Market Dynamics

A NextBillion E-Book

Why it matters, and how it improves health

next billion

Acknowledgments

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Cover image courtesy US Army Africa via Flickr.

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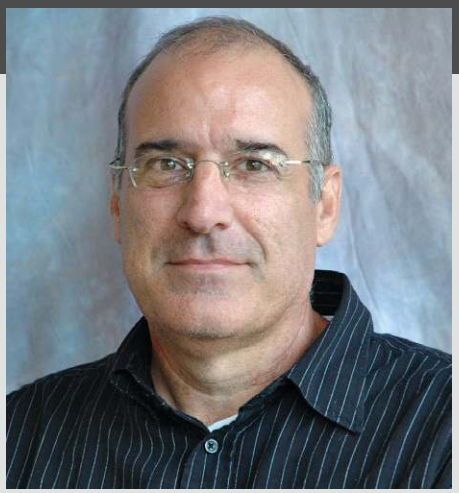
Market Dynamics, Your Time Has Come

NextBillion Health Care launches a new initiative; let the debate begin

May 12, 2014

By Kyle Poplin — WDI



NextBillion Health Care is a growing community of practitioners, business leaders, entrepreneurs, academics and students dedicated to providing health care to the base of the pyramid. The key term is "growing." We want to continue to evolve as we reflect the changing face of global health care that harnesses market intervention. That's why in spring 2014 we launched our Market Dynamics initiative.

It's not as if NextBillion hadn't covered this topic before. We've long recognized and written about the inefficiencies in markets that prevent the production and distribution of life-saving products. It's just that the term "market dynamics" began popping up more and more frequently in a health care context, as more people realized the importance of its role in a healthier planet.

The fact is, our planet is getting healthier. People around the world are living longer than ever, spurred in part by new technologies. But there is still a disheartening amount of room for improvement. Too many people in developing countries are still dying of preventable, curable diseases, and it too often boils down to the fact that medicine doesn't get into the hands of those who need it. The market — the same supply and demand interplay that has helped create order and prosperity in the developed world — all too often is failing to serve the developing world.

The reasons for this failure are complex and nuanced and have to do with such fundamentals as pricing, quality, research and development, and supply chains. Solutions are hard to find and the implications are non-trivial; about 4 billion low-income people on the planet are in vital need of health care solutions. That's why "market dynamics" has become a term du jour in global health and why NextBillion Health Care is dedicated to exploring its key principles.

Our initial discussions are consolidated in this e-book, which includes in-depth blogs by key players in the emerging field while covering a wide array of topics. But we realize we've only just scratched the surface. We plan to further focus our discussion going forward on NextBillion and future publications like this one.

Numerous conflicts are built into health care market dynamics, including public vs. private concerns and local vs. global production. We'll delve into these topics — or, more to the point, provide a forum for the world's foremost experts to delve into these topics. We'll include people who help fund global health interventions, those who negotiate prices for funders and those who create awareness and encourage debate about how markets can function better. We want to hear about their experiences with price points, profitability, subsidies and unintended consequences.

We also want to hear from newcomers in the field. We want to know about their experiences as they discover and confront inefficiencies. Do they see things differently through fresh eyes?

We hope our initiative and this e-book — and the ones sure to follow — serve as a resource and help launch even more discussion and discovery.

To access additional features such as links to research and extended author profiles, simply click on each article's headline to find the full version on NextBillion.

Kyle Poplin is the editor of NextBillion Health Care.

Rx for Global Health

New drug-diagnostic combos are emerging, but are our market structures ready to support them?

January 28, 2014

By Prashant Yadav — WDI

We are experiencing rapid advances in the development of new and innovative technologies that address health problems of the poor in developing countries. Scientists and developers are working hard to create new drugs and new diagnostics for disease conditions such as diarrhea, HIV/AIDS, TB, malaria and pneumonia that afflict mostly the poor. We are also seeing technologies across the boundaries of prevention, diagnostics and treatment.

One area where we see immense potential of technologies to interact and combine is diagnostics and treatment.

As we exhaust low-hanging fruits in drug development for infectious diseases, we may find that our new drug candidates can work well only for selected patient segments. Treatment guidelines for infectious diseases of the poor would then gradually transition from a single global treatment regimen to more patient-customized regimens. We would then need to use diagnostics to identify and segment patients into targeted populations for specific drugs. In the developed world we call this personalized medicine. While low and lower middle income countries are still far from benefiting from the potential benefits of personalized medicine, some examples that require special testing before and during treatment make me wonder if this may not be all that far away.

The lines are blurring

Malaria elimination looks more plausible now than ever before. But for its feasibility (especially for P. vivax) we will need to scale up the use of drugs such primaquine that can reduce the transmission of malaria parasites. However, certain people who have a specific enzyme defect known as glucose-6-phosphate dehydrogenase (G6PD) deficiency have the risk of developing severe adverse reactions from primaquine at higher doses. Scaling up the use of primaquine will thus require testing for G6PD deficiency. (According to estimates there are more than 400 million people with G6PD deficiency.) Current methods of G6PD testing require specialized reagents and equipment, and are expensive and time consuming. New rapid diagnostic tests for G6PD deficiency are now in the pipeline. But for these to be used effectively we would need to start thinking about a platform approach for G6PD deficiency testing and primaquine for P. vivax malaria elimination regions.

As malaria burden for plasmodium falciparum (the more dominant strain in Africa) decreases, many patients in sub-Saharan Africa who presumptively treat episodes of fever as malaria end up taking expensive antimalarials (ACTs), when they actually don't have malaria. Inexpensive rapid diagnostic tests (RDT) for malaria provide an easy way to diagnose malaria. However, the prices of malaria medicines/ACTs and rapid diagnostic tests are such that the incentive structures do not naturally lead to patients choosing adequate diagnosis. Creating ACT/RDT "price bundles" has been challenging because the market structures do not support such pricing or distribution schemes.

Continuous monitoring of individuals receiving antiretroviral therapy (ART) for HIV/AIDS is important to identify adherence problems and determine whether and which ART regimens should be switched in case of treatment failure. In the past, decisions to switch regimens in low income country settings were based on clinical and immunological monitoring. New guidelines from the World Health Organization recommend the use of viral load testing to assess treatment failure. However, most HIV programs in resource-limited settings still do not have access to viral load testing. Viral load testing is currently done on sophisticated instruments by highly-trained technicians.

A number of new point of care viral load monitoring devices are now in advanced stages of development. Viral load monitoring is also critical for treatment initiation for patients infected with hepatitis C. Given that treatments for hepatitis C are still quite expensive and there are side effects, viral load testing can help understand early virological responses and identify nonresponders for whom treatment can be discontinued or switched. As we start thinking about hepatitis C treatment access programs in resource-limited settings this becomes an important issue to consider.

Abacavir is a drug used in conjunction with other antiretroviral agents in the treatment of HIV/AIDS. Abacavir is generally well tolerated but can cause hypersensitivity in 5 percent to 8 percent of patients. Hypersensitivity to abacavir occurs only in individuals with a specific gene, HLA-B*5701 allele. The U.S. Department of Health and Human Services' Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents recommends screening for HLA-B*5701 before initiating treatment with abacavir. While the HLA-B*5701 allele is less predominant in African populations, HIV treatment

programs with abacvair in Eastern Europe require screening patients for the HLA-B*5701 allele.

Dx-Tx combinations

These examples demonstrate that our traditional ways of looking at diagnostics and drugs separately are starting to blur. In the developed world these combined diagnostics and treatment continuums are putting pressure on pharmaceutical and diagnostics companies to create new business models based on new partnership structures. We are seeing the emergence of some new business and partnership models to cope up with these Dx-Tx combos.

However, in most of the developing world, the structures for financing, procurement and delivery for diagnostics and drugs have not imbibed or fully internalized the need for adapting to this drug-diagnostic platform approach. This creates barriers for the effective use of such technologies in the developing world.

We need new business models for getting these boundary-spanning new technologies to the intended populations in low income countries. What new models and ideas have you seen that address this issue?

We also need a new understanding of market dynamics which does not look at each drug and diagnostics category separately but instead analyzes markets with broader definitional boundaries.

Prashant Yadav is a senior research fellow at the William Davidson Institute and director of the Health Care Research Initiative at WDI.

It's Time to WASH Up

Three lessons for developing effective water, sanitation and hygiene interventions

April 1, 2014

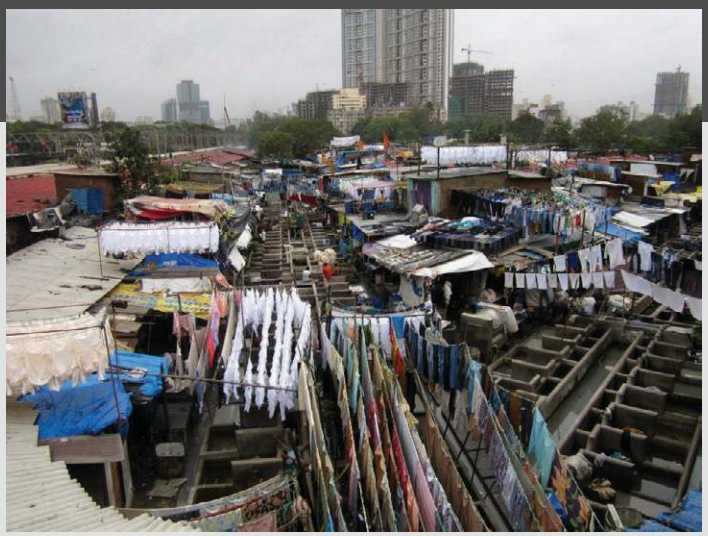
By Ben Brown

Access to sanitation is recognized as a fundamental human right, but the global community is still far from meeting its 2015 Millennium Development Goal target to halve the proportion of the population without sustainable access to safe drinking water and basic sanitation.

On March 22, we reflected on World Water Day with reminders of grim statistics. Diarrheal disease is the second biggest killer of children under 5 years old globally, and every day approximately 2,000 mothers lose a child to the disease, which is primarily caused by a lack of access to safe toilets and clean water.

Given the extreme need for improved WASH (Water, Sanitation & Hygiene) products and services in low- and middle-income countries, the R4D Market Dynamics team spent the past six months exploring potential opportunities to broaden access to improved WASH interventions in urban India. The team leveraged deep experience in the global health and nutrition sectors along with expertise applying market-shaping approaches to provide insight into assessing market needs and opportunities.

This was R4D's first engagement in the WASH sector and there isn't a more appropriate time to highlight some the organization's preliminary findings and takeaways from its



The Dhobi Ghat laundry district in Mumbai. Photos by Ben Brown

market dynamics work.

First, WASH solutions should ideally be locally tailored to meet the needs of the end user:

To develop, deliver and scale up a new solution in any geography, particularly large markets like India, where each state can feel like its own country, it is critical to first assess the needs and capabilities of the targeted community. This is especially true in the WASH sector, where the ways people go to the bathroom, wash their hands and procure water are deeply embedded in cultural norms and lifestyles, making

a one-size-fits-all solution unlikely to be effective on a large scale. Building a successful WASH intervention requires first asking key questions about consumer needs, identifying gaps in the landscape and evaluating consumer behavior and willingness to try new practices.

For example, PATH, a global nonprofit that develops lifesaving health technologies, has an array of household products in its WASH portfolio, including water filters, latrines, clean cook stoves, solar lanterns and hand-washing stations. For each of these interventions, PATH takes stock of the products and practices already in the market to identify needs, gaps and challenges that currently exist. What do current practices look like? Which products are available? How much do they cost? Who is using them and how are they working?

By asking these key questions and taking an inclusive market approach that brings together local experts in manufacturing, marketing, financing, nonprofits and government, PATH has designed improved low-cost water filters for low- and middle-income consumers in multiple countries. Most notably, PATH notes its improved ceramic water pot filters realized highly positive results after an 11-month field trial in Cambodia:

- Outsold the earlier designs 17 to 1 when offered with microfinance loans;
- Use had increased to 43 percent among microfinance members;
- Approximately 90 percent of the original users were still using their ceramic water pot filters;
- Commercial partners recovered all of their costs, allowing them to expand the model without more donor support.

Second, strong service delivery, beyond a technically-sound product or technology, is a key component to success:

It is commonly thought that once everyone has a toilet and a water filter, the water and sanitation problems of a community are solved. However, what happens if a toilet has a leak? What does a household do with all the waste that is collected in its septic tank? How can a person fix or replace a broken water filter? A single product or intervention cannot address all of these challenges at once.

Proper infrastructure along the value chain, ranging from complex underground pipe systems to the simplest of water containers, is required to effectively deliver WASH interventions and ensure sustainable impact. In order to determine where inefficiencies within the existing infrastructure occur, local manufacturing and sourcing capabilities, monitoring and evaluation competencies, and human capital capacity of a targeted community must all be evaluated and built into the design and introduction of any new innovation. In short, not only should engineers develop WASH products hand-in-hand with the users, but they should also collaborate with market-shapers for a holistic approach to delivering sustained impact. In doing so, more innovative service delivery models can be identified and effectively targeted to fill in those critical distribution gaps.

Sanergy is a notable WASH group that incorporates strong service delivery and user-centered design throughout its value chain. Sanergy has built a network of more than 170 high-quality "Fresh Life" branded toilets in the slums of Nairobi by franchising them to local micro-entrepreneurs. Employees collect waste from the toilets daily and deliver it to a central processing facility where the waste is converted into organic fertilizer for farmers. The model ensures marginalized communities have increased access to affordable, improved sanitation facilities while also providing a safe way to treat human waste and capitalize on its reuse value. The company now has more than 8,000 users daily and plans to scale to thousands of toilets serving more than 50,000 low-income customers every day.

An urban water spout in India.

Finally, WASH is inextricably linked to other development challenges:

The lack of access to safe sanitation and clean water holds back social and economic development through negative impacts on health, education and livelihoods. Most affected are women and girls, whose physical, economic and social growth are disproportionately hampered by walking long distances to carry heavy buckets of water, and missing school due to bathrooms that are often not gender-segregated. In addition, diarrhea and poor WASH services contributes significantly to malnutrition, stunting and the overall global burden of disease.

Access to WASH improves maternal, newborn and child health in a multitude of ways and has effects that can last for generations. The most effective WASH interventions must take this into account in design and implementation processes in order to serve the most vulnerable populations and address their critical needs and challenges.

World Water Day is a time for the global community to recognize the severe effects poor sanitation and unsafe water have on a large portion of the world's population (more than 40 percent of the world lacks access to adequate sanitation!) and the extent to which these challenges impact the lives of women and children. Yet these challenges are preventable and treatable – nearly nine out of 10 cases of diarrhea can be prevented, with sufficient WASH interventions.

Through interventions that place an emphasis on the end beneficiary and leverage local private-public expertise in design and delivery, there is potential to dramatically improve not only WASH outcomes, but to also impact the health and economic opportunity outcomes that are so closely linked to this critical sector. In doing so, we can use our resources effectively to tackle this crisis together and create lasting impact for those who need it most.

Ben Brown is a senior program associate at the Results for Development Institute.

Why, How Market Dynamics Matters

Interventions can improve health outcomes, but it's a time-consuming and complex process

May 13, 2014

By Brian Smith

Why are so many global public health experts talking about "market dynamics" these days?

Whether we call it "market shaping" or "market facilitation" or the "total market approach," there is a large and growing interest in the idea that we'll be more effective in improving health outcomes at the base of the pyramid if we frame challenges in terms of markets. Why?

