to local collaborators, who are often in a better position to scale up an intervention in their regions.
- The strategic launch plan should initially focus on a specific (small) set of countries based on clear selection criteria. The newer and more disruptive the technology, the smaller the target introduction may need to be. Once a product is proven, however, the launch strategy should be expanded to achieve scale.
- Building and sustaining demand can be a very high-touch, high-resource, and long-term activity when building a new market in low-resource settings.
- Accurate demand forecasting is essential for a successful launch. It can help to benchmark demand forecasts against similar products in the market to improve its accuracy.
- The “little things” make all the difference. Practitioners need to be vigilant in addressing all of the bottlenecks.
- Country-level implementers (e.g., ministries of health, regulators) are the ultimate decision makers. Continued consultations with these key stakeholders on resource planning, costing studies, and other decision factors should continue in Stage 3.



“ In developing markets, it’s better to have both an emergent strategy **and** a deliberate strategy because it allows you to get out there and try different things so you can pivot quickly.

• • Hari Nair, Global Managing Director, Kimberly Clark Innovation Center

Stage 3: Activities in action

In this stage, as development and testing continue, the delivery focus shifts to registration, marketing, and distribution. Before a new product can be sold in a country, it may need to be registered and licensed by national authorities and/or recommended for use by WHO or another global policy body. Some products require official regulatory approval as well, and in the case of vaccines and many other controlled products, pre-approval by WHO. The case study on misoprostol describes the process of clarifying global treatment guidelines for extending use of **misoprostol** to community settings. Similarly, the case study for **chlorhexidine** describes complexities of listing the 7.1% formulation for umbilical cord care on the WHO Model List of Essential Medicines.

For products that already have approval or do not require it, the focus may turn to distribution channels and manufacturing options. The case study on **cookstoves in India** shows how different manufacturing, distribution, and financing options can influence product uptake. In this case, several distribution and financing options were explored in different settings before arriving at the most effective strategies.

Some health products are not distributed in the commercial sector, but are distributed through the public health system. In these scenarios, supply chain management and health worker training needs to be carefully managed and considered. As the case study on **CycleBeads® in Mali** shows, it is easy to overestimate demand and set overly ambitious launch targets, especially in untested environments where there is considerable enthusiasm and buy-in from partners.

The pre-launch stage is also the time to develop and test demand generation or marketing strategies. The case study on **Pampers in China** shows how companies can adjust these strategies, based on early feedback from target customers, and develop messages that more effectively match the concerns and desires of households in the target segment.



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CASE STUDY 3.01
CycleBeads® in Mali



CASE STUDY 3.02
Pampers in China



CASE STUDY 3.03
Misoprostol



CASE STUDY 3.04
Chlorhexidine



CASE STUDY 3.05
Cookstoves in India



Overestimating demand in nascent markets

Why researchers struggled to scale up a new family planning method in Mali

SITUATION

When researchers at Georgetown University's Institute for Reproductive Health (IRH) discovered that women could significantly reduce the chance of getting pregnant by abstaining from intercourse between the 8th and 19th days of their menstrual cycles, they set out to promote this very simple and practical family planning method around the world. To make the method, called the Standard Days Method[®], easy and intuitive for women to use, they developed a simple, color-coded string of beads, called CycleBeads[®], which allow women to keep track of the days in their cycle. They found a manufacturer, Cycle Technologies, to manufacture the product and establish sales and distribution channels, while IRH focused on research, pilot introductions, and rollout in emerging markets.

One of the first countries to welcome the new method and product was Mali. In Mali at the time, family planning was used by only 4 percent of women of reproductive age, and the government was eager for a nationwide rollout.



Groundbreaking new products require stakeholders to adopt new systems and behaviors—all of which take time and patience.

Photo: Institute for Reproductive Health, Georgetown University

Excited by the prospect of a quick scale-up in Mali, IRH began working with the Ministry of Health to train health workers in the use of the Standard Days Method[®] and CycleBeads[®].

Meanwhile, Cycle Technologies began fulfilling the initial order for 40,000 sets of the product. But after months of work, the product was not moving from the warehouse into actual use. Health workers were reluctant to promote the new method. Ordering and delivery systems were failing in multiple locations. Most troubling, women did not seem to be interested in using the new product.

PRIORITY ACTIVITIES HIGHLIGHTED

- Develop strategic launch plan with uptake targets
- Develop demand generation strategies and create marketing material
- Update demand forecast

SOURCES (full citations on page 71)

- Kavle 2012
- Stanford University 2012



ACTIONS TAKEN

In response, IRH scaled back its introduction plan to four pilot districts and narrowed its focus to address three priority areas: health worker training, logistics, and demand generation. To address the training issue, IRH partnered with CARE, an organization that was already working with health workers in Mali and had built on-the-ground relationships and trust. They developed a comprehensive training course that could be given to all community health workers in the regions. To address logistics, IRH worked closely with government delivery and procurement teams to ensure that better systems were in place to accurately forecast and order CycleBeads® and to deliver them to remote health centers. For example, they facilitated the inclusion of CycleBeads® on the order forms that community health care workers completed to procure products and provided training on how to accurately complete the forms. To help generate demand, IRH partnered with social marketing experts at Population Services International (PSI) to test an approach to attract new users, during which women were given postcards to invite three friends to learn about the Standard Days Method® and CycleBeads®.

RESULTS

During the first year of the project, approximately 10,000 sets were sent from the central warehouse to districts, but uptake was difficult to monitor using existing information systems. Sales of CycleBeads® through social marketing channels were monitored by PSI and showed an increase from 3,000 units in 2008 to 5,000 units in 2009. Unfortunately, as IRH began seeking information on uptake from other sources, a coup d'état occurred in Mali requiring IRH to close its operations in the country.

Undeterred by the change in events in Mali, CycleBeads® continues to expand its distribution network and is now available in more than 50 countries through non-governmental organizations, ministries of health, health care providers, and retailers.

LESSONS LEARNED

- A good product, even with political will, does not guarantee scale without a detailed understanding of the target user. Implementers need to decide who to target and what this target group cares about, and identify how to best reach them with the resources available.
- Enthusiasm for new products can mask important underlying market dysfunctions. Careful market research and analysis will illuminate a realistic pathway to success, especially in new markets.
- Smaller-scale pilot introductions are often invaluable for identifying problems that may arise in new markets and testing strategies for overcoming those problems.
- Low-income countries often do not have the systems or infrastructure in place to deliver health products and services within their existing health systems. These systems may need to be built or supported by the implementing partner to increase product uptake.
- Non-governmental organizations with existing relationships and complementary skill sets can be invaluable partners when introducing new products and understanding lower-income consumers.

“Perceptions matter most. If people think a product is valuable, they will use it. If people think a product isn't good, they won't use it. Remember that there is a difference between perception and reality; you have to work hard to create positive perceptions around your product.

• • *Tim Calkins, Clinical Professor of Marketing, Kellogg School of Management, Northwestern University*

Generating demand by tapping into aspirations

How Procter & Gamble figured out how to sell disposable diapers to Chinese parents

SITUATION

When Procter & Gamble (P&G) first entered the nascent disposable diaper market in China in 1998, its initial efforts stumbled. At the time, most Chinese mothers were in the habit of using simple cloth diapers on their children, or no diapers at all. Making the switch to a disposable diaper was a difficult proposition for lower-income households. P&G's first move was to improve the product design and reduce the price point, but sales still lagged. P&G was convinced they had the right diaper at the right price, and came to accept the idea that Chinese consumers were not motivated by marketing messages around Pampers' convenience and dryness. The company sought to find out how to position their product as a solution to a significant problem, concern, or desire of Chinese parents.



Extensive consumer research helped Procter & Gamble understand what mattered most to Chinese parents: sleep.

Photo: courtesy of istock/Getty Images

ACTIONS TAKEN

P&G conducted additional in-depth consumer research to better understand the nuances of the Chinese market as it related to diapers, including visits to consumer households. What they found was a concern among parents about the quality of their baby's sleep as well as a desire for more sleep for themselves. In addition, they found that the image of a sleeping baby stimulated a mother's thoughts of the baby's future.

PRIORITY ACTIVITIES HIGHLIGHTED

- Update end-user needs assessment
- Develop demand generation strategies and create marketing material

SOURCES (full citations pg. 71)

Adesina 2013
Frazier 2010
Mathur 2010



“ Don't underestimate what it will take to generate demand. Adoption is one thing; ensuring consistent use is another.

• • *Molly Christiansen and Liz Jarman, Living Goods*

The company then initiated a clinical study with the Beijing Children's Hospital Sleep Research Center that revealed that babies wearing Pampers fell asleep 30 percent faster, slept an extra 30 minutes every night, and had 50 percent less disruption throughout the night when compared with babies wearing cloth diapers.

In 2007, P&G launched the Pampers “Golden Sleep” campaign, highlighting the value of its disposable diapers in improving the quality of sleep for babies and their parents. The advertising mentioned data from the clinical study and noted how uninterrupted sleep leads to better cognitive development—an especially compelling point for an educated target market focused on academic achievement for their offspring.

LESSONS LEARNED

- The needs and desires of consumers can vary dramatically between markets. Messages that resonated with mothers in other parts of the world did not resonate in China. P&G needed to develop a new value proposition for mothers in China—one that solved an important problem.
- Marketing matters. P&G knew it had a viable product and made it available at the right price, but until they had the right message to convey the product's value to the consumer, uptake was low. Even in later stages, in-depth research may be needed to better understand what aspects of a product will resonate the best with the desired target market.
- Consumers everywhere—rich and poor—have hopes and aspirations. Tapping into those strong emotional sentiments and showing the consumer how the product helps them achieve their desires can be a powerful motivator for product use.

RESULTS

P&G's efforts to re-imagine their marketing approach created unprecedented growth for the Pampers brand as well as the entire category of disposable diapers. Sales of Pampers diapers increased by 55 percent and the disposable diaper market in China as a whole grew to nearly \$3 billion between 2006 and 2011. Pampers continues to be the top-selling brand in China, with an estimated market share of more than 30 percent.

A strong communications campaign is not the only way to generate demand. Other factors, such as financial incentives (e.g., conditional cash transfers, vouchers) and access to capital can also drive demand. When thinking through a demand generation strategy, pinpoint the factors that are driving the behavior of the target audience, whether they are end-users, hospital administrators, or high-level bureaucrats.

Pairing advocacy with science to change global guidelines



Photo: Fintrac Inc.

How partners helped get misoprostol approved for postpartum hemorrhage in community settings

SITUATION

Postpartum hemorrhage (PPH) accounts for the majority of cases of obstetric hemorrhage and more maternal deaths than any other individual cause. Most cases can be prevented or treated with the use of uterotonics such as oxytocin, the WHO first-line drug for PPH prevention and treatment. However, as an injection susceptible to heat damage, oxytocin is not always feasible in low-resource settings, especially in home deliveries.

Oral misoprostol was proposed as a possible alternative to oxytocin, as it is relatively inexpensive, stable at room temperature, and easy to store and administer. The 2007 *WHO Recommendations for the Prevention and Treatment of Postpartum Haemorrhage* listed misoprostol for prevention of PPH, but not in community settings. However, by 2010, randomized controlled studies had shown misoprostol to be safe and efficacious in reducing the risk of acute and severe

PRIORITY ACTIVITIES HIGHLIGHTED

- Support inclusion in treatment guidelines and on country-level essential medicines lists
- Execute communications, advocacy, and key opinion leader engagement strategy

SOURCES (full citations pg. 71)

- FCI and Gynuity 2012
- Ahmed, et al. 2012



PPH in community settings. Several non-governmental organizations, including Family Care International and Gynuity, evaluated current misoprostol strategies and determined that the most frequently mentioned barrier to misoprostol use was the lack of strength and clarity of the WHO guidelines. Given the newly available evidence, it appeared to be an opportune moment to advocate for guideline changes.

ACTIONS TAKEN

There are many effective ways to disseminate evidence for policy change, including expert panel sessions, journal articles and communications materials, training workshops, and policy briefings. In partnership with key international and regional stakeholders, an evidence-based advocacy agenda and communications plan was developed to harmonize and disseminate messages on misoprostol use. Importantly, the plan was shared with multiple organizations for agreement and alignment. In 2011, more than 50 leading advocates, health providers, program managers, and policymakers came together to discuss and further develop advocacy strategies; they emerged from the meeting with a clear action agenda and a set of messages for audiences at global, regional, and country levels. This effort provided stakeholders and decision-makers with an up-to-date understanding of the current evidence and put them in a powerful position to influence change.

In 2011, more than 50 leading advocates, health providers, program managers, and policymakers came together to discuss and further develop advocacy strategies.

LESSONS LEARNED

- In addition to requiring strong scientific evidence, advocacy efforts are most effective when they include active participation and buy-in from key stakeholders. It can be useful to canvas the decision makers to understand and address their key questions and concerns.
- Practitioners are often better off when they plan for both regulatory approval and WHO endorsement. Global endorsement by WHO can be critical to a product's long-term success.
- Advocacy needs to follow science. Consistent messaging is important when it comes to requesting changes in policy, especially when requests are made simultaneously at multiple levels. Partners should agree on a communications strategy and messages before requesting changes in policy.

RESULTS

In 2012, WHO revisited misoprostol guidelines using an evidence-based approach: identifying priority questions and critical outcomes; retrieving, assessing, and synthesizing evidence; formulating a recommendation; and planning for dissemination, implementation, impact evaluation, and updates. Later that year, WHO released new guidelines including a recommendation for misoprostol administration by community health workers.

The recommendation was echoed in the 2012 publication, *WHO Recommendations: Optimizing Health Worker Roles to Improve Access to Key Maternal and Newborn Health Interventions Through Task Shifting*. These guideline changes, as well as others at the global and national levels, were necessary to provide access to misoprostol to women giving birth in community settings.

Navigating the requirements of the WHO Model List of Essential Medicines

How partners got 7.1% chlorhexidine digluconate on the WHO Model List



By applying 7.1% chlorhexidine digluconate to the umbilical cord of a newborn, health workers can reduce neonatal infection and sepsis. Various manufacturers' products are shown here.

Photo: PATH/Patrick McKern

SITUATION

Research over the past ten years has shown that 7.1% chlorhexidine digluconate, when applied to the umbilical cord of a newborn, reduces neonatal infection and sepsis. Other concentrations of chlorhexidine have been widely used as medical cleaning disinfectants for decades, but both the 7.1% concentration and use indication for newborns are novel. Seeing an opportunity to improve newborn care in developing countries, the Chlorhexidine Working Group began the process of listing the 7.1% concentration on the WHO Model List of Essential Medicines, which is generally used as a model for national-level essential medicines lists (EMLs). Requests for changes to the WHO Model List are accepted only once every two years.

Six years after the initial request, the WHO Expert Committee listed the specific 7.1% formulation with an indication for neonatal cord care.

PRIORITY ACTIVITIES HIGHLIGHTED

- Support inclusion in treatment guidelines and on country-level essential medicines lists
- Execute communications, advocacy, and key opinion leader engagement strategy

SOURCES [full citations pg. 71]

Chlorhexidine Working Group 2014
WHO 2013



ACTIONS TAKEN

In 2008, the working group submitted a formal request to WHO to update its chlorhexidine listing and include the 7.1% formulation on its Model List with the specific indication for umbilical cord care. WHO responded with a minor change: indications for the 20% solution now stated “dilute for cord care,” but without a specific listing of the 7.1% formulation. In 2009, the WHO Expert Committee on the Selection and Use of Essential Medicines stated that since no 7.1% solution was commercially available at that time, it could not be included on the Model List.

By the time the 2011 window for WHO Model List updates opened, commercial production of the 7.1% formulation was underway in Nepal to serve domestic public- and private-sector markets. However, the Expert Committee again rejected including the 7.1% formulation on the grounds that production in Nepal did not constitute wide commercial availability. However, an expanding number of influential stakeholders began recognizing the potential impact of this innovation, including the UN Commission on Life-Saving Commodities and UNICEF, which added the product to their lists of available drugs.

RESULTS

Within the following 2013 WHO Model List update window, the working group again submitted a revised request, this time noting that UNICEF had added the 7.1% formulation to its list of available products. This time, six years after the initial request, the Expert Committee listed the specific 7.1% formulation with an indication for neonatal cord care. The product is now gaining a foothold in Asia and Africa. After a successful pilot in Sokoto State, the Nigeria Ministry of Health made 7.1%

LESSONS LEARNED

- Inclusion on the WHO Model List can be particularly important for scale-up beyond early-adopter countries, as many countries use the WHO Model List as the basis for their own EMLs. Practitioners should plan for and initiate EML work at both the international level (with WHO) as well as in targeted early-adopter countries as soon as the product launches.
- In general, the EML updating processes (in particular, the WHO process) run on a fixed schedule with long time gaps between updates. Practitioners should identify the relevant EML update time windows early in the development process, and to the greatest extent possible, align activities to facilitate timely submission of requests for changes to EMLs.
- WHO will consider only products (drugs) that are already commercially available, so a new drug (or new formulation of an existing drug) must first gain regulatory approval and some level of routine use in early-adopter countries before being submitted for inclusion on the WHO Model List. Practitioners should identify potential early-adopter countries during the development process and prioritize countries with drug regulatory systems capable of approving new drugs and/or new formulations of existing drugs.

chlorhexidine digluconate a priority commodity for newborn health and committed to scaling it nationally. Both Liberia and Madagascar have completed formative research and are now beginning pilot introduction programs of 7.1% chlorhexidine digluconate for umbilical cord care. Several other countries in sub-Saharan Africa and South Asia are also in the process of adopting chlorhexidine for umbilical cord care.