First of all, the space where health care seekers meet health care providers – the health market – is big, even in developing countries. And it's big not only because the public sector – the major market player for the BoP – is big. The poor in most developing countries depend heavily on the private sector to help meet their needs, especially for curative services. In many countries where Population Services International (PSI) works, the private sector can also provide anywhere from one-third to more than half of all modern contraception.

By understanding the forces that affect supply and demand in those markets – by understanding market dynamics – we're better able to design, implement, monitor and evaluate interventions that improve health outcomes by improving the "health" of markets.

That's important because many of these markets are underperforming – at least from a public health perspective. Products and services don't reach many of those who need them most. Where they do reach them, quality can be very low and prices can be devastatingly high for families in precarious financial conditions. Even where there are effective health solutions theoretically within financial reach of the BoP, those solutions often don't get there because supply chains are too weak or regulations too restrictive.

Organizations like PSI (where I serve as chief strategy and resources officer) have been using market-based approaches for decades to improve health outcomes. The standard approach of many of these programs has been to introduce a subsidized product into the private sector (to increase affordable access), and brand and promote it like many non-health goods (to increase consumer demand). But while this "gap-filling" approach may be appropriate for markets in early stages of development – where not only knowledge and awareness are low but infrastructure and supply chains are also weak – today many markets have evolved to where they can respond to "lighter touch" interventions that lead to sustained performance gains which are less dependent on external subsidies.

Market interventions include lots of moving parts.
Flickr image credit: Jan Willem Schoonhoven

In a world where markets are evolving and developing at an ever fast pace, those who are serious about improving health outcomes in a transformative and sustainable way, must take a step back and consider where they can stop filling gaps. We must start asking what we can do for the current market to deliver products and services rather than ask what the market can do for us to deliver the same.

This can be challenging. For development partners to understand entire market systems and where they best add value to improve systems is a time-consuming and complex process. Even when systems are understood and decisions made on the best way to facilitate or catalyze a market (rather than be a gap filler) it will take time to produce large-scale, measurable impact on health outcomes. That means it is difficult to demonstrate the cost effectiveness of interventions. Meanwhile, people continue to get sick and die from preventable conditions.

But in the right conditions, a market development approach should lead to longer-term gains. It seems to many of us that market strengthening interventions based on an understanding of market dynamics in the health sector has the potential to reduce morbidity and mortality on a larger and more sustainable scale than traditional short-term projects. It

may also have significant knock-on effects for the livelihoods of those working along the supply chain all the way down to the health provider.

(PSI is implementing a five-country project, funded by UNITAID, to create a private sector market for malaria rapid diagnostic tests. Otieno Chemist, left, is one of the registered private sector outlets in Kenya. Photo courtesy of UNITAID)

Two examples from PSI's current work illustrate how we are trying to put a market dynamics approach to work.

UNITAID has funded PSI to create private sector markets for malaria rapid diagnostic tests (RDTs) in five malaria endemic countries. An RDT is a simple test that can be used in the field outside of laboratory conditions to quickly detect if a patient has malaria. For example, a lay drug seller in a corner store can correctly administer the test. This project aims to increase both access to and demand for quality-assured RDTs, while improving private providers' fever case management skills.

More than 40 percent of the population in endemic countries seeks care and treatment for fevers in the private sector. Appropriate use of RDTs is critical to ensure appropriate treatment. Currently, RDTs are either not available or, where available, are more expensive than the recommended frontline treatment for malaria — artemisinin combination therapy (ACT). This means consumers and providers presumptively treat fevers for malaria, wasting antimalarial drugs and contributing to resistance development — while not correctly treating the fever from which the patient is suffering.

To address this, we are taking a market dynamics approach. We are mapping Kenya's RDT market to identify key systems constraints acting as barriers to RDT uptake in the private sector. This in-depth analysis reveals key barriers, such as:

- The regulatory environment does not allow certain types of outlets, such as informal drug shops, to stock or sell RDTs;
- Providers have no incentive to stock RDTs when demand is low and supply chains to restock are weak;
- Consumers do not demand a test because they may lack knowledge of the benefits of RDTs or are unable to afford one;
- Providers choose not to adhere to negative RDT results due to lack of confidence in the test results, loss of profit from a foregone ACT sale and/or demand from customers to treat with an ACT anyway.

Working with market development experts from the Springfield Centre, we have analyzed the key functions in the market and worked out who best performs the functions and who best pays for the functions. Moving forward, we want to leverage the natural incentives of the existing market players to perform key functions better in terms of serving the poor. Not replacing the existing market players or distorting their incentives offers a well-reasoned approach to sustainability — system change rather than gap filling.

Under the Gates-funded ACTwatch, my second example of a PSI market dynamics program, we are monitoring how ACT markets are responding to market-based interventions. Strong market development programs require robust market data to make informed decisions. ACTwatch provides this data to the global malaria community by measuring which antimalarials are available, where they are available, at what price, and who uses them. This data helps monitor the results of the system change interventions within the market.

Indicators are measured over time and across countries through three study components: outlet surveys, supply chain studies and household surveys. Nationally representative outlet surveys examine the market share of different antimalarials passing through both public facilities and private retail outlets. Research provides a picture of the supply chain serving these outlets and measures mark-ups at each level of the supply chain. On the demand side, nationally representative household surveys capture treatment-seeking patterns and utilization of antimalarial drugs, as well as respondent knowledge of antimalarials in the seven countries.

If we develop our understanding of market dynamics, design interventions using those insights, monitor those interventions effectively and make informed adjustments to our approaches along the way, we'll go a long way to improving the performance of health markets, so that they sustain high performance even at the BoP.

Brian Smith is Population Services International's chief strategy and resources officer.

To access additional features such as links to research and extended author profiles, simply click on each article's headline to find the full version on NextBillion.

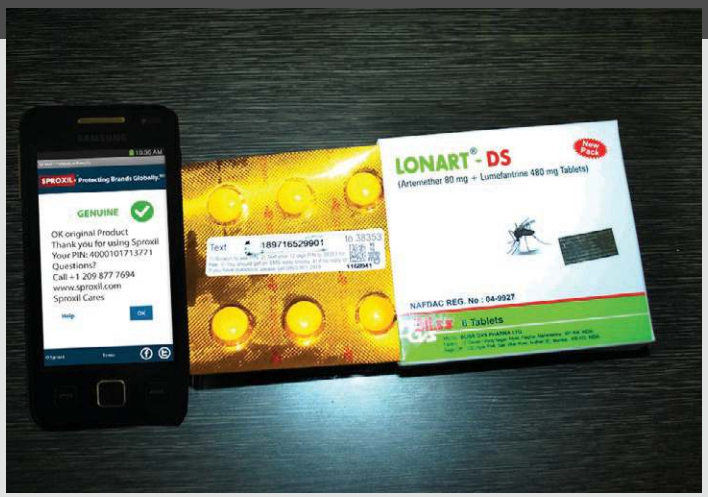
Anti-Counterfeit Technologies Can Save Your Supply Chain

New products help overcome delivery challenges in emerging market health systems

May 19, 2014

By Lila Cruikshank and Andrea Taylor

Sproxil, an anti-counterfeiting technology company, developed Mobile Product Authentication. Photo courtesy of Sproxil



Counterfeit drugs are a growing public health crisis: In 2010, the Center for Medicine in the Public Interest reported that worldwide sales of counterfeit medicines could top U.S. $75 billion, a 90 percent rise in five years. The WHO International Medical Products Anti-Counterfeiting Taskforce (IMPACT) estimates that in many developing countries more than 30 percent of medicines may be counterfeit.

The impact of fake and falsely labeled medicines is significant. In developing countries, where problems with medicines' safety are particularly acute due to limited resources for surveillance and enforcement, the medicines most often targeted are life-saving drugs such as anti-malarials and antibiotics. While deaths from counterfeit drugs are difficult to measure, one study by the International Policy Network estimates that fake tuberculosis and malaria drugs alone cause 700,000 deaths annually.

Rapid development of new technologies to prevent counterfeit medicines from entering the supply chain and from reaching the end user hold great promise to reduce counterfeit medicines. But these new technologies don't stop there – the infrastructure and capabilities created by anti-counterfeit technology can also be applied to other supply chain and medicine delivery challenges.

Around the world, inadequate health care supply chains result in stock-outs that prevent millions of people from accessing life-saving medicines. Like counterfeit drugs, chronic medicine shortages disproportionately affect developing countries, where infrastructure is limited and supply chain management severely under-resourced. A study conducted by the International Partnership for Innovative Healthcare Delivery (IPIHD) (which the authors represent) concludes that recent innovation in anti-counterfeiting technology presents a new set of solutions to address key challenges in medical supply chains.

Anti-counterfeiting technologies are designed to enable authentication of a product (whether by regulators or by end users) and to deter counterfeiting by increasing the likelihood of detection and, eventually, prosecution. Anti-counterfeiting is a broad category that includes two types of technologies: one technology enables product authentication and another enables product tracking and tracing (TnT) through the supply chain. Authentication technologies include methods such as watermarks or serial product identification that can be user verified. TnT systems use machine-readable technology such as radio frequency identification (RFID), electronic product codes (EPCs) and barcodes, combined with a system that enables verification of the product provenance and current location.

For example, Sproxil, an anti-counterfeiting technology company in IPIHD's Innovator Network, originally developed Mobile Product Authentication (MPA) in response to the single biggest problem with fake and falsely labeled medicines: consumers often cannot identify them. MPA addresses this problem by enabling end users to verify product authenticity using a security label. At the point of purchase, customers scratch the label to reveal a unique code on the product which they can validate via SMS, voice call or website. The system immediately provides information about whether the purchased product is authentic or suspicious and can provide instructions in the case of a suspicious product. Originally focused on authentication, Sproxil's MPA now includes an optional TnT feature that enables tracing via confirmation of product delivery at each point in the supply chain.

Though developed to meet a need for product authentication, anti-counterfeit technology has relevance for other significant supply chain and delivery challenges faced by emerging market health systems.

Reducing product theft and diversion

Diversion occurs when products are transferred from one market to another without authorization. For example, medication may be smuggled across borders or stolen from a

public health system for resale in private or informal markets. Theft and diversion of health commodities is a significant problem around the globe. A 2010 study in African markets found that more than 25 percent of artemisinin-based combination therapies purchased in private pharmacies had been diverted.

Anti-counterfeit technology innovations like MPA can help protect purchased and donated commodities against product theft and diversion by using the TnT features, which enable the confirmation of product delivery at each step in the supply chain, and also by capturing information at the point of sale. When consumers attempt to authenticate a product flagged as diverted, the system generates an immediate alert, facilitating the identification of resellers and the tracing of agents involved in diversion.

Improved inventory management

Failures of information in the supply chain cause both stock-outs, which decrease access to medication, and stockpiles, which create inventory waste due to expired medications. The product tracking functions of anti-counterfeit technology can provide actionable information about stock levels to improve supply chain management and reduce stock-outs. When products arrive at a warehouse or service delivery point, product verification via simple SMS, two-dimensional barcodes or other methods registers secure arrival. This verification can be done at the shipment or pallet level and can provide valuable data about stock levels throughout a health system.

Increasing patient engagement and adherence

In addition to addressing supply chain challenges, technologies such as Sproxil's MPA can facilitate engagement with patients after receipt of medication to encourage appropriate use of medicines. At the point of purchase or dispensing, when a patient authenticates the product, the system can automatically initiate a protocol for follow-up communications, without burdening health care workers to record phone numbers in a system. When authenticating a product, the system can also record any relevant voucher or referral numbers, facilitating integration with other program initiatives.

Ensuring treatment adherence is a particular concern in the context of rising drug resistance and extended drug regimens, such as with tuberculosis treatment and anti-retroviral therapy. To address these challenges, health outreach programs are incorporating text messaging in various ways, and studies have documented their impact on improving adherence, which directly affects health outcomes. Short-duration treatments such as anti-malarial regimens may also benefit from text message follow-up.

Emerging market challenges slowing widespread adoption

While anti-counterfeit technologies can help solve key supply chain and service delivery challenges, there are several barriers to their broad adoption in developing markets: cost, ownership and global standards.

Although anti-counterfeit technology product offerings range in price and complexity, a system-wide implementation (across a large portfolio of products) may not be feasible for developing country health systems. However, there could be significant value to targeted implementation of anti-counterfeiting systems for high-value and/or high-priority products.

The second challenge is the tension between multiple stakeholders in global health supply chain management. Competing objectives may contribute to political resistance to a proposal to create systems that favor specific products (such as HIV drugs) versus investing in system-wide improvements.

Finally, multiple standards and regulations for anti-counterfeit technology globally create uncertainty across markets. Countries around the world and states/provinces within countries are adopting different policies, which makes coordination and implementation of anti-counterfeit technology difficult in a context of multinational supply chains.

Leveraging the full promise of innovative technology

Despite these challenges to adoption, anti-counterfeit technologies hold promise not only to protect against fake medicines, but also to significantly improve other supply chain issues. While costs vary, anti-counterfeit technologies can be implemented at a cost of cents per unit and generate significant net savings to public health systems. It represents an opportunity for health care providers, companies, and governments to work together for a mutual win.

The size of the counterfeit drug problem calls for a solution that can scale to meet the needs of the sector. Technology-enabled solutions, such as those provided by Sproxil, hold promise of scale and efficiency with the potential to create step-change improvements for drug supply chains in emerging markets.

Stay tuned for more learnings from the forthcoming paper "Innovations for the Global Health Supply Chain: Additional benefits of Anti-Counterfeiting Technology," to be released by IPIHD later this month, and read more about Sproxil's innovative model.

Lila Cruikshank has a background in business and global health and currently works as a consultant with Global Impact Advisors, and Andrea Taylor is the research project manager for the International Partnership for Innovative Healthcare Delivery.

How a Blended Model Can Solve Some Market Failures

Foundation-owned social enterprise combines features of philanthropy, business

By Mike Miesen

Rob Dickinson, Gradian's expert biomedical engineer consultant, trains technicians on the UAM in Ethiopia. Photos courtesy of Gradian Health Systems

Part 1 — Published May 28, 2014

My organization, Gradian Health Systems, uses an atypical business model to get our product into the hands of those who could benefit from it.

We produce a unique medical device, the Universal Anaesthesia Machine (UAM), which is designed to provide anesthesia in any environment — including infrastructure-poor hospitals that lack consistent access to electricity or compressed oxygen (necessary to run typical anesthesia machines).

The model we use to manufacture, sell, distribute and support the UAM, foundation-owned social enterprise — more technically, a limited liability corporation wholly owned by a 501(c)3 private foundation — is a novel means to combine the best features of philanthropy with the best features of business. It allows us to serve as a commercial entity using market mechanisms to sell a product, and as a nonprofit using philanthropic dollars to address significant market failures.

To understand why we use this model, you really need to understand the challenges that low-income country markets create for medical equipment manufacturers and why conventional models haven't worked.

In high-income countries, medical device manufacturers have developed an effective and lucrative business model predicated on accessing multiple revenue streams. As you'd expect, the initial sale is one such stream, but lesser-known complements are the sale of a high-margin, long-term service contract and the recurring purchases of (often proprietary) spare parts and consumables.

And the model works. In these markets, strong infrastructure and a robust supply chain ensure comparatively low prices for proprietary spare parts and consumables — all of which hospitals can afford. Just as critically, facilities and regions have a deep supply of highly trained biomedical engineers to fix the often quite intricate and sophisticated devices.