Testing distribution options

How the Advanced Cookstoves Initiative developed and fine-tuned its distribution strategy

SITUATION

After extensive user and market research in Uttar Pradesh, India, the Advanced Cookstoves Initiative (ACI), a USAID-funded public-private collaboration implemented by Abt Associates, Futures Group International, the Monitor Group, Population Services International, and Banyan Global identified a segment of low-income households whose cooking needs were not being met by existing cooking devices and who were willing to invest in a more efficient, less polluting cookstove. One of the challenges ACI faced, however, was how to distribute high-quality cookstoves to these cash-poor rural households.

ACTIONS TAKEN

ACI decided to test a number of distribution strategies and evaluate which ones might be scalable. At the time, ACI was in discussions with two manufacturing partners whose products were suitable for consumers in northern India and priced at less than 2,000 rupees (~\$30). The first, Philips, a well-established electronics manufacturer, was an attractive potential partner because it had its own extensive distribution network throughout India and a natural draft stove priced at 1,250 rupees (~\$20). The second was Envirofit, a U.S.-based stove company with manufacturing facilities in China and a growing distribution network in southern and western India. Their two biomass natural draft stoves were priced at 1,599 and 999 rupees (~\$25 and \$15).



Improved cookstoves like Envirofit's natural draft stove reduce dangerous emissions while improving efficiency.

Photo: SLOW LIFE Foundation/Thomas Abbott

PRIORITY ACTIVITIES HIGHLIGHTED

- Establish manufacturing strategy
- Establish distribution strategy
- Identify partnership opportunities

SOURCES (full citations pg. 71)

Koh 2014
Singh and Pathy 2012



With two manufacturers willing to collaborate, ACI now had several models it could evaluate for distribution. Philips had an attractive three-tiered, vertical distribution structure that reached nearly every significant town in Uttar Pradesh, whereby goods were sent to a carrying and forwarding agent in the capital of Lucknow, then to a district-level distributor, and on to a town-level retailer. Envirofit had no distribution presence in Uttar Pradesh, so ACI established a three-way partnership between Envirofit; Project Dharma, a distributor with a network of village-level entrepreneurs already selling water purifiers, solar lighting, and cooling solutions in Uttar Pradesh; and Sonata, a microfinancing partner with experience in offering product financing and promotion to its 150,000 clients in Uttar Pradesh.

A third distribution model was envisioned using a microfinancing partner to play the sales/marketing, distribution, and financing roles, thereby reducing the number of partners involved and potentially improving margin structures. Envirofit piloted this third model with two different microfinance partners: Pahel and Appropriate Technology India. ACI provided extensive technical assistance to partners to establish new systems and protocols, including a recruitment protocol for entrepreneurs, sales processes, compensation and incentive structures, and loan processing.

“**Make sure you have contingency plans in place for sourcing materials in case your suppliers can't deliver.**

• • Carol Kim, L'Oreal

LESSONS LEARNED

- To identify both manufacturing and distribution partners, ACI conducted thorough situation assessments of the cookstove industry, met with potential partners, and narrowed the list based on a set of criteria it had developed. Quick trial-and-error pilots enabled ACI to select the best distribution strategies for broader scale-up.
- Distribution models may take shape over time and require extensive discussion and negotiation with partners. Facilitating these partnerships required formal memoranda of understanding and distribution contracts that were neutrally brokered by ACI.
- Distribution models in developing countries often must be designed to reach consumers who lack access to financing, have limited cash flow, or live in areas with very limited supply chain infrastructure.

RESULTS

Of the four distribution options studied, two proved to be successful. One was the three-way partnership between Envirofit, Project Dharma, and Sonata, and the other was the partnership between Envirofit and Appropriate Technology India. The Philips distribution strategy never got off the ground because Philips felt that this cookstove was not a viable commercial product for India and was reticent to adopt a product in its Lighting Division that was unrelated to the category. The Pahel microfinance partnership was abandoned because Pahel lacked the working capital to invest in and purchase cookstove stock.

Introduce and Scale

Monitor execution and optimize

All of the work across the previous stages culminates in Stage 4, when the new product is launched and scaled. There is no common definition of scale that applies to all products; instead, scale can be considered the maximum utilization rate in a target country and globally for a clearly defined end-user segment. The activities in this stage focus on launching or introducing the product, monitoring progress, and expanding the product to other countries and regions. While this stage may be the “shortest” in this Guide, it is absolutely critical in achieving maximized health impact at scale over the long term. It requires persistence, adaptability, and long-term investment in time and resources.

Photo: PATH/Gabe Biencycki



Priority activities

MARKET AND USER UNDERSTANDING

- **Evaluate strategic launch plan progress and achievement of uptake targets**
As soon as a product is launched, systems must be in place to monitor uptake and other key indicators. Based on initial uptake numbers, it will be possible to pinpoint and address bottlenecks, identify and replicate early successes, adjust introduction strategies, and make projections of progress toward targets.
- **Evaluate progress against prioritized barriers and update bottleneck analysis**
Supply and demand bottlenecks never completely disappear. Some previously identified bottlenecks may not have been addressed or persist despite these efforts, and other new bottlenecks or constraints may arise. Since markets are not static, it is important to update these analyses to reflect the latest changes. Identifying the latest set of bottlenecks and prioritizing action can smooth the introduction process and decrease the likelihood of delays or disruptions on both the supply and demand sides.
- **Introduce into new markets and to new user segments**
Identifying additional markets and/or users of the product becomes more important as the product reaches scale in the initial market. Initial market segmentation can be used to inform where product expansion is most viable—new markets and/or new user segments.
- **Expand demand generation campaigns for new markets and user segments**
As the new product is introduced in broader geographic areas, and as new population segments are targeted, the demand generation strategy should be revisited, adapted, and expanded to suit the context.

MANUFACTURING AND DISTRIBUTION

- **Evaluate manufacturing and distribution footprint and adjust as necessary**
Sometimes it will be necessary to revisit manufacturing locations and capabilities to ensure the product can be made available in greater quantities without compromising quality or speed to market. Given the rate and nature of uptake, it will also be important to reassess the distribution strategy in terms of both different geographies and channels. As scale continues, new manufacturing and distribution locations may be required.

- **Redesign and optimize product and/or packaging (if necessary)**

Based on real-world feedback from actual users and other stakeholders during actual introduction and scale-up, it is sometimes necessary to refine or redesign the product or packaging. This is often seen as the “next generation” version of a given product or service based on real-world use, feedback, and other competitive entrants into the market.

POLICY AND ADVOCACY

- **Continue to support inclusion in treatment guidelines and on country-level essential medicines lists for new markets**
As the product enters new markets in different countries, it will be necessary to include it in global/national treatment guidelines and on essential medicines lists.
- **Validate impact and cost-effectiveness analysis**
Most products are developed and launched based on potential impact at scale and with cost-effectiveness assumptions. As more experience is gathered at scale, practitioners can validate initial impact (e.g., disability-adjusted life years, lives saved) as well as cost-effectiveness.

CLINICAL AND REGULATORY

- **Continue with national regulatory authority approval(s) for new markets**
As products are scaled up beyond initial pilot regions, it will be necessary to lay the groundwork for future launches by continuing to track regulatory requirements and build sensible timelines for review and approval.
- **Conduct post-market surveillance**
Post-market surveillance is conducted to monitor the safety of a drug or device after it has been released on the market. Since drugs and devices are approved on the basis of clinical trials, which involve relatively small numbers of people who have been selected for this purpose, post-market surveillance can further refine or confirm the safety of a drug after it is used in the general population.



Photo: USAID/Kelly Ramundo

“ Neither the elegance of the science nor the strength of the effect predicts the ease of implementation.

•• David Stanton, Director, Office of HIV/AIDS, USAID

“ It’s not about just handing off a solution once it’s been manufactured and approved. Achieving scale requires close partnership and collaboration with local players from the beginning.

•• Nancy Godfrey, Health Office Director, USAID/India

TIPS FROM EXPERTS

- Because markets are dynamic by nature, practitioners would benefit from establishing a system to constantly assess supply and demand bottlenecks, even after launch.
- After launch, demand generation strategies need to be evaluated and refined to address the unique requirements of each new user segment in each new geographic area.
- By tracking scale-up progress (utilization rates globally and by country), project teams can more readily evaluate overall progress and make more informed decisions about when and where to launch or scale up a new product.



“ People often take their eye off the ball at Stage 4, scaling up for mass uptake. Having an end-to-end, long-term view will force us to be honest about what we’re actually trying to achieve.