In low-income countries, though, a dearth of hard and soft infrastructure strains this model to its breaking point. To take just one concern, it can be very difficult to find biomedical engineers trained to maintain and repair intricate and sophisticated devices; there are nine in Malawi, for example. Bringing in outside expertise is a time-consuming and expensive process, leading to long inoperability periods and high costs for already cash-strapped hospitals.

And all of this assumes that the product is right for the environment, which, as I've discussed before, simply isn't the case for low-resource environments. Even if a hospital can pay for spare parts, consumables and repair, a machine that requires compressed oxygen still won't consistently function in a hospital that often runs out of it.

Organizations not seeking to profit when trying to fill this gap have thus far generally failed to do so in a cost-effective and sustainable way. The most common model we've seen to address this low capacity to pay is to donate used, second-hand equipment (which I've written about previously for The Atlantic).

This donation model is problematic for two reasons. First, like the new, for-sale equipment described above, most used, donated equipment simply isn't designed to function in infrastructure-poor environments. And second, sometimes donated equipment is positively ancient and simply should not have been donated in the first place; an old, out-of-production machine likely won't have spare parts or consumables in production, making them more difficult to source.

The end result of these models is a staggering percentage of inoperable medical equipment in low-resource environments. Estimates vary, but 40 percent to 80 percent of medical equipment in sub-Saharan Africa is considered non-functional.

This makes us believe that there is a significant market failure in the manufacture and sale of medical devices in low-resource countries; improper devices are being sold or donated

and are largely failing to serve the communities in which they're placed.

We think it's time for a new solution.

Foundation-owned social enterprise remixes conventional for-profit and nonprofit models to create something new. Combinatorial creativity at its finest, the model draws on the best of both business and philanthropy to sustainably address old problems.

Part 2 — Published May 29, 2014

A bit of background is necessary to help illustrate how we use this foundation-owned social enterprise model. In the 1990s, a British anesthesiologist working in Malawi, Dr. Paul Fenton, created the Universal Anaesthesia Machine (UAM) in what was a textbook case of necessity birthing invention: When the electricity cut out or the supply chain failed to provide oxygen canisters on time, the conventional anesthesia machines he used to provide anesthesia wouldn't work. Without the ability to provide general anesthesia, some surgeries couldn't be performed and patient care suffered.

The machines Fenton had on hand weren't designed to function in such an environment. So he built his own anesthesia machine that would function without electricity or compressed oxygen, and the forerunner to the UAM was born.

Later, Fenton partnered with a foundation to refine his design. Market research and clinical feedback confirmed what he and his colleagues intuited: There was and still is an enormous need for a device like the UAM in many low-income countries and resource-constrained hospitals around the world.

With a compelling product on its hands, the foundation had to decide how to get it to hospitals around the world. For a variety of legal and technical reasons (an entire future blog in itself), the foundation chose to begin by spinning off the idea into a separate legal entity, and Gradian Health Systems was created, with the foundation as its sole owner and investor.

Like any organization, we have a limited budget and we use it to maximize the return on investment. But the foundation judges its success based not on how much profit can be generated but on the "extra-financial value" created — known in philanthropic circles as the "social return on investment" (SROI). The more people that have access to safe surgery and anesthesia through the use of the UAM, the higher the SROI.

A biomedical equipment technician in training.

Early on, we decided that donating UAMs was an inefficient way to produce this SROI; our impact was constrained by the number of machines we could donate based on a yearly budget. Demand exceeded supply.

So we chose to use a model that allows us to scale according to demand: selling machines at their marginal manufacturing and shipping cost. This frees up our philanthropic funding to build out a potential market for the machine and address the post-sale market failures described above.

Like a traditional business, we're investing in the creation of the market by spending money up front — on marketing, research and development, international quality certification and the like — to drive future sales of the machine. Unlike a traditional business, we don't expect to recoup that cost; it's paid for with philanthropic funding so that we can offer the machine at as low a cost as possible — an important factor in hospitals' buying decisions.

Crucially, the foundation's investment allows us to address the market's failure to address the post-sale needs of the customer: robust machine training for clinicians and biomedical technicians; easily accessible, open-source spare parts that can often be procured locally; timely maintenance and repair backed by warranty. Using philanthropic dollars ensures that these critically important components will be high quality and ubiquitous, even if they aren't profitable.

To be sure, these components are expensive, but they are vital to ensuring the provision of safe surgery and anesthesia and, to our customers, produce the highest and longest-lasting SROI.

The idea of a foundation owning a commercial entity seems to be a novel subset of venture philanthropy that offers any number of exit options: the social enterprise could spin off as a for-profit, a nonprofit, or could stay a long-term investee of the foundation. Ultimately, this decision simply depends on the aims of each organization and the needs of the customer.

Whatever the decision, it's critical that the foundation and social enterprise commit to one another; it would challenge the sustainability of philanthropic investment to, say, have the foundation simply stop funding at the wrong time.

And this model isn't right for every situation. Foundations should not waste fixed philanthropic dollars on markets that aren't failing, and some philanthropic solutions simply can't rely on a market to offer goods and services. But it can be an effective solution when, as in our case, a market exists but is largely failing to serve the customer.

Foundation-owned social enterprise is a novel philanthropic model that has the potential to help solve market failures in a variety of contexts. It's so novel, actually, that we don't know of many other instances of its use; if you know of an organization doing something similar, let us know.

Mike Miesen is a business strategy analyst at Gradian Health Systems, a nonprofit social enterprise that equips low-resource hospitals to deliver anesthesia in any environment.

In Market Dynamics, Creativity Matters

Global organizations using a variety of interventions to leverage their work

June 3, 2014

By Kanika Bahl

Private sector markets are known for their efficiency in reaching the far corners of the globe. If you're looking for soap, soda or shampoo, there aren't many places where you'll have trouble finding any of these products – including countries with limited infrastructure and challenging regulatory environments. To achieve this omnipresence, private sector companies such as Unilever and Coca-Cola rely on a value chain of importers, wholesalers, distributors and retailers that ensure successful market entry and that supply meets demand.

Yet in the international development context, vital products that are proven to have dramatic impacts on nutrition, health and sanitation are often not accessible to those who need them most. For example, every year more than 1 million children under age 5 die of pneumonia, an illness that can be simply and effectively treated with antibiotics for as little as 21 cents per treatment course. These deaths could be easily averted, but a complex and sometimes poorly functioning marketplace – involving manufacturers, regulators, country purchasers and donors – currently prevents this.

This is just one of many challenges that our market dynamics team at Results for Development is actively working to solve.

Our team focuses on ensuring widespread access to products like antibiotics for children by improving product markets in health, nutrition and sanitation. We work across the global value chain to align the needs of manufacturers, countries, financiers and regulators. Our goal is to ensure that the most marginalized populations have reliable, high-quality, affordable access to products such as HIV/AIDS treatment, neglected diseases drugs and sanitation technologies.

Consider the potential impact of this approach for funders of health programs, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, which spends $2 out of every $5 of its multibillion-dollar portfolio (U.S. $3.9 billion in 2013) on products such as medicines and diagnostics. These strategies ensure the organization can spend its dollars effectively on purchasing and delivery, achieving significant savings that can contribute to protecting and treating millions more people.

One application of market dynamics is to ensure a cost-effective and efficient marketplace which dramatically increases product access. For example, in 2012 a 40 percent global funding gap meant that millions of families and children would not receive life-saving anti-malaria bed nets. Our team

R4D identified two key issues which were undermining efficiency in the bed net marketplace. Photos by Maggie Hallahan/Sumitomo Chemical

at R4D engaged actively in the bed net market, working across more than 100 different actors to understand opportunities for efficiencies.

R4D identified two key issues which were undermining efficiency in the marketplace. First, there were more than 200 colors, shapes and sizes of bed nets. This fragmentation was driving much higher costs and prices, despite the fact that this diversity had little impact on net usage. Second, there was effectively a race to the bottom because suppliers were only rewarded on the basis of price rather than price and performance – undermining bed net quality. We developed and are now implementing global strategies which address these issues and achieve more than $600 million in savings, which in turn can purchase bed nets to protect more than 300 million additional people.

Market dynamics can also be utilized to accelerate market entry of vital products. For example, when a new treatment technology is developed, getting it into the market at scale can often take decades. This is in part because activities to address challenges in global and in-country regulation, supply capacity, financing and demand generation often occur in disjointed or sequential fashion.

In 2007, the Clinton Health Access Initiative (CHAI) recognized this challenge with pediatric AIDS drugs. Low demand and insufficient financing drove low supply and high

costs of $600 per child per year, fueling a vicious cycle which made these drugs virtually inaccessible to the hundreds of thousands of children in need. With UNITAID support, CHAI engaged simultaneously across the marketplace to rapidly advance adoption of a breakthrough drug treatment. CHAI worked with suppliers on new child-friendly formulations, facilitated international and in-country guideline changes to drive demand, and jumpstarted donor financing, dropping pediatric drug prices from $600 to $60 per patient per year in the process. As a result of this work, in just two years the global community went from a situation where only a handful of children were receiving treatment to one where more than 100,000 children were reached.

Market dynamics can dramatically increase product access.

There are many other examples of the power of market dynamics, from traditional mechanisms like pooled procurement and volume guarantees to new, innovative methods of financing and targeting product improvements. All of these strategies have the potential to be applied not only to health, but also nutrition, water and sanitation, and education.

The success of creative interventions like these has created a global push to institutionalize market dynamics as an approach. This progress can be seen in the strategic plans of important global actors like UNICEF Supply Division, the Global Fund and UNITAID, which are all investing in market dynamics as a way of improving the impactful work they already do. As market dynamics becomes more established, its value as an approach will only be limited by the applications we can find to extend its impact.

Kanika Bahl is a principal and managing director at the Results for Development Institute, where she established and leads the market dynamics practice.

Can Investing in the Rich Serve the Poor?

Questions about quality complicate cross-subsidization

June 9, 2014

By Beth Bafford

In the past decade, we have seen an increased ability for developing countries to support private enterprises, due to advances in infrastructure, talent development, technology, a growing middle class and access to various forms of capital. In the past few years, we have seen this growth affect the private health care market, causing investors to increasingly look at health care in developing countries as an investable sector instead of one dependent on government or philanthropic subsidy. And why wouldn't they? Private health care in most developed countries is a trillion-dollar industry, with the sector making up approximately 20 percent of the U.S. economy. There is plenty of precedence for thriving private health care marketplaces.

With this increased interest, and an assumption that there needs to be private sources of health care in developing markets to adequately serve the growing populations, there is an acute need to find the business models that work to ensure the market dynamics are favorable for investment. One way to do so is to understand which market tools should be translated and adapted from developed countries and which should be left behind.

One of the market mechanisms used often in the developed market context is cross-subsidy. So the question I'll explore today is: Does the global health delivery market need cross-

subsidization to survive? And if yes, are investments in goods or services targeted to the middle- or high-income brackets also investments that benefit the bottom of the pyramid?

Cross-subsidy typically comes into play when morality enters the marketplace, in industries or sectors like health care, education and housing. In these sectors, there is a moral obligation of the government and the people to provide goods or services to all, regardless of their ability to pay, and there is a public good created when a greater portion of the population has access to these services. This effect — however noble and just — skews the equation and creates a market flooded with demand without the necessary incentives for adequate supply.

To counter this effect, governments and policymakers tend to set up Robin Hood-esque business models and industry structures to take from the higher income populations to subsidize the services for the poor. The question then becomes one of quality, and whether this cross-subsidization creates one, better system for all or bifurcated systems serving different populations.

In education and housing, at least in developed countries like the U.S., it has skewed toward the latter. In education, the cross-subsidy comes from parents who send their children to private schools, but continue to pay property taxes to fund the local public school system. This model does not promote one, improved system, but creates two types of schools — arguably of much different quality — one that serves families who have the ability to pay and one for those who do not.

Similarly in housing, the government assesses a fee on every home purchase and taxes homeowners to help fund affordable or public housing in the community. Historically, this has also fueled separate systems with differing quality, although there are some interesting trends toward mixed-income housing that attempts to break down the barriers between the two systems.

In health care, cross-subsidy is baked into the current system, with commercially insured patients paying significantly more for goods and services than those on Medicaid or the uninsured, but in most areas this cross-subsidy incentivizes providers of care (medical professionals and hospitals) to increase the quality of care for all populations served. More than education and housing, this attempts to build one system to serve everyone.

This is, of course, nowhere near perfect, and there are plenty of providers who refuse to see the uninsured or those with Medicaid (hopefully this will change as more of the population becomes insured under the U.S. Affordable Care Act), but every person has the right to walk into any hospital's emergency department for care.

When investors and intermediaries start to think about building more robust, private health delivery systems in developing countries, it is natural to look at existing systems for lessons from past successes and failures. In general, because most of my work experience has been focused on the dysfunctional U.S. health care system, my immediate reaction is to replicate nothing and build a new system from scratch. But it is hard to ignore the effect of income disparity on the health system in developing markets and even harder to imagine a system that does not leverage the cross-subsidy model to ensure that the poor have access to quality care.

If you believe that for the private health care system to thrive, you have to target middle or higher income populations to improve access and quality for poor, then perhaps impact investors and other "field builders" should be thinking more broadly about which investments have the greatest impact on the populations we all want to serve.

As the Calvert Foundation looks to understand the global health marketplace to see if there is a need and role for our capital to build systems, these are the types of questions swirling in our heads. I recognize that there are scores of people out there who have been grappling with these questions for much longer, and with more depth, than I have and I would love to hear about any new or established solutions that address these questions.

Beth Bafford is a senior officer of strategic initiatives at the Calvert Foundation.

The Long Road to Scale

Deciphering the mHealth value chain for family planning

July 10, 2014

By Charu Chadha

By now, we all know that the rise of mobile phones will help plug the infrastructure gap in developing countries. Many initiatives have demonstrated the potential for mobile phones to tackle some of the most pressing developmental challenges. For example, look at the phenomenal successes such as M-PESA in Kenya.

However, only a handful of solutions have reached such scale and market dominance. According to a recent USAID Global Development Lab Digital Development report, very few Kenyans use Mobile for Development (M4D) "value added" services beyond M-Pesa. The report's authors propose that the major roadblock to adoption has been consumer awareness and technical limitations. I couldn't agree more. My colleagues and I at Georgetown University's Institute for Reproductive Health (IRH) face the challenges of raising consumer awareness every day.

Building the product

Our product, CycleTel, is an mHealth service; we help women use the Standard Days Method (SDM) of family planning directly on their phone by alerting them via SMS of their fertile days. SDM is an easy-to-use, scientifically proven, natural family planning method based on identifying the fertile days of a woman's menstrual cycle.

When we began developing CycleTel at Georgetown University in 2010, our main objective was to see whether we could help women access a family planning method by leveraging technology. We started with product development – we had to understand the nuances of delivering personal information on a mobile phone, which in some cases may be shared with others. We also explored different aspects of customer experience including:

- frequency of messages
- time of delivery (morning, evening, specific hours, etc.)
- language (English, Hindi, local languages)
- clarity of messages being delivered
- how customers were using this information
- who they were sharing it with
- how much they were willing to pay

Georgetown University began developing CycleTel, an mHealth service, in 2010. Photo courtesy of PSI, India

After extensive user experience studies, we developed our product and tailor-made it to suit the needs and demands of women in India. CycleTel now has the opportunity to become a direct-to-consumer family planning product that could be scaled as a market-based solution outside the public health delivery system.

Building the business

In 2012, we started actively exploring the business case for CycleTel, developing financial analysis for sustainability. In late 2013, we moved CycleTel outside of controlled research environments to conduct a market validation study. The objective was simple – to test business model assumptions, especially those related to the direct-to-consumer, subscription-based model.

With an initial enrollment of more than 450 customers, we hit a hiccup when we saw that only 21 percent of customers were using the service after two months. However, since 79 percent of continued-usage customers agreed to pay a monthly fee of 30 rupees (about 50 cents) for the service, we knew there may be a market segment for us to continue to explore.

Today, we are trying to enter the market and reach new customers who have never heard of CycleTel, including some who never heard of family planning. The biggest challenge we face is answering the question, "How will customers discover and value that such a simple family planning tool is available literally at their fingertips?"

This goes far beyond simple marketing and promotion. This relies on a complex ecosystem.

We looked for analogous product adoption examples in traditional business, which relies critically on a developed supply chain of sales, marketing and distribution. With mobile-enabled products, we don't need the brick and mortar stores, but we still need the principles that have, over the years, nudged walk-in customers to try a new product. We still need training, support and attractive incentives for sales forces directly interacting with customers. We need a pitch to convert a latent need into a desire, belief, value and, ultimately, a purchase. After all, this is a massive behavior change.

Building the ecosystem

The traditional business' value chain, in addition to ensuring product availability, is critical in customer engagement. Typically, the financial incentives across the chain — distributors, stockists and retailers — would be structured to create a "pull" effect. This "pull" is further enhanced with marketing efforts targeted toward raising customer interest. If the product is difficult to sell (i.e., it is a "push" product), then significant investment may be needed not only to introduce the product, but also to create a whole new market category.

The family planning field has been trying to stimulate a market for years, often with subsidies for early research, demand generation and commodity purchasing. Cultivating the market is common for many of us working with new lifesaving and enhancing products — and you know it isn't easy.

A mobile service, particularly a stand-alone push product like CycleTel, does not naturally have the ecosystem of players with strong incentives to drive demand and get CycleTel into the hands of customers. Established mHealth value chains are rare at best; this is untapped territory. But we're learning quickly that creating an integrated consumer experience for mobile products doesn't just stop at making a method available via phones; we need a value chain of salespeople and marketers to facilitate adoption.

CycleTel helps women use the Standard Days Method of family planning directly on their phone. Photo courtesy of the Institute for Reproductive Health, Georgetown University

Our next step is to leverage an ecosystem approach to identify partners that will help us build the value chain we need to better reach and serve our users — and hopefully, create a pathway for mHealth innovations along the way.

* CycleTel and the Standard Days Method (SDM) are both trademarks of Georgetown University's Institute for Reproductive Health.

Charu Chadha works for the Institute for Reproductive Health at Georgetown University and is currently managing and expanding India operations for CycleTel.

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How to Be an International Dealmaker

Market nudges are building global vaccine markets

July 22, 2014

By Angela Rastegar Campbell and Ya'ir Aizenman

Vaccines are among the most effective and high return-on-investment health interventions in global development. However, while the work of innovative health actors such as the GAVI Alliance and its donors has massively expanded access to basic lifesaving vaccines over the past decade, many potential vaccines are never developed, distributed or tailored to work effectively in the Global South, causing millions of children and adults to suffer from ailments that could have been prevented.

For-profit pharmaceutical companies in both developed and developing countries should be the best placed actors to remedy this situation, given their extensive experience with vaccine research and development (R&D) and production. But pharmaceutical companies often do not enter these markets because developing and expanding vaccine production lines is both extremely expensive (with costs in the hundreds of millions of dollars over several years, including high up-front costs) and risky (given potential adverse outcomes such as failed R&D, lack of funds in the Global South for purchases, or competitor entry). Companies selling other products in developing markets often employ a basic low-cost, high-volume business model, but this method is less feasible in the case of vaccines because success is usually dependent on reaching scale in the tens of millions of doses.

What can be done to build global vaccine markets?

Measures to reduce the costs and risk of developing global vaccines can take a number of forms; all of these methods allow third-party donors such as developed country governments, foundations, nonprofits or consolidated groups of private donors to lubricate global vaccine markets and accelerate vaccine production for the Global South.

The most basic of these methods is for donors to directly subsidize the purchase of vaccines by health nonprofits or governments in the Global South. Subsidies can be complex, however, as it is still unclear how to most effectively balance paying pharmaceutical companies prices that are high enough to motivate further development, while also prioritizing reasonable costs and good value-for-money for the purchasers of these vaccines.

Measures that reduce risk for pharmaceutical companies offer a more promising solution; they often achieve the same results as subsidy models, at a much lower cost for global donors. One common example of risk reduction is for donors to provide some form of insurance to a pharmaceutical company – in case its R&D efforts do not pan out – in exchange for better pricing when the product is released. Effectively, this method allows donor programs to use their large size and balance sheets to act as insurance agents for pharmaceutical firms, especially smaller companies. To help pharmaceuticals manage upfront capital investments, global donors can increase the transparency of market sizes by providing pharmaceutical companies with improved market intelligence (such as GAVI's Strategic Demand Forecasts) or can help reduce unpredictability in funding flows (with programs such as the Pledge Guarantee for Health).

Donors can also leverage volume guarantees to lower vaccine prices and jump-start markets. Volume guarantees commit nonprofits or donors to purchase a predetermined, minimum number of vaccine units from a particular pharmaceutical company, guaranteeing that supplier a certain market size.

The GAVI Alliance has used volume guarantees to achieve a record low price for human papillomavirus (HPV) vaccines with Merck and GlaxoSmithKline, lowering it from the U.S. price of about $130 per dose to under $5 per dose in developing countries. The Jadelle Access Program has reduced the price for a best-in-class contraceptive implant from $16.50

Pneumococcal vaccination in Kenya. Photo by Evelyn Hockstein, courtesy of GAVI Alliance.

to $8.50 by providing a purchase guarantee of 27 million doses over five years. Additionally, GAVI's Advanced Market Commitment (AMC) for Pneumococcal Vaccines provided a guarantee to would-be manufacturers of pneumococcal vaccines that if they developed and produced the product, the demand would be there. In the end, the AMC secured a price per vaccine of $3.50 instead of the earlier price of more than $100 per dose.

How can donors deploy these innovative methods of market creation?

Dalberg's evaluation of the Pneumococcal AMC revealed several specific lessons on how to negotiate and partner with international vaccine manufacturers to reduce their risks while setting affordable prices for vaccines in the developing world. Providing commitments such as insurance or volume guarantees to pharmaceutical companies can be difficult for donors, however. Such commitments require donors to put substantial funds on their balance sheet years before they are actually spent, which can be challenging for governments or organizations with budgets allocated on an annual basis. Moreover, guarantees need to be well-tailored in timeline, scope, price and structure. Yet, when done right, insurance, volume guarantees and market interventions are extraordinarily powerful mechanisms to drive markets for vaccines.

Often, the dialogue on how to increase innovation and reduce costs of expensive pharmaceuticals for low-income countries focuses on how much donors should directly subsidize product development. In the past, donors focused on the price and negotiation process rather than considering a broader suite of risk mitigation strategies that can encourage pharmaceutical company interest. A new approach – reducing risk for manufacturers by using donors' balance sheets and the promise of future purchases – may more effectively entice pharmaceutical companies to enter and compete in the market.

Recent risk reduction measures such as the GAVI Alliance's deal for HPV vaccines, the Jadelle Access Program and the GAVI Alliance's Advanced Market Commitment (AMC) for Pneumococcal Vaccines show the promise of such approaches to reduce prices and increase access while engaging manufacturers and stimulating innovation in the vaccine market.

Angela Rastegar Campbell is the founder of Agora Fund and Ya'ir Aizenman is a project leader at Dalberg Global Development Advisors, where he focuses on improving the design and delivery and global health interventions.

Sustainable Access to Safe Drinking Water and Sanitation

Lessons learned from market-based approaches in India

August 7, 2014

By Urvashi Prasad

Globally, an estimated 780 million people live without clean drinking water and a staggering 2.5 billion lack access to sanitation. Annually, more than 800,000 children below age five, mostly in the developing world, lose their lives because of diarrhea. Improving access to these basic human necessities is an integral part of the United Nations' Millennium Development Goals.

While considerable progress has been made over the past few decades, nearly 100 million people in India alone lack access to safe drinking water and more than 700 million continue to defecate in the open. While the government has sponsored several programs to address this issue, gaps in provision of services as well as their maintenance and usage persist.

Given the enormity of the challenge, there is clearly an opportunity for private players and a number of market-based organizations have entered the space over the past few years.

In the context of clean water and sanitation, market dynamics is about facilitating access to basic services for those who need it the most in a scalable and sustainable manner.

Having collaborated with a number of these players and keenly observed the progress made by others, here are some of the lessons I have learned:

1. Customer centricity is key

Water and sanitation are among the most fundamental of requirements for human beings; however, the reasons for

demanding these services vary considerably. While for some people the driver is better health, for the majority, convenience, dignity, privacy, social prestige and safety of women and children are far bigger motivations. Also, while some families are willing and able to pay for these facilities, others need support, in the form of government subsidies, for instance.

It is therefore crucial that organizations have a detailed understanding of their customer base and segment it according to motivations, preferences and financial capacity. This will help with developing tailored marketing strategies and ultimately generating sufficient demand for sustaining the business. Sarvajal, a social enterprise that sets up community water purification plants in villages and slums across India, segments its user base to distinguish regular customers from those who purchase drinking water occasionally (e.g. when they have guests at home) or seasonally (e.g. during the summer and monsoon).

2. Balance quality, acceptability and affordability

Free toilets constructed under government programs often fall into disrepair, partly due to lack of ownership but also on account of poor quality. The latter is especially important in areas which are prone to hostile weather conditions like floods. Also, a number of government schemes have inflexible toilet designs which cannot necessarily cater to the varying requirements of families. It is therefore important that private enterprises in the space offer a range of options to customers, taking into account their differing preferences as well as affordability levels. While some families are content with a basic toilet design, others want a more elaborate structure (e.g. bathing area with a partition) and are willing to pay for it.

Saraplast Pvt Ltd., which is a commercial company that installs and maintains portable toilets in slum areas across India on a fee-based model, modified the design of its toilet cabins to ensure that they are more culturally acceptable (e.g. squatting units). Similarly, operators of community water purification plants like Waterlife, Sarvajal and Saathi have a menu of options for delivery of purified drinking water that customers can choose from (e.g. while some users prefer to collect water from the plant, others opt for home delivery of ice-cold water for a surcharge).

Sarvajal, which has designed automated teller machines (ATMs) for dispensing purified water at a nominal charge through prepaid cards in space-constrained slum environments, adapted the design of the machines to ensure that they are more resistant to vandalism and theft.

Saathi provides a menu of options for delivery of purified drinking water that customers can choose from. Photos courtesy of Saathi Distribution Pvt. Ltd.

3. Build partnerships with government and non-governmental organizations (NGOs)

While there are problems with the government system (e.g. delays, inefficiencies), it is unrealistic for organizations to harbor ambitions of scaling up without securing government buy-in. Not only do they require permissions to operate (e.g. in slums) but they are often dependent on the government for resources (e.g. land, water connection, electricity) as well, especially during the early stages of establishing their businesses. In fact, governments themselves are recognizing that they cannot address these challenges singlehandedly and are increasingly entering into public-private partnerships (e.g. maintenance of public toilets by private operators for a fee).

NGOs are another important stakeholder and can provide vital support for understanding the needs of local communities, building trust and tackling any opposition from vested interests. Collaboration, in any case, is good practice because no single organization can meet the multiple needs of a community and functioning in a silo can be detrimental to an organization's own business prospects. For instance, if a community perceives drinking water to be their greatest need, they are unlikely to prioritize sanitation services until the former is met.

4. Be patient and look beyond the profit motive

When Saraplast began experimenting with a portable sanitation model for slums it realized that while the potential business opportunity was huge (more than 100 million people live in slums in India), making the business commercially viable would be time-consuming and challenging. In fact, the initial pilot in one slum in Delhi took more than two years of planning before it could be launched. It is therefore imperative that organizations do not put all their eggs in one basket, but pursue a mix of opportunities (e.g. toilet installation plus maintenance; toilet installation followed by handover to local entrepreneurs for maintenance; operation and maintenance contracts for public toilets).

This would enable cross-subsidizing of the less profitable and more challenging business segments by the more profitable ones. For instance, Sarvajal's recently launched pilot program, which aims to provide clean drinking water to children in government schools, can be subsidized by water sales made in neighboring communities, until such time that a financially viable model can be worked out for schools. Also, while some opportunities might never be highly profitable (e.g. provision of drinking water and sanitation in schools), they can help fulfil important social goals that many for-profit enterprises in this space pursue (e.g. improving retention of girls in schools by providing clean toilets) and gain credibility with the government and other stakeholders in the sector.

Of course, market-based enterprises are not the panacea for delivering water and sanitation services at scale. In fact, for every organization that succeeds there are several others that fail. In addition to establishing strategic partnerships with community-based organizations and being customer-centric, the successful ones are able to make markets work for

the poor by leveraging relevant subsidies from governments (e.g. subsidized or free land for setting up a water treatment plant) and "patient" capital from private foundations (e.g. funds to cover initial revenue losses). Subsidies and philanthropic capital help these organizations to spend the requisite time understanding their customer base, developing a viable business model as well as offering affordable prices to customers. A combination of these ingredients can certainly enable for-profit players to fulfill the dual objectives of making profits and doing social good by bringing essential services to people who need them the most.

Urvashi Prasad, who is pursuing a master's degree in public health at the London School of Hygiene & Tropical Medicine, previously managed the health, water and sanitation portfolio of the Michael & Susan Dell Foundation in India.

Portable toilets provided for schoolchildren by Saraplast.

How Price Discrimination is Good for Global Health

Professor Patricia Danzon of The Wharton School discusses differential pricing in pharmaceuticals

By Kyle Poplin — WDI

Part 1 — Published September 17, 2014

Editors Note: When NextBillion Health Care launched its market dynamics initiative earlier this year, we did so in full recognition that it is a nuanced, complicated topic. Markets, particularly emerging markets, are not at equilibrium, where supply adjusts to meet needs. This is particularly important in global health, where markets often require manipulation to get medicine in the hands of those who need it.

Below, in Part 1 of a discussion with NBHC, Patricia Danzon, the Celia Moh Professor at The Wharton School, University of Pennsylvania, explores some of the basic principles involved in differential pricing in the context of pharmaceuticals. (Part 2 of her discussion follows. And an opposing view on differential pricing, written by Suerie Moon of Harvard, can be found on pages 31-33.)

Kyle Poplin: What is differential pricing as it relates to market dynamics?

Patricia Danzon: Differential pricing could well arise in markets without direct regulatory intervention. It does not require an overarching, cross-national regulatory framework, but it does require that countries generally accept the basic principles. The basic idea of differential pricing has been developed by some academics and some practitioners, as both appropriate and feasible in the context of pharmaceuticals.

Photo courtesy of taxrebate.org.uk, via Flickr

The idea is that manufacturers in unregulated markets have incentives to charge different prices in different markets around the world simply because different countries have very different income levels and therefore different abilities to pay. For example, the price levels that consumers can pay in the U.S., being a wealthy country with extensive insurance coverage, are very different from the price levels that consumers in India or Africa can pay, which have lower per capita income and very little insurance coverage for drugs. No manufacturer wants to set prices that customers cannot afford. So it usually makes sense to charge different prices to customers in different markets, based on differences in income and other factors that affect ability or willingness to pay.