•• Ya’ir Aizenman, Dalberg Global Development Advisors

Stage 4: Activities in action

Once a new product receives regulatory approval, a number of activities can be implemented to actively launch and scale up the product in selected markets. Demand generation activities are especially important in the launch stage, and can have a significant impact on uptake. Many health products and services require education along with promotional activities, as was the case with **contraceptives in Ethiopia**, which were promoted in a radio drama series over the course of several years. The radio drama allowed the government to promote contraceptives to both men and women while also educating audiences about family planning, HIV/AIDS, and other reproductive health topics.

After a launch, uptake data will quickly reveal whether end-users are responding. Reducing costs, easing financing constraints, and adjusting manufacturing and distribution strategies can make a difference, as was the case with the Safe Water and AIDS Project when project vendors began selling durable **ceramic water filters** to households in Kenya.

Naturally, the next stage after launching a product in initial target markets is to expand availability into other geographic areas. Sometimes this requires additional regulatory approval and registration in target countries. The case study on **misoprostol for postpartum hemorrhage** shows how a group of medical doctors in Kenya, Nigeria, and Tanzania helped facilitate registration in their countries.

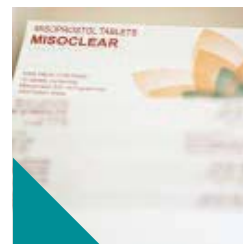


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CASE STUDY 4.01
**Contraceptives
in Ethiopia**



CASE STUDY 4.02
**Ceramic water
filters**



CASE STUDY 4.03
**Misoprostol for
postpartum
hemorrhage**



Using radio drama as an educational tool



Actors performing for a radio drama.

Photo: PATH

How an entertainment-education program generated demand for contraceptives in Ethiopia

SITUATION

In 2002, family planning stakeholders in Ethiopia, including government agencies, non-governmental organizations, donors, and researchers, came together to address the high levels of unmet need for family planning in the country. At the time, only 12 percent of married women were using a modern contraceptive method. Formative research on the issue suggested that part of the unmet need for family planning was related to demand issues, including negative attitudes about contraceptive use, misperceptions about family planning, and low levels of communication between spouses about family planning.

PRIORITY ACTIVITIES HIGHLIGHTED

- Expand demand generation campaigns for new markets and user segments

SOURCES (full citations pg. 71)

Salem 2008



ACTIONS TAKEN

Recognizing that mass media campaigns are often highly effective in changing attitudes toward family planning, the group hired Population Media Center (PMC), an international non-governmental organization that specializes in entertainment-education. PMC proposed creating a radio serial drama to be played on the country's most popular radio station.

They designed the radio drama using a methodology developed by a Mexican television producer, Miguel Sabido. The goal was to improve contraceptive knowledge and practices, improve attitudes and behaviors related to HIV/AIDS, and elevate the status of women. An advisory committee made up of local professional script writers, producers, gender and health experts, and theatre arts advisors was formed to oversee the project, and technical advisors reviewed scripts for medical accuracy.

Four pilot episodes were pretested in focus group discussions with target audiences. Listener groups, letters from listeners, and exit interviews at hospitals and clinics allowed PMC to collect timely feedback and develop content for new episodes. PMC worked closely with the government to prepare for increases in demand for services when the first episodes were aired.

“In communication, focus is critical. If you tell someone many things, there is a good chance they will forget everything. Identify your key message and get that across.

• • Tim Calkins, Clinical Professor of Marketing, Kellogg School of Management, Northwestern University

LESSONS LEARNED

- Entertainment-education efforts are most effective when they promote a specific behavioral outcome for each target audience. Making behavioral goals clear from the outset enabled stakeholders to get the most out of the radio program.
- Learning can be fun. Driving use of a new health product through entertainment can be more effective than sober messages about a health need.
- Media campaigns can be highly effective vehicles for putting pressure on key influencers or decision makers. In this case, the radio program was designed to educate both women and men, key influencers of women's family planning decisions, about modern contraception and to de-stigmatize family planning services.
- Sustaining demand may require official policy changes and sensitization of stakeholders that make, recommend, use, or benefit from the product. Before implementing the radio drama, the Ethiopian family planning program provided extensive training to health workers on modern contraceptive methods and counseling techniques.

RESULTS

More than 250 original episodes of *Yeken Kignit* aired on Radio Ethiopia from June 2002 to November 2004. An endline survey of 3,000 men and women revealed that 77 percent of men and 78 percent of women had heard *Yeken Kignit*. Among listeners, 40 percent were now using a modern contraceptive method, compared with 25 percent of nonlisteners, an increase of approximately 28 percent.



Photo: PATH

Good to better manufacturing partners

Why a Kenyan organization switched to a better-fit manufacturer

SITUATION

Based in Kisumu, Western Kenya, the Safe Water and AIDS Project (SWAP) is a non-governmental organization that engages community health promoters—mostly members of HIV support and self-help groups—to promote and sell water treatment products along with other health products as an income-generating activity that also benefits the wider community. SWAP offers training on social marketing and behavioral change techniques and provides an initial inventory along with a list of household targets. Community health promoters then sell health products to customers at retail prices and replenish their inventories paying wholesale prices.

In 2011, SWAP expanded their water treatment offerings (which included known brands of chlorine tablets and liquids) with a durable ceramic water filter. For the pilot project, they contracted with Chujio Ceramics, a Kenya-based manufacturer whose Ceramic Water Pot (CWP) was certified by the Kenya Bureau of Standards and with a track record of sales to non-governmental organizations for distribution to low-income communities. During the pilot, customers could purchase the CWP with cash or by installment using mobile phone money transfers.

PRIORITY ACTIVITIES HIGHLIGHTED

- Evaluate manufacturing and distribution footprint and adjust as necessary
- Redesign and optimize product and/or packaging (if necessary)

SOURCES (full citations pg. 71)

Abt Associates Inc. 2012



Each actor in the value chain requires incentives and adequate profit margins for sustainability.

Unfortunately, sales of the CWP were very low during the pilot period. An evaluation of the pilot pinpointed several challenges related to uptake, including ones related to manufacturing and distribution. Not only was the product itself relatively expensive, transportation cost from the factory to the organization added additional expense. Vendors also found it difficult to transport heavy, bulky CWPs to their villages. Yet potential customers wanted to see and examine the item in person before committing to this large purchase—a brochure with a picture was not nearly enough. It was clear that the program would not be sustainable without changing the manufacturing and distribution strategy.

ACTIONS TAKEN

SWAP re-evaluated their choice of manufacturer, and changed to a previously identified manufacturer, Kenya Ceramic Project, which had recently gained certification from the Kenya Bureau of Standards and had transitioned to entirely machine-based production. This increased filter rate production and improved efficiency. In addition, Kenya Ceramic was located closer to the SWAP area of focus (which would decrease transportation costs) and was able to price their product, the CeraMaji, at about half that of the Chujio CWP.

To solve the vendor transportation issues, SWAP outfitted each vendor with a bike with a customized carrying rack, allowing them to travel longer distances with multiple water

filters for both sales and delivery. SWAP also enhanced its distribution strategy by selling to partner organizations in addition to individuals and families.

RESULTS

The change from the Chujio CWP to the CeraMaji, with its new manufacturer, was a success on all fronts. The new product could be produced and distributed to customers at a lower cost. Customers could also examine and try the CeraMaji prior to purchasing, and flexible sales terms made it easier to purchase. Sales of the filters jumped in 2012 and increased by an additional 60 percent in 2013.

LESSONS LEARNED

- By switching manufacturers, SWAP was able to offer a higher-quality product at a lower price point, and was able to demonstrate the product to users before purchase.
- Operational pilots can be an important way to highlight supply-side issues, such as manufacturing or distribution challenges, and allow for course correction.
- It can be valuable to analyze whether the current manufacturing and distribution model has the capacity to deliver the most cost-effective product in quantities sufficient to meet anticipated demand. It was clear from the start that Chujio's price point was too high, especially given distribution costs, but the partnership with Chujio allowed SWAP to test the product in the target market before finding a more suitable manufacturing partner.
- Each actor in the value chain requires incentives and adequate profit margins for sustainability. Sometimes manufacturing or distribution partners are willing to accept lower margins while a product is still being proven, but they need to operate a sustainable enterprise at scale.

Shepherding a product through registration

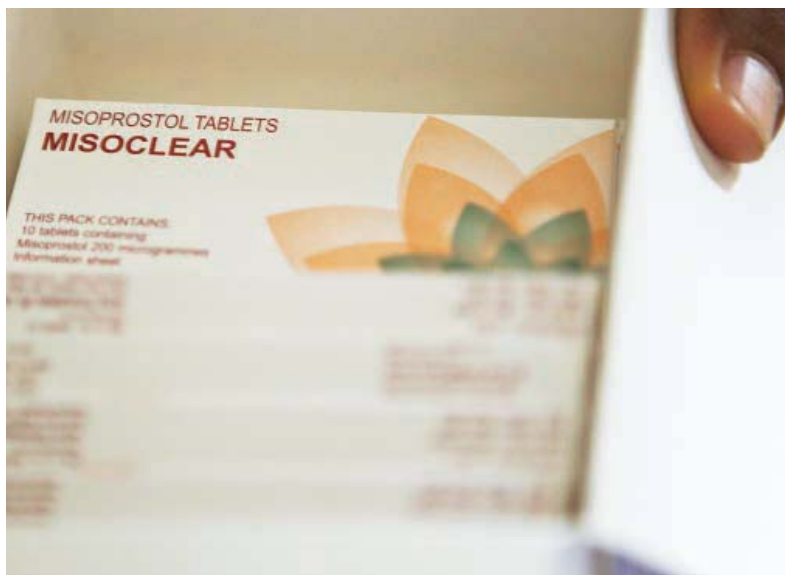


Photo: PATH/Evelyn Hockstein

How national partners obtained approval to use misoprostol for postpartum hemorrhage prior to official WHO recommendation

SITUATION

Several years before misoprostol was recommended by WHO in global treatment guidelines, clinicians in Africa recognized the value of misoprostol in preventing and treating postpartum hemorrhage (PPH) in low-resource settings and were eager to begin using it. Recognizing that global colleagues were already in the process of assembling studies and other prerequisites for WHO approval, the clinicians felt they could make the biggest impact by changing policies at the national level.

PRIORITY ACTIVITIES HIGHLIGHTED

- Continue to support inclusion in treatment guidelines and on country-level essential medicines lists
- Validate impact and cost-effectiveness analysis
- Continue with national regulatory approval(s) for new markets

SOURCES (full citations pg. 71)

Holden 2006
 Jadesimi 2006
 Venture Strategies for Health and Development 2014



ACTIONS TAKEN

Three leading African obstetrician-gynecologists from Kenya, Nigeria, and Tanzania partnered with the University of California Berkeley School of Public Health and the nonprofit organization Venture Strategies for Health and Development to get misoprostol registered and approved for prevention and treatment of PPH in their three countries. The partners reviewed preclinical and clinical evidence and assessed the procedural and political requirements for registering misoprostol. They then focused resources on: (1) conducting operations research studies to help governments understand the value of the medicine for obstetric indications; (2) convening policy meetings on maternal health in conjunction with the government; (3) assessing and selecting pharmaceutical manufacturers to produce high-quality misoprostol; (4) preparing and tracking the regulatory dossier for importing and distributing misoprostol; and (5) advocating for policy change to integrate misoprostol into health systems.

RESULTS

In January 2006, the Nigerian National Agency for Food and Drug Administration approved the drug for use in hospitals and clinics for controlling PPH, a historic moment for maternal health. Subsequent to this approval and using a similar approach, Venture Strategies for Health and Development, Venture Strategies Innovations, Marie Stopes International, Population Services International, and others facilitated regulatory approval for PPH use of misoprostol in more than 25 countries. These approvals paved the way for expanded access to this lifesaving drug for pregnant women even though WHO did not recommend misoprostol for prevention and treatment of PPH until 2007. WHO recommended misoprostol for use in community settings in 2012.

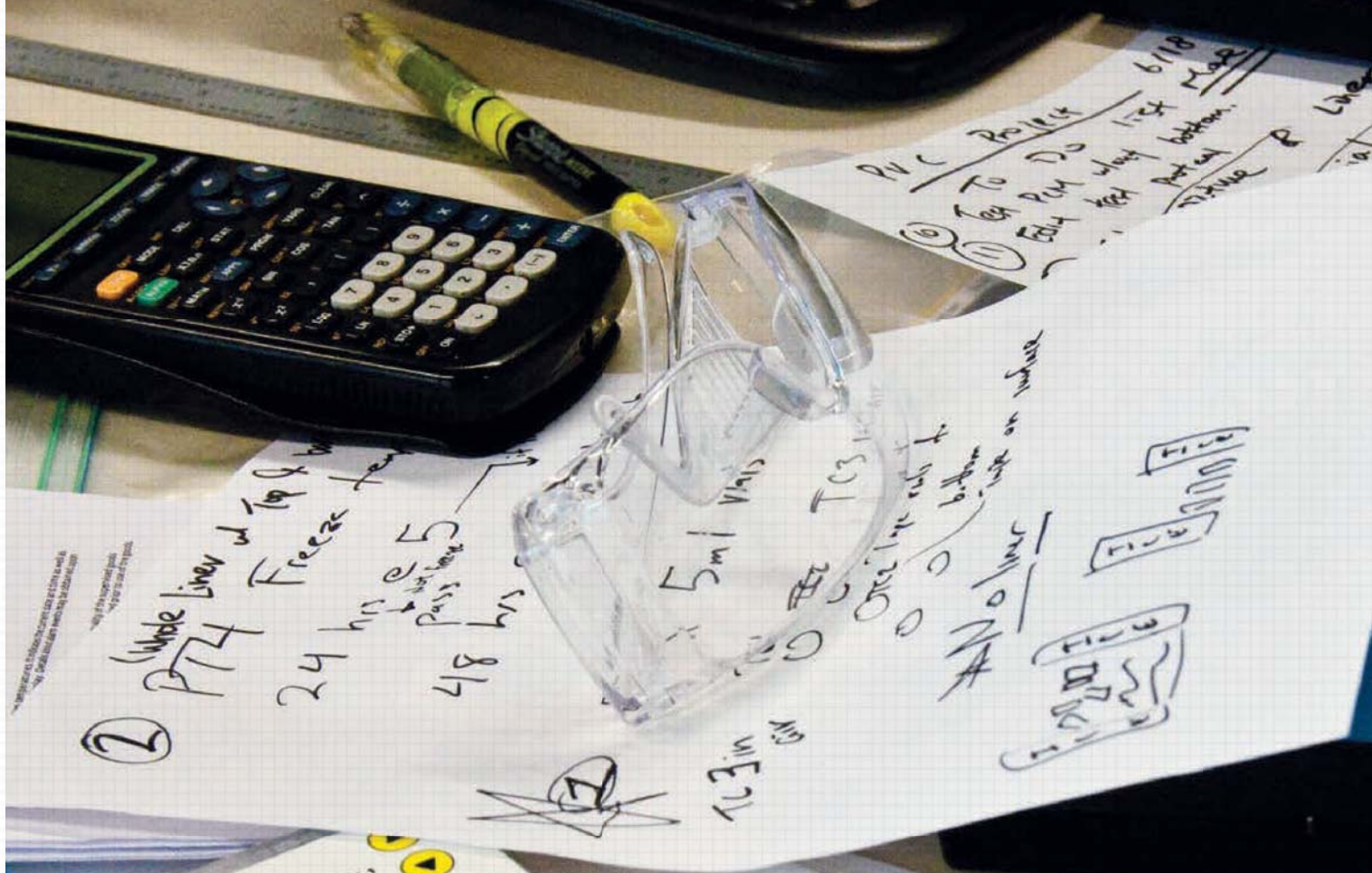
LESSONS LEARNED

- Although WHO guidelines carry weight with national governments, it is possible to change guidelines at the country or regional level first, especially when those changes are essential to expanding access.
- Support from the ministry of health and all levels of the medical community is essential for building credibility and mobilizing additional support for a solution.
- Policy meetings can be effective in mobilizing and building awareness of a solution.
- “Fast-track” options are available from most regulatory agencies, especially for high burden of disease with no current treatments.
- The sequence for product listing and registration may be different for each country; some will first add it to their essential medicines list, while others will begin with product registration.

“The regulatory landscape changes often in low-resource settings. Nurture your relationships with the right people who can help you understand implications of changes that may affect your products, and navigate through the system. Stay informed because changes can drastically affect your efforts.

• • Molly Christiansen and
Liz Jarman, *Living Goods*

Making it all happen



Why an Uptake Coordinator?

While Uptake Coordinators (also known as Market or Project Managers) are an integral part of industry-led initiatives, they are a more recent addition to large, multi-partner efforts in the public sector. Given the diversity of organizations supporting the development and introduction of a global health product, it may be difficult to appoint a single Uptake Coordinator. However, since the range of activities through all four stages spans sectors, disciplines, and geographies, and needs to be closely coordinated, it can be highly beneficial to consider ways this practice can be applied in global health.

Photo: PATH/Patrick McKern



Priority activities

STAGE 1

Identify Needs and Design

Establish early project plan with stakeholders, timelines, and budget

Given the large number of activities that happen over many years, creating an early, high-level project timeline and budget—and refining with more specificity over time—is a critical element in planning and setting expectations. Uptake Coordinators assign milestones, deliverables, and budget estimates to the priority activities outlined in this document. They also set expectations for launch and scale-up, ensure allocation of resources to partners and actors across each functional area of expertise, and provide donors with better information to inform their annual budgeting process.