Differential pricing for pharmaceuticals is very similar in concept to what in economic theory is called price discrimination. In standard economic theory, when a firm has the ability to differentiate prices across market segments, the firm's incentive is to charge different prices to different segments, based on the price elasticity of demand in those different market segments, charging higher prices where demand is more inelastic and lower prices where demand is more elastic or price-sensitive.

There is often opposition to differential pricing because it may seem unfair for the same product to have a very different price in different markets – indeed, "price discrimination" sounds intrinsically unfair. But if producers are able to charge different prices to different groups of consumers based on their ability to pay, then more consumers will be able to afford the medicine and utilization of medicines will likely be greater than if all consumers are charged the same price. If utilization increases with differential pricing, overall social welfare increases because lower-income consumers are able to afford medicines when they face prices commensurate with their ability to pay. Increased utilization also means higher overall profitability for manufacturers and therefore greater incentives to invest in R&D. So although "price discrimination" may sound undesirable, if it increases utilization then it can increase consumer welfare overall. The intuition is clear: If manufacturers charge the same price for drugs in poor countries as in wealthier income countries, fewer people in those poor countries will be able to afford the drugs, compared to differential prices that are related to income.

One common objection to differential pricing comes from people in the countries that face higher prices, who tend to conclude that they are subsidizing those who face lower prices. Specifically, the argument that the U.S. is subsidizing other countries is very common. But this misses the point, that manufacturers will tend to engage in differential pricing when it increases utilization. As long as the prices paid by middle- and low-income countries exceed the marginal cost of supplying them, they are contributing to the fixed costs of R&D. Put differently, the revenue that the manufacturer needs to raise from the richer countries to achieve a given total revenue is less under differential pricing, as long as those consumers who are brought into the market by the lower prices are paying more than their marginal cost. If so, consumers paying these lower prices contribute something to covering the joint costs of R&D, even though they pay less than consumers in richer countries. Differential pricing is particularly important for pharmaceuticals because R&D is a much larger component of total cost for drugs than for most other goods. If sales in middle-income and lower-income countries generate some revenue above marginal cost, this increases manufacturers' total revenue and their incentive to invest in R&D.

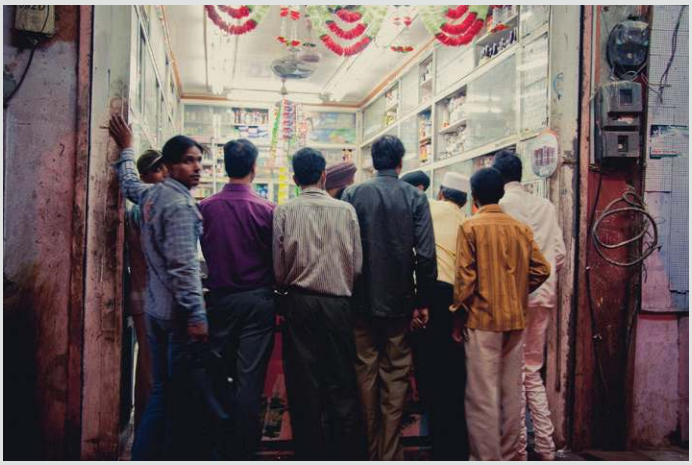
KP: What's the primary argument against differential pricing?

PD: Another common argument – and I believe a misinformed argument – is that the U.S. pays higher prices because some other countries pay less. This is another variant of the notion that the U.S. is subsidizing other countries, and it is incorrect. If manufacturers can charge different prices in different countries, their incentive is to charge the profit-maximizing price in each country, regardless of prices in other countries. In other words, prices in the U.S. reflect market conditions and willingness-to-pay in the U.S., regardless of whether or not other countries are getting the same products at lower prices. Put it another way: Assume, for example, that India or Europe were willing to pay higher prices … that would not bring down prices in the U.S. That would simply mean more revenue to fund R&D.

KP: What are the important factors to consider when implementing a differential pricing scheme?

PD: Most people are willing to accept the basic principle of differential pricing for low-income countries, once they understand that we're not paying more just because other countries pay less. Where it becomes contentious is: How much less should other moderately wealthy or middle-income countries pay? Most people seem to agree that the poorest countries should pay less than rich countries. But there is real disagreement on the appropriate price differentials between, say, Europe or Canada versus the U.S. Also, how much should middle-income countries like Brazil pay? That's where it becomes less a debate about whether or not there are price differences, and more about what the absolute price levels and differentials should be. Those questions of practical implementation are more difficult.

The theory of differential pricing implies that differential pricing can raise overall consumer welfare, but this theory does not answer the question of what the absolute price level should be in any country. For example, countries may accept



Men in front of a pharmacy in India. Photo by Hendrik Terbeck, via Flickr

the principle that prices should be differentiated based on per capita income. But let's say, for example, that average per capita income in Europe is 30 percent lower than in the U.S. Europeans may still resist paying a price 30 percent below the U.S. price because they may believe that the U.S. price level is too high. So even if countries were to agree on what the percentage differentials should be, that still leaves open the question of how high the absolute prices should be. That's where much of the practical debate is.

There also remains disagreement over whether per capita income is the only factor relevant to appropriate price differences; for example, should burden of disease or insurance coverage be taken into account? In practice, companies often start with setting price in the U.S., which has relatively few regulatory constraints and is an early launch country. Then they consider what discounts they are willing to give to other countries, relative to the U.S. price.

Another very difficult issue is price differentials within countries. In many low- and middle-income countries, such as India or Brazil, there is huge disparity in income between rich and poor. So, if the price in India or Brazil is based on average per capita income, the drug would still be unaffordable to the poor majority. Moreover, the wealthy minority in these countries may be wealthier than many middle-income people in the U.S. who face a higher price. It's easier to get general agreement on the principle of average differences across countries than on price differences within a particular country that has very big disparities in income. But if people are not covered by insurance, so are paying out-of-pocket for drugs in lower-income countries, a price that is based on the average income will be unaffordable to the majority of the poorer people.

Part 2 — Published September 18, 2014

Editors Note: In Part 1 of her interview with NBHC, Patricia Danzon, the Celia Moh Professor at The Wharton School, University of Pennsylvania, explained differential pricing as it relates to market dynamics and why some people oppose it, but why she and many others see it as especially useful and appropriate in the context of pharmaceuticals. "If producers are able to charge different prices to different groups of consumers based on their ability to pay, then more consumers will be able to afford the medicine, and utilization of medicines will likely be greater than if all consumers are charged the same price," she said. "If utilization increases with differential pricing, overall social welfare increases because lower-income consumers are able to afford medicines when they face prices commensurate with their ability to pay."

Kyle Poplin: Is it possible to have differential pricing within a country?

Patricia Danzon: In fact, this is common in the U.S. and in some other countries with pluralistic insurance arrangements or drug purchasing schemes. For example, in Brazil there is one price for drugs purchased in the private sector and another, lower price given to the public system which serves predominantly lower-income people. So there is at least rough differential pricing within the country based on average per capita income. But this works less well in a country like India, where insurance is less well developed and most people pay out of pocket for drugs in pharmacies. It then becomes difficult for a manufacturer to differentiate prices based on per capita income of customers, although coupons and patient assistance schemes can be effective.

KP: How prevalent is differential pricing in the pharmaceutical industry today?

PD: It depends on the type of drug. Biologics tend to be priced at fairly uniform price across most countries. But they achieve some de facto differential pricing by patient assistance programs that provide free drugs to some poor people, and other methods of discounting. Looking at the list price does not necessarily tell you what all patients are paying.

Some companies have explicit policies to differentiate their prices across countries. For example, Sovaldi, Gilead's new drug to treat hepatitis C, got a lot of press for its price in the U.S.. Gilead traditionally follows a differential pricing policy that is not exactly based on average per capita income but does give much lower prices to low-income countries. Gilead recently announced that it is licensing Sovaldi to several Indian generic companies for sale in 91 low-income countries. This should establish a competitive market and Gilead will simply receive a royalty on sales.

So differential pricing in practice depends on the type of drug, the strategy of the company, and also on reimbursement policies and the extent of competition in each country. For example, some low-income countries have aggressive generic competition, so there may be one or more branded generic, copy versions of a multinational company's brand drug available at lower prices. In such cases, the originator brand drug may be priced quite high, reflecting the multinational company's strategy of targeting primarily the wealthier customers, leaving the middle- and lower-income segments of the market to the generics.

Cross-national differential pricing is also common for vaccines, where government purchasing plays a relatively large role. However, in general the evidence suggests that for most drugs low-income countries face higher prices, relative to their average per capita income, than do richer countries. So in practice differential pricing is not working very well.

KP: Who has the power to increase the use of differential pricing?

PD: Primarily governments and payers, those who have power over price and reimbursement policies in wealthier countries, and also in some middle-income and poorer countries. For example, the European Union explicitly permits parallel trade. In other words, wholesalers can purchase drugs in a low-priced EU country and ship them in higher-priced countries, arbitraging the price differences. This undermines the manufacturer's ability to maintain differential pricing. It is also very common for EU countries to regulate their own prices based on average prices paid by other EU countries. If many EU payers or governments regulate their own prices based on the average EU price, then obviously it's impossible for companies to maintain differential pricing between the high-income countries and lower-income countries in Europe. Such "external referencing," whereby one country references prices in other countries to set their own prices, makes it impossible

for companies to pursue differential pricing.

So the starting point is governments that either regulate or are themselves payers for pharmaceuticals in many countries. More generally, if richer countries that observe lower prices in other countries insist on having similar prices in their own countries, manufacturers will be unwilling to give discounted prices in lower-income countries, even if that means selling fewer drugs or simply not selling in lower-income countries. Wealthier countries must be willing to ignore lower prices given to lower-income countries. Similarly, middle-income countries also need to be willing to pay higher prices than poorer countries, in order to preserve access to low prices in the poorest countries.

Finally, it would be helpful if the middle- and low-income countries that lack comprehensive insurance coverage would facilitate within-country differential pricing, developing mechanisms to enable big discounts to be given to lower-income consumers, while richer citizens pay higher prices that are commensurate with their relatively high incomes. Politics is thus, obviously, a big obstacle to implementation of differential pricing in practice.

Kyle Poplin is the editor of NextBillion Health Care.

Separating Potential from Panacea

USAID's primer offers a disciplined approach to market shaping

October 30, 2014

By Amy Lin

Global health is inextricably linked to the health of the marketplace that delivers lifesaving products to low-income populations. A well-functioning health care market with public and private sector participation requires manufacturers to produce high-quality products, distributors to deliver the necessary quantities, providers to administer them correctly and patients to be educated and active participants in their own health.

However, markets sometimes fall short. Developers may not see enough demand to develop a new product, manufacturers may not know how much to produce and distributors may not see enough profit to justify delivery. A single breakdown in this complex, interactive system can keep lifesaving products from those most in need.

Actors at both ends of the market — producers and purchasers — may face high transaction costs, knowledge gaps or imbalanced risks that hamper their participation in the market and lead to market shortcomings. Countries, donors and procurers can use their purchasing power, financing, influence and access to technical expertise to address the root causes of market shortcomings and influence markets for improved health outcomes. By disrupting current practices or transforming market structures in this way, market shaping can achieve better health outcomes for the poor.

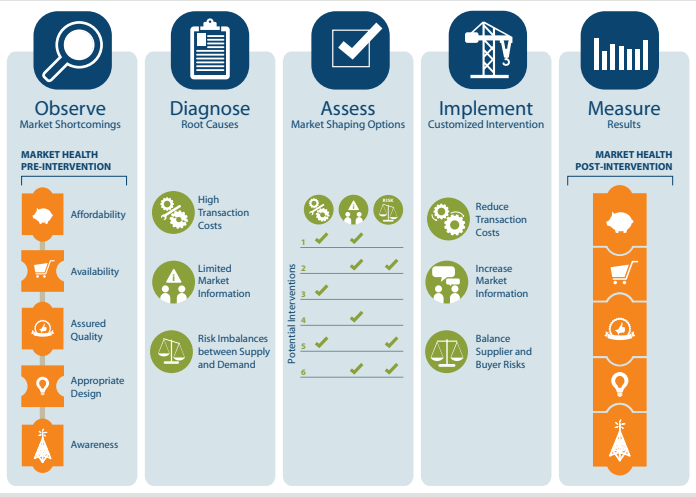
Designed to be transformative, market shaping has

demonstrated its potential to enhance value for money, diversify the supply base, increase shipment reliability and ultimately increase access for end users. Between 2003 and 2013, GAVI strengthened the pentavalent vaccine market by increasing the number of suppliers and achieving price reductions, leading to a projected savings of up to $150 million and a more than tenfold increase in the number of children immunized.

In the HIV sector, the USAID-administered Supply Chain Management System established regional distribution centers that used demand forecasting and greater delivery efficiency to decrease costs and increase reliability – improving on-time deliveries in South Africa, for example, from 60 percent to 90 percent in four years (Larson, Burn, et al, "Mitigating Supply, Demand and Cost Risks in ARV Supply Chains"). The U.S. Food and Drug Administration helped expand the supply base for HIV drugs through its expedited drug review process, which enabled the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) to procure from more generic manufacturers for developing countries.

Drawing from these and other experiences in market shaping from across the vaccine, HIV, malaria, family planning and other health sectors, USAID's Center for Accelerating Innovation and Impact (CII) in partnership with practitioners and experts outlined a "market shaping pathway." Encapsulated in its recent report Healthy Markets for Global Health: A Market Shaping Primer, this disciplined approach consists of five steps for evaluating and implementing market shaping opportunities. Importantly, this pathway does not point to market shaping as a panacea to solve all market access issues within global health. Addressing all of these issues requires a multifaceted approach, and market shaping builds on a foundation of other critical global health efforts – from health care provider training to civil society engagement to product introduction planning – in order to succeed.

In the market shaping pathway, Step 1 is to observe market shortcomings that limit health impact. Market shortcomings could include a high product price; overreliance on a single supplier; cycles of shortages and gluts; prevalence of substandard products; ill-suited products; or low user interest in superior innovations. The Market Shaping Primer groups these and other market characteristics into the following mnemonic set of "5As": Affordability, Availability, Assured Quality, Appropriate Design and Awareness.



Step 2 is diagnosing the root causes underlying these market shortcomings. A range of analytical tools can help examine market actors, their interactions or their regulatory systems to pinpoint whether root causes fall into one or more of the following three groups:

- High transaction costs
- Limited market information
- Risk imbalances between supply and demand

After tracing market shortcomings to their underlying root causes, Step 3 is to assess market shaping options. This is essentially a matchmaking operation between the market and its most appropriate market shaping intervention, if any. Each intervention should be evaluated against how it would address the root cause of the shortcomings and consider the benefits, drawbacks and implementation constraints.

Step 4 of the pathway focuses on implementing a customized intervention, recognizing that close collaboration with market actors is essential in undertaking complex, interconnected activities like market shaping. Similarly, practitioners should be mindful of any tradeoffs required, whether between competing objectives or execution styles, so these decisions can be made strategically and transparently.

In Step 5, the emphasis shifts to measuring results at the health output and health impact levels as well as the more immediate market level. In addition to providing valuable feedback on the intervention, this tracking can help practitioners quickly adapt the intervention to changing market and health conditions as needed.

These five steps of the market shaping pathway recognize that while market shaping can be transformative, it should be undertaken with rigorous analysis, careful preparation and close coordination. The Market Shaping Primer offers a disciplined approach to examining a health product market and evaluating whether and how market shaping could increase access for end users. Ultimately, the goal of the primer is to inform practitioners as they seek to catalyze health markets and enhance health impact in poor communities.