STAGE 2

Begin Research and Development (R&D)

Select and empower Uptake Coordinator

Early in the project, an Uptake Coordinator should be selected and given authority to oversee activities. Depending on the scope and scale, this could be an individual or, more likely, an organization. Regardless of the stage, the Uptake Coordinator's focus should be on ensuring adherence of all contributing partners to a timeline as well as prioritization and execution of the many activities at each stage.

Update project plan with stakeholders, timelines, and budget

As more information emerges and the project progresses, the Uptake Coordinator continually updates the project plan. A refined project timeline will drive the global work forward and move stakeholders through decision gates more efficiently. More rigorous stakeholder mapping is an exercise that includes identifying all the various people and organizations involved in bringing a product to market (e.g., end-users, sales people or health workers, distributors, manufacturers, regulators, global and national

policymakers, researchers, designers, and engineers) and mapping them to activities in each stage. Conducting stakeholder mapping early and revisiting it often will ensure that key people and processes are appropriately included and involved at the right time.

Further engage all key stakeholders by functional area

Keeping stakeholders well informed will make it easier to move forward with a detailed operational launch plan. The updated project plan can be used to leverage the expertise of key stakeholders and keep them informed of the overall project and timeline.

STAGES 3 AND 4

Plan for Introduction, Introduce and Scale

Hold stakeholder meetings to ensure progress and adherence to the timeline

As the work progresses through the four stages, key stakeholder groups will need to be assembled more frequently to share progress and discuss overlapping concerns. Some of these meetings need to occur in person, but can occur on video or in teleconferences depending on language and time-zone barriers. As the R&D stage progresses toward planning for introduction, potential stakeholders—whether focused on supply, demand, or enabling factors—should be engaged and support the co-creation of the plan moving forward. Based on the timeline and project plan, these stakeholders should agree on goals, commit to assigned activities, and have access to adequate funding.



See complementary Workbook and Toolkit at www.usaid.gov/cii.

“ It is critical to keep a laser-like focus on your high-level goals and quickly determine whether an activity, planned or underway, will get you there.

•• *John Borrazzo, Division Chief, Maternal and Child Health, USAID*

Best practices within industry suggest assigning a single person or group focused on uptake and commercialization from early design through launch.

“ Early on, we did not have a central person who was accountable for gathering data and processing the implications to better inform our efforts. Balls were dropped, as no one person was responsible for connecting the feedback from consumers back to the manufacturing and packaging people.

•• *Molly Christiansen and Liz Jarman, Living Goods*

TIPS FROM EXPERTS

- While other players often have their own defined area of responsibility, the Uptake Coordinator is ultimately accountable for global scale-up (e.g., not just in the first few countries). The Uptake Coordinator needs to see the big picture and should be granted the authority to lead, make decisions, and influence outcomes.
- A rigorous launch plan should always be based on specific country selection criteria.
- Timelines and budget estimates should be established by stage and priority activity, even if it is very high level and flexible.
- A project plan is a useful guide for investors and partners; it articulates what will be delivered, when, and how much it will cost.



“ Project coordination is important, particularly in global health where you’ve got multiple actors. You want to make sure everyone is going at the same problem in the same way.

•• Dan Collins, Global Health, Eli Lilly

Uptake Coordinator: Activities in action

When introducing a new product, it is crucial to connect decisions and research from one functional area to another. Issues across these sectors are closely interlinked; for example, more complex procurement requirements may raise manufacturing costs, or selecting certain marketing channels may limit distribution points. As described in the first case study from the private sector on an HIV/AIDS diagnostic tool from **BD (Becton, Dickinson and Company)**, these issues are often examined by a cross-disciplinary team with a single lead, all working toward clearly defined goals and timelines.

In the global health sector, coordinating activities and decisions can be more complicated, so sharing timely information and its implications becomes even more important. In the case of global introduction of chlorhexidine for umbilical cord care, a non-governmental organization was asked to lead a global **Chlorhexidine Working Group** and eventually began to take on all the necessary roles of an Uptake Coordinator. Had an Uptake Coordinator been assigned earlier in the product lifecycle, introduction and scale-up may have occurred earlier and the product would likely be available in more countries to date.

One global health project that did successfully identify an Uptake Coordinator from a very early stage was the **Meningitis Vaccine Project (MVP)**. Empowered to take this role through significant funding from the Bill & Melinda Gates Foundation and agreement between WHO and PATH, MVP is an example of a global health development and introduction initiative that did many things right the first time: hiring multi-disciplinary teams, convening both technical experts and country stakeholders on a regular basis, establishing a clear clinical and regulatory pathway, pursuing an aggressive timeline, and sticking to an early target product profile. MVP achieved scale quickly and effectively because it recognized the value in orchestrating the stages of product development and introduction from a position of leadership and not acting alone.



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CASE STUDY 0.01
BD



65

CASE STUDY 0.02
**Meningitis
Vaccine Project**



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CASE STUDY 0.03
**Chlorhexidine
Working Group**



A proven process for accelerated development and introduction



Photo: BD

How BD's "Global Product Development System" enabled a more efficient launch of a new point-of-care diagnostic for HIV/AIDS patients

SITUATION

In 2009, Becton, Dickinson, and Company (BD), a global medical device company, identified the need for a new, lower-cost, and more appropriately designed point-of-care diagnostic tool for staging and monitoring HIV/AIDS patients. The goal was to complement their larger, high-volume instruments, FACSCalibur™ and FACSCount™, with a smaller near-patient instrument suitable for smaller-volume CD4 tests in resource-limited countries. Using their Global Product Development System (GPDS), a similar framework to the four stages presented in this Guide, BD approached the product development and introduction planning effort in a systematic way.

PRIORITY ACTIVITIES HIGHLIGHTED

- Select and empower Uptake Coordinator
- Further engage all key stakeholders by functional area
- Hold stakeholder meetings to ensure progress and adherence to the timeline



ACTIONS TAKEN

Before the project got off the ground, BD completed a situation analysis that defined the problem they were trying to solve, provided a competitive landscape of the point-of-care HIV/AIDS diagnostic field, considered how the product would be procured and used, and evaluated the intellectual property landscape. This initial situation analysis was continually updated over time as more information became available. As the launch approached, the most recent situation assessment was reviewed by company leadership at “Commercial Excellence Reviews” to pressure test the work against the changing market landscape.

After the initial situation assessment was completed, BD formed a core team with expertise in operations, manufacturing, finance, marketing, regulatory affairs, quality, and clinical operations. This team met weekly and provided monthly internal updates to executive leaders. Using a Gantt chart, the project team followed a strict timeline that tracked every function and progress against all project milestones (time and budget) and key deliverables. The schedule was visible to all team members and company leadership at all times.

A project lead, or “Core Team Leader,” drove the process. This lead had project management training and an executive presence needed to represent the project internally and sometimes externally. The Core Team Leader was responsible for managing multiple activities simultaneously and meeting the needs of a diverse internal team. This required a “360 degree understanding” of the project issues.

LESSONS LEARNED

- There is no shortage of issues that will arise that could derail progress. The project manager needs to be persistent and empowered with a clear focus on the end-goal and a path to get there.
- Given all of the activities being performed across many months and by many people, a project timeline, clear expectations, and accountability limit surprises and keep the whole team “on the same page.”
- Regular team meetings—weekly, monthly, or quarterly—allow for vetting of issues and addressing bottlenecks as they arise.

“The GPDS provides a place for resolving open-ended issues. The coming together of functional experts ensures we quickly identify and address roadblocks and issues as they come up.

• • *Renuka Gadde, Vice President, Global Health, BD*

RESULTS

The FACSPresto™ Near Patient CD4 Counter system launched on March 28, 2014 within budget and on time. BD’s global marketing team is now incorporating early customer feedback and is reviewing adoption rates in these initial markets relative to their projections. As part of its phased launch plan, BD is also planning for expansion to new markets in Africa and Asia.

Charting a course for a new vaccine for Africa

Why global coordination was so valuable to the Meningitis Vaccine Project



Photo: PATH/Gabe Bienczycki

SITUATION

When Dr. Marc LaForce was hired as Meningitis Vaccine Project (MVP) Director, he faced a daunting managerial challenge. The timeline to develop the vaccine was short, the technical challenge was significant, the number of stakeholders was daunting, and the regulatory pathway in many target African countries was unclear. He and his team would need to align technical, political, regulatory, scientific, and commercial experts toward the common goal of developing and deploying a safe, efficacious, and affordable meningitis vaccine for Africa.

ACTIONS TAKEN

Dr. LaForce began by assembling a strong technical team with skills and experience in vaccine development and clinical trial design in Africa. He also hired a dedicated project manager/administrator who compiled, maintained, and monitored a detailed overall project timeline and budget using input from the project technical staff.