For more information, visit the USAID Center for Accelerating Innovation and Impact (CII) website.

Amy Lin is a senior market access adviser at USAID's Center for Accelerating Innovation and Impact (CII), where she develops and implements market-based strategies for adoption of priority health solutions.

Shaping the Market for Global Health Data

Why collecting information on lower-income countries should be 'first order of business'

November 6, 2014

By Prashant Yadav and Amanda Glassman

The most valuable currency in global health programs today is accurate and reliable data, but such data – abundant in rich countries – does not exist for most low-income and lower-middle-income countries. And without data on past consumption and unmet needs, program planners and global financiers cannot budget appropriately, pharmaceutical and vaccine companies cannot plan investments, and it is harder to understand how programs are performing and how patients' needs are changing over time.

In OECD countries like the United States, Japan, and those of the European Union, organizations such as IMS Health collect data from a wide array of data sources throughout the health care delivery chain. These data sources include medical claims submissions, retail and hospital pharmacy transaction records, electronic medical records, market research, and physician panels. Having data from different sources and from different points of the health care process allows for an in-depth understanding of how the overall health system functions. It enables all stakeholders in the system to identify and better understand the unmet needs of patients and to improve service (through benchmarking cost and quality across providers). It also allows for advanced forecasting methodologies, innovative pricing models, "market-shaping," and strategic contracting.

Photo courtesy of IMF Health

Data is harder to come by outside rich countries, and the reasons are simple: collecting and collating such data is costly. When organizations such as IMS Health see a market for such data, they make the upfront investments to routinely and systematically collect this data. None of IMS Health's conventional customers (health plans or payers, pharma companies, or government agencies) presently purchase such data for low- and lower-middle-income markets.

In recent years there has been increased recognition that systematically and routinely collected market data can provide a rich source of information to improve value for money. A 2006 CGD report on demand forecasting also stressed the need for collecting relevant, timely, and comprehensive information about global health markets. Since then several new initiatives have been created that focus on systematically collecting data. The ACT Watch project was a multi-country project designed to collect availability, price, and use data on malaria medicines and diagnostics in the private and public sectors. UNITAID has funded different groups to collect different data elements that are relevant for a deeper understanding of market shortcomings. Together these "push" mechanisms have jumpstarted a market for such data. Large data suppliers are slowly waking up to realize that this may be a market opportunity worth the investment.

However, the need for data on health markets in low-income countries cannot be met with ad hoc one-time fixes or the slow waking up of data suppliers. The needs for data will only increase in the future, and new technology may lead to new data sources becoming available. In order to truly catalyze the market, both large data suppliers like IMS Health and small, innovative data suppliers that might emerge over time need to see the real potential of the market for low-income-country data.

Therefore it is important to be more ambitious about the efforts to collect market data in the long term. In recent years many new innovative "pull" financing mechanisms have been designed to create and catalyze markets through partial risk sharing with a private-sector entity (a pharma company or vaccine manufacturer). These include the advance market commitment for pneumococcal vaccine, volume guarantees for rotavirus vaccine, and volume guarantees for contraceptive implants. The rationale for such arrangements is simple. They

share some of the manufacturers' demand-side risk and, as a result, give manufacturers an incentive to make upfront investments in the market, and in return the mechanisms also negotiate lower prices in the long term. Overall, these new vehicles help to jumpstart small markets by accelerating the flow of upfront private investment. When designed well, such schemes also give governments an incentive to provide the data which can help reduce the demand-side market risk.

Can't such a scheme be designed to catalyze the market for global health market data? Something like an advanced market commitment for global health market data? It could be a market commitment for data that is made jointly by global funding agencies, pharmaceutical and vaccine companies, and other groups that have the potential to derive the most value from such data. Such a commitment would stimulate large data suppliers to invest in low-income markets and would also create the market for smaller data providers, who do not presently engage in such markets but may be more efficient and cost effective. Most of the grant-funded multi-country global data collection projects are currently carried out by large global health organizations.

Admittedly, figuring out the operational mechanics of such a market commitment is challenging, but the potential benefits from a partial risk sharing mechanism are high, making it certainly worth a deeper exploration.

Nudging markets requires quick and timely information about past consumption, prices, unmet need, preferences and supply landscape. Shaping the market for such information should be the first order of business for those who endeavor to shape global markets for health technologies.

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Business Models, Best Practices and Measures in Access to Medicine

Index released Nov. 17 ranks pharmaceutical companies' efforts to improve availability in developing countries

November 13, 2014

By Prashant Yadav and Andrea Bare — WDI

The 2014 Access to Medicine Index was released on Nov 17. This powerful tool speaks to the performance evaluation of the 20 top research-based pharmaceutical companies across 95 indicators in providing access to medicines for 47 high-burden diseases in 106 low- and middle-income countries.

The Access to Medicine Index has dramatically impacted how the pharmaceutical industry approaches low-income markets and historically low-priority diseases by building awareness, speaking industry's language, applying metrics and assembling evidence to inform strategic business practices. The index has undoubtedly supported a shift in mindset from predominantly philanthropic to a broader commercial orientation. This has garnered greater voice for emerging markets and neglected diseases within these pharmaceutical companies and informed long-term corporate strategies around issues such as disease opportunities and priorities, collaborative R&D, intellectual property, and investment in infrastructure and access.

Historically, the pharmaceutical business model has centered on research and development of new medicines for the developed markets of the United States, European Union and Japan. Over time, emerging markets attracted more interest due to demographic and epidemiology changes as well as increased competition and maturation of the developed markets. With this interest in emerging markets came considerable challenges to traditional pharmaceutical investment strategies, given internal competition for corporate resources, infectious disease portfolio requirements and the various unknowns and idiosyncrasies of emerging markets.

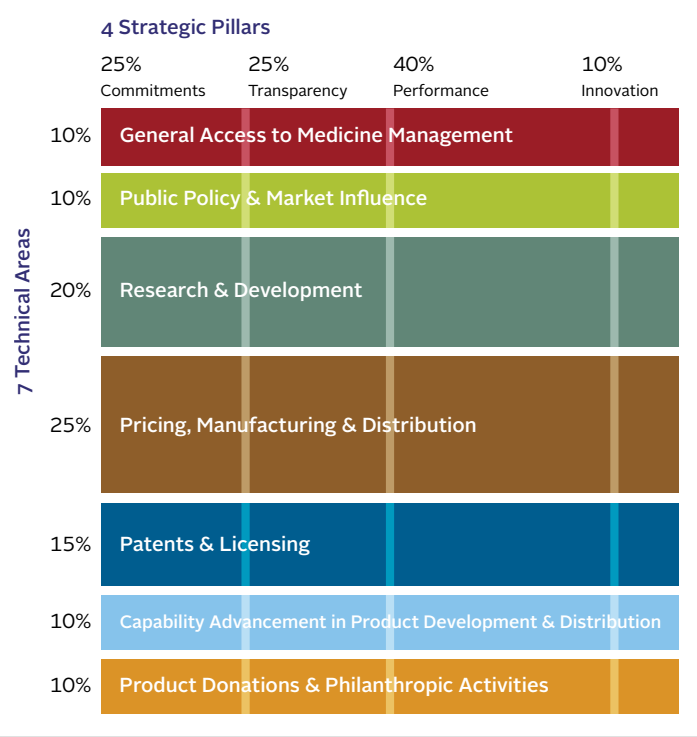
First published in 2008, this year's Access to Medicine Index is the fourth in a biennial series that originated from founder Wim Leereveld's vision that pharmaceutical companies' role in tackling the world's challenge of access to medicines would be better directed through systematic and aggregated measurement. The index fills a critical role for global health stakeholders by providing an impartial, systematic evaluation and tracking tool through which these leading 20 pharmaceutical companies can view their access efforts in emerging markets over time. Support for this vision has grown since 2008, as the index has generated ongoing

reflection and exchange in publications such as Forbes and The Lancet. The resulting dialogue has informed pharmaceutical manufacturers' corporate strategies for emerging markets as well as continued refinement of the index's research and analytic methodology.

The Access to Medicine Index Foundation is fully independent from the pharmaceutical industry, receiving funding from the Bill & Melinda Gates Foundation, the Dutch Ministry of Foreign Affairs, the UK Department for International Development, Cordaid, the Humanist Institute for Cooperation with Developing Countries, and the Interchurch Organization for Development Co-operation. This independence lends substantial credibility and autonomy as well as opportunity to engage with the multiple stakeholder groups in the global health community.

Through its work with the pharmaceutical companies as well as investors, academicians, civil societies, global health practitioners and multilateral organizations, the index foundation has generated information and insights that have been transformative to the drug manufacturers' role in global public health. Just as physicians are taught to practice evidence-based medicine, the pharmaceutical sector and its investors are driven by analytics and evidence, which the index has galvanized for emerging markets. Deutsche Bank's recent industry report on seven large-cap pharmaceutical companies is an excellent example. Analysts referenced the Access to Medicine Index and characterized pharma's engagement as "both doing the right thing and strategic investment," noting that 40 percent of the world's population lives in the tropics, including most of the least developed countries.

Since its inception, the index has refined its methodology and become increasingly robust. (Editor's note: Prashant Yadav has served as a technical committee advisor to the Access to Medicines Index.) The 2014 index applies the same basic framework as prior years with minor enhancements, enabling both individual and aggregated progress tracking. The analysis is constructed along seven technical areas, with 95 indicators measured across four strategic pillars. The four strategic pillars include Commitments, Transparency, Performance and Innovation, with Performance the most heavily weighted at 40 percent. The technical areas are also weighted in the evaluation, with Pricing, Manufacturing & Distribution; Research & Development; and Patents & Licensing weighted the most heavily at 25 percent, 20 percent and 15 percent, respectively. The remaining technical areas of Public Policy & Market Influence; General Access to Medicine Management; Capability Advancement; and Product Donations are all weighted at 10 percent, respectively.



The 2014 methodology places greater emphasis on the need for access to medicines to become "business-as-usual" within the companies, i.e. maintaining profitability while fostering access. This is apparent in adjustments to the technical area indicators, such as measuring business model innovation that is economically viable and beneficial for access to medicine. Notably, the disease scope has expanded considerably from 33 to 47 disease states. The geographic scope has also expanded from 103 to 106 low- and middle-income countries. The disease scope expansion highlights the breadth of the index and reflects important epidemiological trends as reported by the World Health Organization, based on global burden of disability-adjusted life years and the relevance of pharmaceutical interventions. The 47 conditions fall into four categories – communicable, non-communicable and neglected tropical diseases, and maternal and neo-natal health care.

In a workshop leading up to the 2014 index, pharmaceutical company participants highlighted three key themes in best practices for access strategies: 1) external stakeholder expectations, 2) the importance of internal corporate support, and 3) opportunities for industry-wide collaboration. The Access to Medicine Index addresses these themes by building stakeholder expectations into metric development and assessment, producing high-caliber evidence worthy of corporate decision-making and identifying opportunities for increased collaboration. This serves a critical function by enabling emerging market business leaders to gain visibility within their pharmaceutical organizations and incorporate outside expertise and critique. Going forward, the global health world will be watching to see if strong longitudinal performance in the index corresponds to corporate and fiscal success in the emerging markets opportunity.

The overall ranked leaders in the 2012 index were GlaxoSmithKline in the top spot, followed closely by Johnson & Johnson and Sanofi.

Prashant Yadav is a senior research fellow at the William Davidson Institute (WDI) and director of the Health Care Research Initiative at WDI. Andrea Bare is senior advisor, Market Dynamics, at WDI.

The Limits of Tiered Pricing in Improving Access to Medicine

Harvard's Suerie Moon looks at theoretical and empirical drawbacks

By Suerie Moon

Part 1 — Published December 1, 2014

Patricia Danzon, the Celia Moh Professor at The Wharton School, University of Pennsylvania, recently explained (pages 23-26) why she and many others see tiered pricing as especially useful and appropriate in the context of pharmaceuticals. Here, in the first of a two-part counterpoint, Suerie Moon, research director and co-chair of the Forum on Global Governance for Health at the Harvard Global Health Institute, delineates what she sees as the drawbacks in relying on tiered pricing as a strategy to improve access to medicines in poorer populations. (Part 2 follows.)

"Tiered pricing" in the context of global health generally refers to pharmaceutical companies systematically setting prices at lower levels in developing countries than in high-income markets. (It is also sometimes called differential pricing, price discrimination, market segmentation or Ramsey pricing.) Tiered pricing is feasible when markets are separable and when the seller exerts significant power over pricing, such as when there is limited or no competition due to patent protection, data exclusivity or other barriers to market entry (such as inadequate production capacity).

At first glance, it sounds reasonable enough — lower prices for poorer countries and sometimes also mid-level prices for middle-income countries. In theory, tiered pricing is supposed to offer a "win-win" solution — maximizing profits for sellers by enabling them to tap into new markets while increasing consumer surplus by making a product affordable to a greater proportion of the population. In theory, perfect price discrimination under monopoly can lead to efficient market outcomes.

However, there are important drawbacks — both theoretical and empirical — in relying on tiered pricing as a strategy to improve access to medicines in poorer populations.

Theoretical considerations

At least four theoretical aspects of tiered pricing are problematic for pharmaceuticals.

First, perfect price discrimination under a monopoly system (or Ramsey pricing) only leads to an efficient market outcome when a regulator caps the level of fixed costs recouped by the monopolist. For pharmaceuticals, this would mean a regulator knows how much has been spent on R&D and has the power to limit revenues to meet those costs. Yet neither of these is feasible for pharmaceuticals, where R&D costs are tightly-guarded secrets and no single national authority has the ability to control total return on R&D investment in a globalized pharmaceutical market. (Notably, in the U.S. and some other countries, there is very little political willingness to regulate medicine prices at all, let alone calibrated to the level of R&D investment.)

Second, an efficient outcome relies on pricing according to the consumer's demand elasticity — which generally translates into a higher price for a consumer with greater willingness to pay for a drug, and a lower price for a consumer with lower willingness to pay. But for lifesaving medicines, the concept of willingness to pay is ethically problematic — should a patient who is seriously ill and desperate be charged a higher price for a medicine that will save her life (because her demand will be relatively inelastic) than one who is in an earlier stage of the disease, for example?

Third, price discrimination relies on both the ability to separate or segment markets (that is, no products would flow from one market to another) and to know precisely the consumer's willingness to pay. Neither of these is practical in the real world, where markets are not perfectly separable and there is huge variation in the financial resources available to

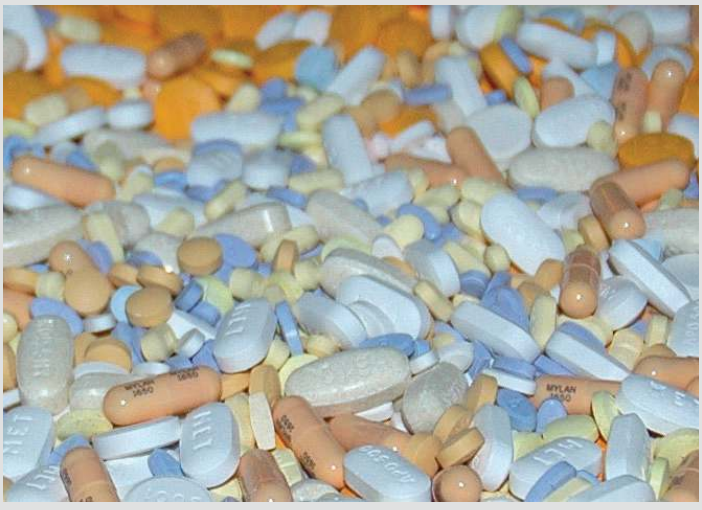


Photo by Carlos Lowry, via Flickr

individual consumers to pay for medicines. Furthermore, most patients living in low- and middle-income countries are not covered by in-depth health insurance systems and frequently pay for medicines out-of-pocket, with health care spending a leading factor driving households below the poverty line. In such contexts, patients may be willing to pay higher prices for a medicine but are either simply unable to do so, or only at the cost of driving their families into poverty.

Finally, while tiered pricing may represent an increase in consumer surplus over the counterfactual of a monopolist charging a single high price to all consumers in the world, it does not necessarily maximize consumer surplus. Nor does the counterfactual necessarily represent reality. Rather, firms often have strong incentives — or are required by regulation — to adapt prices to various markets.

Empirical evidence

These abstract arguments are important, but it is perhaps even more informative to consider what the empirical evidence tells us about how tiered pricing has been implemented in practice.

As summarized in our 2011 study, evidence from the past decade demonstrates that there are a number of drawbacks to relying on tiered pricing as the main strategy to improve the affordability of medicines in low- and middle-income countries (LMICs). Much of the evidence comes from the experience of antiretrovirals (ARVs) for HIV/AIDS, the therapeutic area for which tiered-pricing policies have been most widely implemented and for which the most data on prices and practices is publicly available. For ARVs, tiered pricing has been less reliable and effective than generic competition in achieving the lowest sustainable prices for quality medicines.

In a review of more than 7,000 developing-country purchase transactions from 2002-07, Waning et al. found that the tiered prices for 15 of 18 antiretroviral drugs were 23-498 percent higher than the generic price. Similarly, an analysis of publicly announced ARV prices (2014) found that of the 22 products for which both originator tiered prices and WHO quality-assured generic prices were listed, the generic price was lower for 19 products (86 percent). Generic prices were frequently as low as one-eighth to one-fifth of tiered prices.

These price differences can translate into significant overall savings. A 2013 study from the U.S. Government Accountability Office found that the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) saved nearly $1 billion from 2005-11 by purchasing generics rather than tiered-priced HIV drugs. Analogous cost-savings estimates for the Global Fund are not available, but would likely be much higher given the greater volumes of drugs procured with Global Fund monies.

Not only are generic prices systematically lower than originators' tiered prices, generic entry into the market also tends to push originators to reduce their own tiered prices — as would be predicted by basic economic theory. In the global market for artemisinin-combination therapies for malaria, the tiered price from an originator firm held steady for about five years and only dropped when generic competitors entered the market. Generic competition, often enabled by governments using flexibilities in intellectual property rules, has been central to improving access to HIV and other medicines in developing countries.

Another drawback to tiered-pricing policies are that they are voluntary programs of pharmaceutical companies and as such can be arbitrary. Companies may offer discounts on some drugs but not others, to some countries but not others, for a limited time or with strings attached. The rationale underlying a given price or country grouping is generally not transparent, and the prices offered are not necessarily affordable. This feature of tiered pricing has become particularly problematic in middle-income countries (MICs).

The rise of the MICs is challenging pre-existing arrangements in the development aid system, including the informal norm that "rich" countries pay higher prices for patented medicines to cover R&D costs while "poor" countries purchase generics (at least for some priority diseases). But this rich/poor classification is neither as easy nor useful as it once was. MICs now include more than 100 countries, home to more than two-thirds of the world population, with 75 percent of the world's poor and a majority of the global burden of disease, with per capita incomes spanning from about $3 to $33 per day. At the same time, the pharmaceutical industry is relying heavily on MICs for worldwide growth to offset flat sales in Europe and the U.S. In their current form, tiered-pricing policies are not likely to ensure affordable prices in MICs.

Part 2 — Published December 2, 2014

Editors Note: Patricia Danzon of The Wharton School broached the topic in a two-part Q&A post that detailed how tiered pricing helps get medicine in the hands of those who need it in the developing world. Suerie Moon of Harvard has responded with a two-part post of her own. In Part 1 she highlighted the drawbacks — both theoretical and empirical — she sees in relying on tiered pricing as a strategy to improve access to medicines in poorer populations.

The drawbacks to tiered pricing discussed in Part 1 do not mean it should never be used. Rather, as with any policy tool, the key question is: Under what conditions is tiered pricing an appropriate strategy and how does it compare to alternatives?

In the two cases previously discussed — HIV/AIDS and malaria — markets were large and multi-source production capacity existed, which meant that a competitive generic market was feasible and likely to offer better outcomes in terms of affordability and security of supply. However, in other cases, such as when markets are very risky and/or when volumes are small, or when multi-source production capacity is lacking, tiered pricing may offer the only practical option to improve the affordability of a product (at least until such market conditions change).

Examples of smaller-volume and therefore risky markets include rare diseases, pediatric formulations, some neglected diseases such as kala azar, and multi-drug resistant tuberculosis. Examples of markets where multi-source production capacity is often lacking include newer vaccines and biologics that are complex to manufacture. In such cases, steps should be taken to improve tiered-pricing policies in the short to medium term, and to transition to multi-source supply in the longer-term.

How could tiered-pricing policies be improved in the short-

to-medium term? Here are at least four ways:

- First, the pharmaceutical industry could commit to linking price levels to objective measures of affordability (with marginal cost of production serving as a price floor – that is, sellers would not be expected to price below what it costs them to supply the product).
- Second, industry could commit to more rational, objective, public health-oriented and transparent criteria for setting tiered-pricing policies with respect to both country classification and price levels. For example, firms could base their prices on costs of production and distribution, with additional tiered allocation of R&D costs where appropriate.
- Third, governments and civil society should engage more proactively in discussions on what would make for affordable, appropriate and acceptable tiered prices so that such policies are not made by industry alone.
- Finally, more transparency in the application of tiered pricing is needed (e.g. information on prices, products, other procurement conditions) so that relevant data can be independently analyzed and practices continuously improved through feedback and learning.

Consider the alternatives

Finally, given its drawbacks, it is important to consider alternatives to tiered pricing. One alternative that has increasingly been adopted by sellers is voluntary licensing – granting licenses to authorize the production and sale of generic versions of patented medicines in certain low- and middle-income countries, often in exchange for royalties.

Photo by Kiran Foster, via Flickr

This practice has been most widely implemented for HIV/AIDS, notably with the Medicines Patent Pool acting as an intermediary in negotiating such licenses with the aim of maximizing public health benefit. Such licensing offers the advantages of capturing the dynamics of generic competition to reduce prices to their lowest sustainable levels, capitalizing on the lower cost structures of the most efficient manufacturers and providing a structured means of government and civil society engagement in debating what are acceptable terms and conditions of such licenses. The firms Gilead and Bristol Myers Squibb have also recently announced voluntary licenses for their new Hepatitis C drugs (though not through any intermediary body).

One of the main challenges with voluntary licensing, however, is that firms are unlikely to sign away the profits that could be made in the most lucrative emerging markets. For this reason, a number of the largest middle-income country markets, such as China and Brazil, are almost never included in such licenses.

When medicine prices are unaffordable because of monopoly pricing, governments can and should proactively use a range of policy tools to ensure access to medicines for their populations, including price negotiations, compulsory licensing, price controls, reference pricing, parallel importation, cost-effectiveness analysis, pooled procurement, measures to accelerate registration of generics and raising domestic patenting standards. These measures have been described in detail elsewhere, and highlight the fact that tiered pricing is just one of many approaches to be considered when seeking to make medicines more affordable in developing countries.

In the medium to long term, alternate approaches to driving and rewarding innovation should be implemented. These include push incentives such as public or philanthropic grants that reduce the costs or risks of R&D, and pull incentives such as milestone or end-product prizes that reward the development of new technologies without needing to resort to monopoly pricing – a concept known as "de-linkage." De-linking rewards for innovation from medicine prices would allow medicines to be priced immediately at the cost of production, thereby maximizing consumer surplus far above the levels feasible through tiered pricing, and improving affordability and access to medicines for all.

Suerie Moon is research director and co-chair of the Forum on Global Governance for Health at the Harvard Global Health Institute.

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Matching Uncertain Demand and Supply for Health Technologies

There's much to be learned from others, especially during holiday season

December 9, 2014

By Prashant Yadav — WDI

Each year the holiday season highlights the complex task of matching demand and supply for gifts, Christmas trees and Thanksgiving turkeys. If you live in the United States you are perhaps still recovering from the lingering of Thanksgiving turkey. According to the National Turkey Federation, more than 730 million pounds of turkey (approximately 45 million turkeys) were consumed in the United States during Thanksgiving this year. Grocery stores, where people buy turkey, plan up to six months in advance to ensure they have the right quantity in stock. They establish long-term contracts with turkey producers far in advance of the Thanksgiving season. As a result of the long-term contracts, the turkey producers (especially the smaller farms which cannot afford to invest in their own market research) can better understand any shifts in demand each season. While the system is not perfect, it gets most Americans a Thanksgiving turkey (if they want one) at a relatively stable price (often decreasing in an inflation-adjusted sense).

If you celebrate Christmas and decorate your home with a Christmas tree, matching demand and supply for Christmas trees is also quite a complex problem. Christmas trees must be grown, cut and shipped, all within a short time span. It takes almost five years for a seedling to grow into the size tree that is typically used in homes. Approximately 35 million Christmas trees are harvested each year in the United States. Here again, retailers engage in long-term contracts with tree growers. Christmas tree demand has been decreasing over the past six years, as younger people who live in large cities often don't have space for a real tree and artificial trees have become more common. In addition to changing demand and long lead times of growing and harvesting, matching demand and supply for Christmas trees is complicated by yet another factor: supply uncertainty. Heavy snow early in the season hampers timely tree harvesting. Michigan (where I live) is the third largest producer of Christmas trees and early season snow is not uncommon. Such events lead to increases in wholesale spot market prices for trees, but prices at large retail stores don't fluctuate as much; the retailers have long-term contracts with tree suppliers.

The global market of olive oil (not as much a holiday staple) in many ways exemplifies the complexities of matching demand with uncertain supply. Spain and Italy produce approximately 70 percent of the world's olive oil. While the demand side of the market has been relatively stable in the past few years (global demand of approximately 3,000 tons), the supply side of olives is quite challenging. The olive oil industry is highly fragmented with millions of farmers supplying a few thousand oil extraction mills and a few hundred refineries, many of which operate below capacity. Olive production each year is also highly uncertain due to uncertain crop yield. For example, this year a drought in Andalusia, Spain, has almost halved the country's olive production. A bacteria in Tuscany has significantly decreased Italian production as well. Prices are now rising. The fragmented nature of the industry and the wide swings in production due to uncontrollable events mean that long-term contracts cannot insulate the market from price and supply shocks.

Similar challenges with matching uncertain demand with uncertain supply exist in the market for malaria medicines. A shortage or even a small price increase in this market has far more significant consequences than not having a Christmas tree this year, or having to pay a higher price for Italian olive oil. Undoubtedly, matching demand and supply in this market is a much more serious matter; a shortage or higher prices can lead to death and greater spread of disease.

If you thought matching Christmas tree supply and demand was tricky, consider the much more serious implications in the market for malaria medicines. Photo by Mallory Dash, via Flickr

Artemisinin combination therapy (ACT), the most effective malaria medicine today, is manufactured from artemisinin which is extracted from the plant Artemisia annua. The entire cycle of growing Artemisia to packaging the tablets takes somewhere close to 14 months. The plant is grown by farmers in China and Vietnam and artemisinin is extracted from it by more than two dozen extractors. Patients obtain malaria medicines in government-run clinics or in private sector pharmacies and drug shops. International agencies, most notably the Global Fund to Fight AIDS, Tuberculosis and Malaria and the U.S. President's Malaria Initiative, provide financing to developing country governments for purchasing ACTs. Predicting the demand for ACT remains challenging due to financing delays, changes in epidemiology and many other factors.

On the other hand, there is also a significant supply uncertainty in growing Artemisia annua. Farmers can switch to other crops and sub-optimal rains can hamper crop yield. Long-term contracts with ACT manufacturers were recommended as a strategy in 2006, and recently the Global Fund has initiated two-year contracts with ACT manufacturers. A soft loan program was set up for artemisinin extractors with the hope that it will incentivize more farmers to grow artemisia through pre-financing and long-term contracting. A synthetic form of artemisinin was launched this year that cuts short the long lead time of artemisinin cultivation and allows manufacturing the product in less than two months.

Several options exist to improve the matching of demand and supply in this market. Many have been discussed and a few have been tried. In a recent paper, co-authors Burak Kazaz, Scott Webster and I develop a model of demand and supply matching in the malaria medicines market using the "modeling machinery" we have used to study other markets with uncertain demand and uncertain supply. It turns out that increased forward contracting and better demand forecasting don't yield as strong a benefit as improving average yield of agricultural artemisinin production, and creating a larger and carefully managed supply of semi-synthetic artemisinin.

Markets have great richness in context. Developing tools for improving markets to serve larger societal needs requires a deep understanding of the market context and tailor-made analysis. However, making comparisons with other markets and having close interactions with those who work on a completely different market can be immensely valuable. There is a high chance you will learn something that may apply to your particular market. Worst-case, you will become better at describing the uniqueness in the institutional context, market structure and technological stage of the market you focus on.

So as you walk to work tomorrow think of the newspaper kiosk or the woman who runs the flower shop at the corner and how they manage their demand uncertainty. Do they do long-term contracts? Have they found a new way to reduce risk in their market? Have they found a new way to share their risk with others? Do they get volume guarantees? Have they found new ways to reduce lead time? Don't hesitate to ask. The worst that can happen is they'll call you a market-analysis and supply-chain nerd. And, after all, it's the holiday season!

Prashant Yadav is a senior research fellow at the William Davidson Institute (WDI) and director of the Health Care Research Initiative at WDI.

Tiered vs. Equitable Pricing

Why Access to Medicine Index 2014 takes societal needs, affordability into account

December 23, 2014

By Tara Prasad

Editor's note: Our market dynamics initiative has focused lately on tiered pricing of pharmaceuticals. Patricia Danzon of The Wharton School introduced the concept (pages 23-26) and how it helps get medicine to the developing world. Suerie Moon of Harvard discussed (pages 31-33) the limits of tiered pricing and proposed some policy tweaks. Prashant Yadav and Andrea Bare of the William Davidson institute discussed (pages 29-30) the 2014 Access to Medicine Index, released Nov. 17.

Below, Tara Prasad, lead researcher with the Access to Medicine Index, takes the debate a step further, discussing how and why the Index's pricing methodology evolved from measuring tiered-pricing strategies to measure what the Index terms "equitable pricing strategies" instead. In order to increase access to medicine for the poorest populations, commercial tiered-pricing strategies do not suffice, she says. Rather, companies need to tailor their pricing strategies for different segments within developing countries, taking into account affordability and other socioeconomic factors relevant to the target population.

The Access to Medicine Index independently ranks pharmaceutical companies' efforts to improve access to medicine for priority diseases in developing countries. Funded by the Bill & Melinda Gates Foundation and the UK and Dutch governments, the Index has been published every two years since 2008.

Photo of syringe and vaccine by PATH global health, via Flickr.

The 2012 Index analysed companies' tiered pricing strategies. Specifically, it attempted to capture the difference between the price for mature markets and the price for the poorest markets for each product from each company's relevant portfolio. However, the 2012 Index found that to presume higher discounts were always an effective mechanism for improving access, for different products under different therapeutic areas sold in different markets, was not a robust measure against which to rank companies, and one that did not guarantee the discounted prices of the products were affordable for the end-user.