MVP formed two advisory groups: an Expert Technical Panel of vaccine and immunology experts from the

United States Centers for Disease Control and Prevention and National Institutes of Health, WHO, and other institutions, and a Project Advisory Group consisting exclusively of African public health leaders and researchers from countries affected by meningitis. These groups met formally at least once a year, and participated informally in problem-solving as needs arose throughout the project.

PRIORITY ACTIVITIES HIGHLIGHTED

- Establish early project plan with stakeholders, timelines, and budget
- Select and empower Uptake Coordinator
- Update project plan with stakeholders, timelines, and budget
- Further engage all key stakeholders by functional area
- Hold stakeholder meetings to ensure progress and adherence to the timeline

SOURCES (full citations pg. 71)

Marchetti 2012



“ Make the need (i.e., health challenge) real on a personal level for all members of the core uptake coordination team. At MVP, we made sure members of the team had opportunities to engage directly with community members in the affected countries.

• • Marc LaForce, PATH

As the initial clinical trials showed promising results (see Case Study 2.01 on page 27), MVP conducted numerous rounds of focus group discussions with community members and local leaders to better understand community perceptions of vaccines and meningitis. MVP also enlisted local communications experts to develop strategies to promote the vaccine as soon as it was available. This all fed into a highly orchestrated nationwide launch of MenAfriVac® in Burkina Faso to immunize all people aged 1–29 years in the month before the onset of the 2010 meningitis season. The launch in Burkina Faso was successful, but true scale-up could not be achieved without subsequent launches and a handover of responsibility to countries and donors.

After a moment of exhilaration seeing the vaccine deployed in Burkina Faso, the MVP team began planning the next set of country introductions. Each successive introduction required immense planning, coordination, and partner support.

LESSONS LEARNED

- An Uptake Coordinator should have both management skills and political savvy to drive organizational partners through the inevitable ups and downs of a product introduction.
- Going from initial introductions to real scale requires considerable vigilance, and handover to country adoption (and uptake by the GAVI Alliance) is not a given without continued advocacy and planning. It can be worthwhile to invest in developing communication skills among the core team and key partners/stakeholders. MVP hired professional facilitators for annual retreats and set aside dedicated time for building interpersonal communication skills.

RESULTS

MenAfriVac® was introduced in Mali and Niger in 2011. MVP engaged additional countries in the “meningitis belt” in planning and implementing vaccination campaigns. By the end of 2013, more than 150 million doses of the vaccine had been administered. An epidemiological evaluation conducted during the meningitis season confirmed that the vaccine had a significant impact in reducing the burden of disease. Community members did not need to see the scientific proof—they saw that their neighbors and relatives (or themselves) were no longer suffering from the sometimes deadly and often debilitating disease they had come to expect during the meningitis season. While there is still a low level of ongoing meningitis disease occurring due to other more rare strains, the previously dominant group A meningococcal organism has almost disappeared from detection.

[See related Case Study 2.01](#)



Female Community Health Volunteers in Nepal share materials on chlorhexidine with parents.

Photo: PATH/Karina Collins

Leveraging partners to scale up a health product

How partners improved coordination to accelerate introduction and scale-up of chlorhexidine

SITUATION

Severe infection is one of the top three causes of newborn deaths worldwide, accounting for approximately 13 percent of all neonatal deaths each year. Infection often occurs when the recently cut umbilical cord serves as an entry point for bacteria that causes newborn sepsis and death. Chlorhexidine, a low-cost antiseptic used traditionally in handwashing formulations, proved a promising solution, demonstrating high efficacy in reducing neonatal sepsis (more than 20 percent reduction in neonatal mortality) in clinical trials in Bangladesh, Nepal, and Pakistan. The global health community, led by the UN Commission on Life-Saving Commodities, stood ready to rapidly scale this low-cost, easy-to-use, and exceptionally low-risk intervention.

PRIORITY ACTIVITIES HIGHLIGHTED

- Establish early project plan with stakeholders, timelines, and budget
- Select and empower Uptake Coordinator
- Update project plan with stakeholders, timelines, and budget
- Further engage all key stakeholders by functional area
- Hold stakeholder meetings to ensure progress and adherence to the timeline

SOURCES (full citations pg. 71)

- Arifeen 2012
- Liu 2012
- Mullany 2006
- Soofi 2012
- WHO 2013



ACTIONS TAKEN

Seeing a need to coordinate global scale-up of chlorhexidine, USAID, an early funder of chlorhexidine clinical trials, commissioned PATH to create a Chlorhexidine Working Group. Starting in 2011, the working group convened various stakeholders who could offer expertise in different functional areas. Some offered expertise in supply-side issues and some focused on demand generation; others knew how to navigate global and national regulatory and clinical guidelines to support the global launch of chlorhexidine.

Through regular conference calls and quarterly meetings, the Chlorhexidine Working Group facilitated and helped prioritize work across partner organizations and helped in seeking funding to support priority activities. These activities included conducting in-country market research, forecasting demand, supporting local manufacturers with guidelines and technical assistance, and building the case for a WHO recommendation. The working group also developed a high-level strategic scale-up plan using a methodology for identifying “Tier 1” and “Tier 2” countries. This phased launch plan was continually updated and evolved based on the significance of need, country readiness, and strategic importance. The working group is now helping to set uptake targets for these Tier 1 and Tier 2 countries and coordinating with local government officials and implementing partners to support local implementation in the select countries.

RESULTS

Since 2011, the Chlorhexidine Working Group has supported planning for introduction in more than ten countries. In addition to coordinating activities, it has also served as a knowledge management hub to share lessons across countries. Nepalese colleagues, who rapidly scaled up chlorhexidine coverage to 33 percent of all live births in just four years, actively participate in the working group and serve as a source of best practices and motivation for the other Tier 1 and Tier 2 countries.

LESSONS LEARNED

- The Uptake Coordinator does not have to do everything. In the case of chlorhexidine, different members of the working group offered expertise in different functional areas. Nepalese colleagues, for example, shared their best practices for successful implementation.
- Sometimes launch plans evolve over time and by accident. Even rudimentary selection criteria and strategic planning can help focus efforts.
- PATH was not hired with the explicit “Project Management” or “Uptake Coordinator” mandate; the role evolved over time. More authority and accountability to oversee and coordinate activities earlier on could have led to even more rapid introduction.
- Global coordination requires effort—something not always recognized in the global health community. Significant resources are needed to manage internal communications and logistics alone. However, deep technical and strategic skills and expertise are needed to support, shape, and prioritize all the activities across all functional areas of expertise.

The Chlorhexidine Working Group facilitated and helped prioritize work across partner organizations and helped in seeking funding to support priority activities.

See related Case Study 3.04

Putting the Framework into practice

As we developed this Guide, we consulted a number of experts from industry and the public sector to validate the Framework and hear more about their experiences with development, introduction, and scale-up in developing countries. While each person faced different challenges in bringing a product innovation to scale, certain ideas emerged as themes in conversations. These themes, summarized here, are last words to consider as one moves forward to introduce and scale. Over time, these themes will expand and solidify with input from readers and experts who have scaled new innovations in global health.



PATH/Julie Jacobson

Plan carefully, and relentlessly.

Begin with the end in mind and create a plan that gets you there. A good plan can help a project team navigate uncertainty and anticipate problems before they arise. Even with limited data, plans can provide structure and direction to an uncertain process. Not only should plans describe what success and failure look like, they should include quantifiable metrics, timelines, and responsibilities that hold team members accountable for their contributions. That said, even the most thoroughly planned introductions encounter surprises: material costs increase; laws change; new products enter the market. Plans should accommodate uncertainty and build in flexibility to allow for adjustments when things do not go “according to plan.” To the greatest extent possible, project teams should be structured so they can adapt quickly and manage the unexpected.

Continually iterate, and test your assumptions often.

Every solution must evolve and change to fit the needs of a changing health ecosystem. Project teams must stay connected to customers and other stakeholders and continue gathering extensive feedback throughout all the stages of introduction and scale-up planning. When possible, project teams should conduct rapid experiments and make quick adjustments based on lessons learned.

Understand the value proposition for your product throughout the international and local ecosystem—which can be complex and culturally specific.

The needs of organizations and individuals that play critical roles in making, approving, recommending, buying, distributing, and using an innovative solution must be identified and considered in any product’s design. These needs can vary widely based on the local context. By understanding the impact that the product or service will have on various stakeholders within the system, project teams can adjust and respond appropriately. Overlooking a key stakeholder need or perspective can derail success.

Build a dedicated, multi-disciplinary project team with an empowered leader, well-defined team member roles and responsibilities, and clear goals.

A cross-functional and diverse team has the advantage of being able to look at the needs of the customer—and stakeholders—from different perspectives: manufacturing, marketing, sales, finance, design, and regulatory. An experienced Uptake Coordinator must be accountable for coordinating all efforts and driving overall progress, tracking goals and milestones, assigning roles and responsibilities, and determining who has decision-making rights. The Uptake Coordinator should define from the beginning what success and failure is and clearly communicate it to the entire team.

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Uptake Coordinator

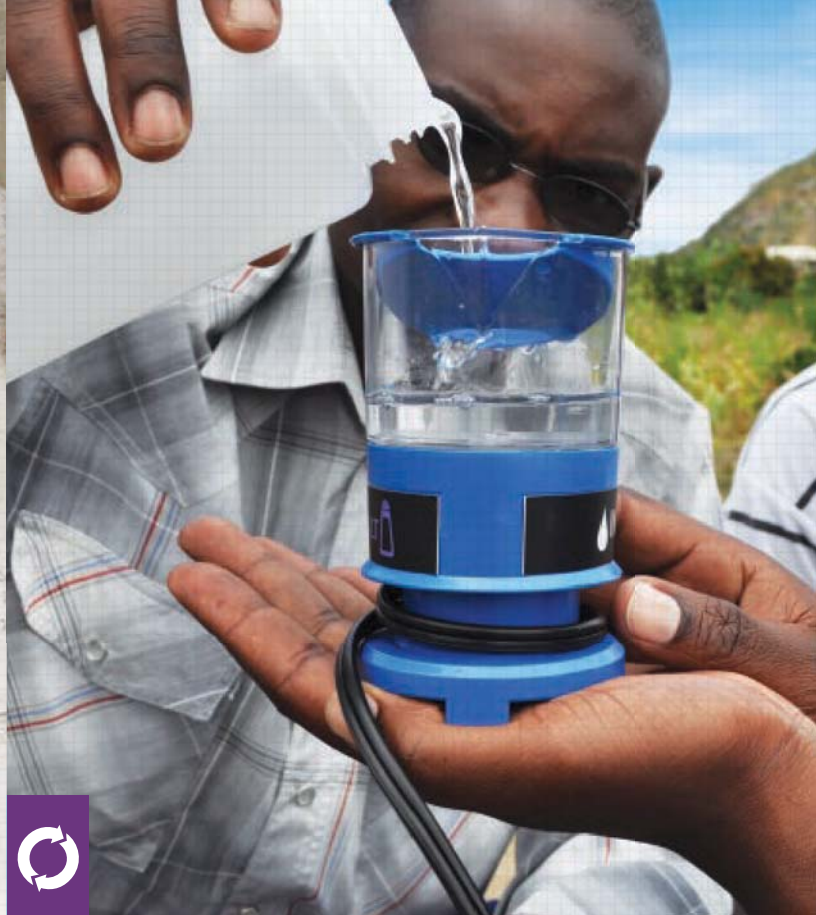
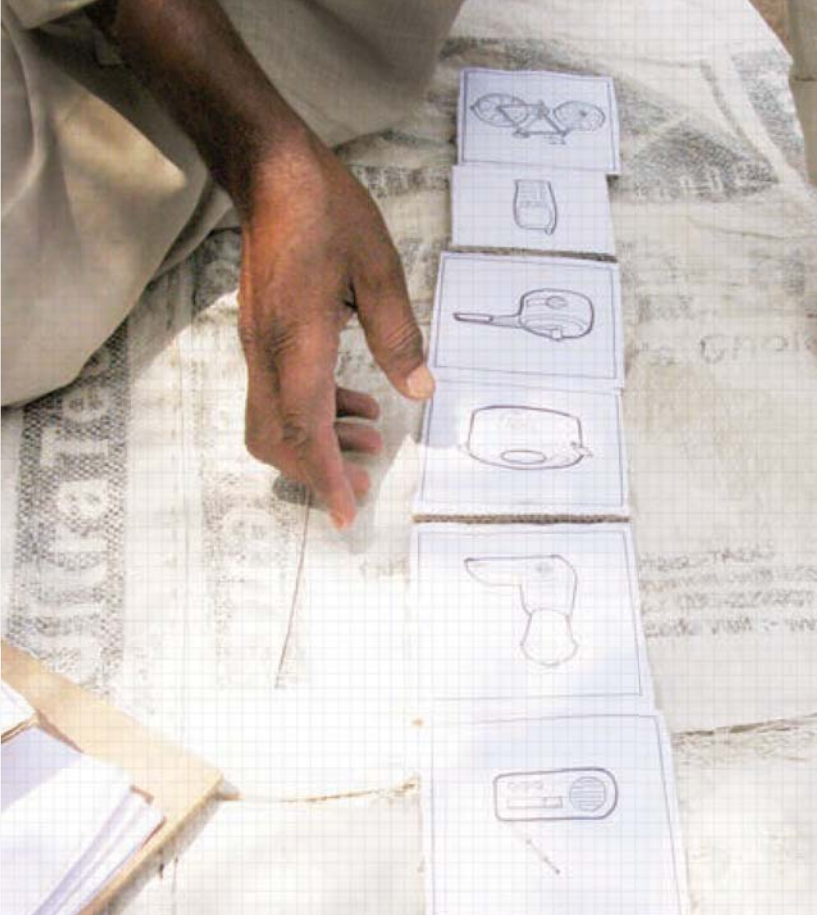
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	 STAGE 1 Identify Needs and Design	 STAGE 2 Begin R&D	 STAGE 3 Plan for Introduction <small>(Complete R&D)</small>	 STAGE 4 Introduce and Scale
DELIVERY FOCUS	Define problem and design requirements	Evaluate market feasibility and potential for scale	Develop and execute an operational launch plan	Monitor execution and optimize
MARKET AND USER UNDERSTANDING	<ul style="list-style-type: none"> Conduct situation assessment Develop value proposition Understand end-user needs through market research and/or human-centered design 	<ul style="list-style-type: none"> Update situation assessment Conduct bottleneck analysis Develop user segmentation Update and strengthen end-user needs through market research and/or human-centered design 	<ul style="list-style-type: none"> Update situation assessment Develop strategic launch plan with uptake targets Update bottleneck analysis Update end-user needs assessment Develop pricing strategy Develop demand generation strategies and create marketing material 	<ul style="list-style-type: none"> Evaluate strategic launch plan progress and achievement of uptake targets Evaluate progress against prioritized barriers and update bottleneck analysis Introduce into new markets and to new user segments Expand demand generation campaigns for new markets and user segments
MANUFACTURING AND DISTRIBUTION	<ul style="list-style-type: none"> Perform manufacturability assessment and landscape Conduct intellectual property evaluation 	<ul style="list-style-type: none"> Develop manufacturing strategy Develop distribution strategy Identify partnership opportunities Develop, test, and refine prototypes (if applicable) Conduct COGS analysis Conduct demand forecast Develop business plan (ROI) for partners 	<ul style="list-style-type: none"> Establish manufacturing strategy Establish distribution strategy Identify partnership opportunities Finalize product and packaging designs Update COGS analysis Update demand forecast Update business plan (ROI) for partners 	<ul style="list-style-type: none"> Evaluate manufacturing and distribution footprint and adjust as necessary Redesign and optimize product and/or packaging (if necessary)
POLICY AND ADVOCACY	<ul style="list-style-type: none"> Evaluate global policy considerations 	<ul style="list-style-type: none"> Develop communications, advocacy, and KOL engagement strategy Conduct cost-effectiveness analysis of TPP 	<ul style="list-style-type: none"> Support inclusion in treatment guidelines and on country-level EMLs Execute communications, advocacy, and KOL engagement strategy Update cost-effectiveness analysis 	<ul style="list-style-type: none"> Continue to support inclusion in treatment guidelines and on country-level EMLs for new markets Validate impact and cost-effectiveness analysis
CLINICAL AND REGULATORY	<ul style="list-style-type: none"> Define the TPP 	<ul style="list-style-type: none"> Develop and execute clinical plan with clearly defined endpoints Conduct regulatory landscape 	<ul style="list-style-type: none"> Complete clinical trials Obtain national regulatory authority approval(s) 	<ul style="list-style-type: none"> Continue with national regulatory authority approval(s) for new markets Conduct post-market surveillance

ACRONYMS:

- COGS: cost of goods sold
- KOL: key opinion leader
- ROI: return on investment
- EML: essential medicines list
- R&D: research and development
- TPP: target product profile

The Framework only includes the priority activities that—when done well and at the right time—can significantly influence and enhance “deliverability.” Only a few clinical and regulatory activities are listed that are most closely linked to a successful delivery. Similar comprehensive R&D frameworks should also be used to support the development of innovations (product development).



This Guide is intended to be continually updated with new thinking, case studies, and tools. We encourage suggestions and stories of putting the Framework to use.

The latest versions of the Guide and contact information can be found at www.usaid.gov/cii.

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