Following a careful methodology review, the 2014 Index no longer captured purely commercial tiered-pricing strategies. Instead, it captured pricing strategies that explicitly take societal needs and affordability into account (referred to as "equitable pricing strategies"). This shift was important for two reasons.

First, tiered pricing is simply "business as usual" in many industries, including the pharmaceutical industry, as taking into account both the willingness and ability to pay of populations in different countries is a way of gaining and maximising market access. However, the role of the Index is not to recognise companies' commercial pricing strategies, but rather to focus on pricing strategies that explicitly aim to reach the poorest people who lack access to medicine. For these segments, it is important that companies do not take advantage of the inelastic nature of the demand for health, which as a necessity commands a high willingness to pay, and instead focus on the poor's ability to pay and the other constraints they face.

Second, gauging the quality of pricing strategies across a highly diverse industry only on the basis of percentage discounts from developed country prices was deemed too arbitrary, especially when applied across hundreds of products.

Based on this thinking, in the 2014 Index, the standards for evaluation changed compared to the 2012 Index. Pricing strategies that lacked evidence of a clear affordability rationale and/or were not clearly and specifically targeted toward a relevant (low-income) population segment were excluded. In addition to inter-country and intra-country equitable tiered

pricing, which stipulate different prices for different countries or population segments, standards for inclusion were expanded to include more types of strategies, including tenders, single-product, single-country discounts, volume-based discounts and patient-assistance cards.

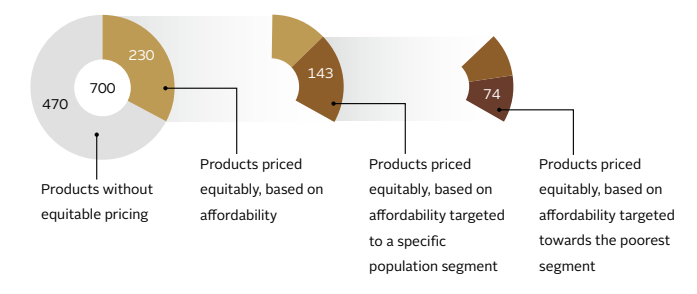
Affordability considerations

Eighteen out of 20 companies analysed by the Index implement some form of equitable pricing for relevant products in relevant countries. Combined, one-third of all relevant marketed products captured by the 2014 Index (230 out of 700 products) were found to be covered by equitable pricing strategies. In turn, one-third of these products (74 out of 230) were found to be targeted toward the poorest population segment, indicating that companies still have a distance to go in terms of pricing strategies to ensure access for the poorest.

More tailored pricing strategies

Intra-country strategies are considered more important than inter-country strategies as they target specific segments within countries, taking into account in-country inequalities, rather than relying on average national income figures. Although intra-country strategies only accounted for 21 percent of all pricing strategies captured by the Index, encouragingly, four companies newly implemented such strategies in Index 2014, suggesting a trend toward more tailored strategies.

For the first time, the Index measured companies' specific activity in middle-income countries and found that 43 percent of all equitable pricing strategies involved MiCs. Of these, 34 percent included intra-country targeting, which is important due to the significant socioeconomic inequalities often found in MiCs. Going forward, it will be interesting to see whether companies respond to the call from the global health community to increasingly segment populations within MiCs rather than categorising them based on GDP.



Socioeconomic factors drive equitable pricing strategies

The Index found that the most comprehensive equitable pricing strategies take multiple factors into account when determining access; discounts from developed country prices are not enough. This means they can be customised to the needs of specific target population groups in terms of affordability and other socioeconomic factors. Specifically, the following were some of the most common responses by companies on the factors that form their pricing strategies.

Decision-making factor	No. of companies who take it into account during pricing decisions
Ability to pay/income level: country level	18
Ability to pay/income level: within country	14
Measures for preventing product diversion	12
Patient education/awareness	8
Disease burden/prevalence	7
Patient assistance/ access programmes	5
Country public financing/ reimbursement	5
Cost recoupment pricing	4
Type of supply chains within country	3
Country's regulatory system	3
No profit pricing	2

This table is not exhaustive but nevertheless, the variety of factors and range of companies that use them show how diverse the industry is in its pricing behaviour. The next step in an analysis of this data is to examine which socioeconomic factors are applied to different pricing strategies according to the geographic locations, diseases and product types.

Conclusion

Access is a multifaceted problem that requires problem-solving across a range of different areas involving multiple actors. Depending on product characteristics and market attributes, fostering competition through licensing and donations can be a more appropriate strategy than equitable pricing. However, for originator and generic products alike, ensuring the products are affordable is of high importance to improve access to medicine for the poor. It is important to acknowledge that setting the end price may be beyond the control of the company. Nevertheless, pharmaceutical companies can still have influence on key sections of the supply chain, whether they sell their products to the public or private sectors.

There is significant room for pharmaceutical companies to improve in the area of pricing as measured by the Index. Companies can ensure that existing equitable pricing strategies are targeted toward poor population segments, within countries. They can also broaden the application of equitable pricing to more marketed products for which it is an appropriate strategy. The Index found that leaders in this area do provide evidence of following these practices.

Although there is still a need for a global consensus on what constitutes access-oriented pricing, the Index provides a framework of equitable pricing for companies to be measured against. It is clear that in order to increase access to medicine, companies' pricing policies need to move beyond conventional tiered pricing and focus on the needs of the local populations, targeting poor segments within developing countries and taking into account not just their ability to pay but other socioeconomic factors that impact their access to medicine.

Tara Prasad is lead researcher with the Access to Medicine Index

CHAI as a Disruptive Market Force

Ensuring access means more than getting the right drugs to the right people at the right time

By David Ripin and Danielle Kuczynski

Part 1 — Published January 12, 2015

Lack of access to medicines is an issue of life and death, with far-reaching impact on individuals around the world:

- The proportion of children with malaria receiving Artemisinin-based Combination Therapies (ACT) was only 16 percent between 2010-12. Of the 627,000 malaria deaths in 2012, 77 percent were children under the age of 5.
- In 2013, it was estimated that there were 3.2 million children living with HIV and that 240,000 become infected every year. Only 24 percent of all children living with HIV are on Antiretroviral Treatment (ART).
- Approximately 29 percent of global deaths of children younger than 5 are vaccine preventable. While routine immunization schedules are improving through the addition of new vaccines, the cost of vaccinating a child has increased 20 fold since 2001.

Why market shaping?

By actively engaging stakeholders on the supply and demand sides of the market, we can help overcome access challenges and get health care commodities to the people who need them the most. One logic trap about health programming is that lack of funds is the biggest barrier to treating more patients and increasing global impact. This argument overlooks the fact that existing programming dollars can yield additional value if they are invested in low-cost, high-efficacy commodities. Without external interventions, markets for health commodities may contain inefficiencies that prevent optimal value for money from being realized. The Clinton Health Access Initiative (CHAI) Access team works to address this issue through market-based solutions that improve the returns on health investments by focusing on a leading cause of inefficiency: high prices for medicines and diagnostics.

Ensuring access means not just that the right drug or diagnostic gets to the right people at the right time. It also means getting the commodities for the right price to maximize donor and domestic resources, ensuring a sustainable market, and making sure that the health benefits of those commodities are realized without unnecessary wastage. Information transparency is a critical component to a market-shaping approach. Partners on both the supplier (i.e. pharmaceutical and diagnostic companies) and buyer (i.e. demand from national treatment programs) sides have become highly sophisticated and evidence-based. Good decision-making is contingent upon these partners accessing all data necessary to come to a solid understanding of tradeoffs of different courses of action, including costs and benefits to using available or potentially available products at potentially achievable prices. To the extent possible, CHAI helps ensure that both parties have the information that they need to make informed decisions.

When CHAI began in 2002, our mission was focused on addressing the HIV/AIDS crisis in low- and middle-income countries by increasing access to diagnosis and treatment through market-shaping interventions. At the time, only about 100,000 people living with HIV were on treatment outside of Latin America and the Caribbean, and prices for Antiretroviral (ARV) drugs used to combat HIV were far too high for most low- and middle-income countries to scale up treatment to the patients who needed it. By June 2014, 13.6 million people were on treatment and annual per-patient ARV costs were as low as $100-$150. CHAI helped facilitate this progress by working with pharmaceutical companies to lower drug and diagnostic prices, as well as countries and global buyers to ensure uptake. Today, 8.2 million people in more than 70 countries have access to CHAI-negotiated prices for HIV/AIDS medicines.

CHAI's work has since evolved to address drug and commodity access issues in health areas beyond HIV. These areas include TB, family planning, maternal and child health (MCH) commodities, vaccines, malaria and other infectious diseases. Through this work, CHAI aims to optimize patient health outcomes while improving the effectiveness of health investments.

How CHAI shapes markets

CHAI works on both supply- and demand-side market issues in order to achieve an impact that is larger than what would be achieved if we worked on one dimension alone. CHAI's approach is supported by like-minded donors including UNITAID, the UK Department for International Development (DFID) and the Bill and Melinda Gates Foundation, and enables CHAI to act as a disruptive market force.

CHAI takes the following steps to help shape markets:

1) Analyze market failure. CHAI first assesses the supply-

and demand-side drivers that are contributing to a particular market failure. Potential drivers of market failure may include information asymmetry, a low-volume/high-cost market trap, inefficient manufacturing processes, insufficient production capacity or fragmented demand.

2) Identify high-potential interventions. Once CHAI identifies the causes of a market failure, a market scoping analysis is conducted to identify high-potential and targeted interventions that could be leveraged to address this failure.

3) Identify specific manufacturers to target. On the supply side, CHAI undertakes a discovery phase to assess potential manufacturing partners and prioritize engagements. The evaluation is based on criteria established in steps one and two, and includes deeper analysis and scoping of relevant manufacturers and products suited to address the market failure.

4) Develop and implement focused strategies. CHAI then develops supply- and demand-side strategies that will help stimulate or improve the efficiency of a specific market. Market intelligence is also used to provide a compelling case for engagement, where we work with parties to implement supply- and demand-side market shaping strategies.

The supply-side strategies that CHAI employs include:

- Improving efficiency through scale. Working with suppliers to spread capital, research and development, and operating costs over higher volumes helps to lower production costs per unit. Automation may also help lower unit costs at scale. These lower costs can in turn be linked to lower prices for developing country buyers.
- Improving capacity utilization. If a factory runs at less than 100 percent capacity or at unpredictable levels from week to week, the costs of production, storage and raw materials can go up. One way to address this issue is to improve access to market information. Demand forecasts made possible by our partnerships with governments lead to predictable order flows and ultimately reduce costs.
- Mitigating market risk. Companies often add a premium to their pricing when they lack confidence in conventional market mechanisms. A number of approaches can be taken to minimize risk to different players in the market, including volume guarantees.
- Lowering barriers to market entry. Existing monopolies, extensive quality certification requirements and other market conditions can act as barriers to market entry for manufacturers. Providing market intelligence, supporting business case development and facilitating certification can dramatically lessen manufacturers' aversion to market entry.

On the demand side, CHAI employs strategies such as:

- Supporting in-country adoption. New health commodity product adoption in-country often requires consensus building by key decision makers and leaders. CHAI works closely with government partners to support both the initial advocacy and the ultimate follow through to development of national guidelines, testing algorithms and training requirements, to support the introduction of new health commodities.
- Strengthening country systems. Changes often need to be made to in-country systems in order for governments to be able to handle increased product volumes, introduce a new product or switch efficiently from one product to another. CHAI supports this by helping to improve forcasting, quantification, procurement and data management systems and enhancing the capacity of supply chains, labs and health care professionals.
- Generating demand. When new products enter the market, communication strategies or targeted outreach is often needed to ensure that governments, implementing partners, clinicians and key populations are aware of product availability and benefits. CHAI works to increase the awareness of these stakeholders.

CHAI remains engaged in market shaping because we see it as an important complement to other global health approaches, and because our strong partnerships with governments, donors and private sector counterparts make us strategically well placed to understand the landscape and effect change. Attempting to shape markets without the insight and trust of our partners would result in limited success. In our next post, we will discuss further how these complex and dynamic partnerships have led to successes and elaborate on existing opportunities and challenges within the market-shaping space.

Part 2 — Published January 13, 2015

The Clinton Health Access Initiative (CHAI) partners with governments, donors, manufacturers and other organizations to implement market-shaping interventions that help to improve health outcomes. "Market shaping" means working in a coordinated way with stakeholders across both the supply and demand sides of the market to ensure that appropriate, affordable and high-quality health commodities get to the people who need them at the right time. Successful market shaping can lead to improved access to health commodities, which results in better patient outcomes and significant cost savings. These cost savings in turn free up critical resources that can be reinvested in health systems so that more people get the life-saving commodities that they need for the same amount of money.

Shaping markets is done in partnership with organizations on the supply and demand sides of a given market, as well as a market-shaping entity, which is an entity that influences incentives and/or mitigates risk to improve access to health commodities. A market shaper can either use a consensus process involving all parties interested in a given market, or can act independently of other parties in the market space. CHAI works with the philosophy that monopsony (or a market situation in which there is just one buyer) approaches to buying and market shaping can present risks to achieving a best possible market outcome much in the way monopoly supply situations can. We approach market shaping with a strategy of coordination with market players, collaboration where it adds value, and pursuit of approaches that, when combined with the efforts of other market actors, result in a better outcome for the overall market than any one of those interventions might be expected to achieve on its own in the absence of additional market pressures.

Current market challenges

Despite successes, a number of challenges remain in the market for health commodities. To name just a few:

- Several new HIV drugs offer significant advantages over existing alternatives, but are not yet available in developing countries that depend on the availability of generic formulations. This is largely due to the lack of a clear demand "signal" in the market that prompts manufacturers to develop these new products. Market interventions are needed to accelerate the pace at which products are developed and made available to patients in resource-limited countries.
- Price reductions allow countries to greatly expand their health programs, but demand for lower-priced commodities can quickly outstrip the production capacity of suppliers. For example, in the case of long-acting reversible contraceptives, reduced prices have resulted in much higher demand and manufacturers have struggled to keep up with the higher volumes. Interventions are needed to increase production capacity of existing suppliers and accelerate introduction of new suppliers into the market.
- A number of countries are graduating from GAVI support in the coming years, at which time many will no longer receive donor funding for vaccines. To make matters worse, these graduating countries may lose access to the reduced vaccine prices that manufacturers offer GAVI countries. To maintain current vaccination rates and ensure access to new vaccines, vaccine prices for these countries will need to remain low.
- New drugs are now available that offer a cure for Hepatitis C. These drugs are significantly better than the existing regimen of low-efficacy, complicated-to-administer drugs. However, the new drugs are prohibitively expensive. In the absence of market-shaping work, the cure will remain unattainable for most patients in developing countries.
- Campaigns to eliminate certain neglected tropical diseases will shrink and ultimately end the markets for the commodities required to achieve elimination. A coordinated approach will be necessary to ensure that sufficient tools are in place to complete those campaigns before suppliers choose to exit the market.

CHAI and our partners remain flexible to identifying and addressing oncoming challenges as they arise and when possible, to preemptively prevent them.

What has been gained from market shaping

A focused market-shaping approach remains a relatively young and rapidly evolving dimension of global health. While there is still much to be done, CHAI and our partners have demonstrated that market shaping can be used to impact health outcomes and achieve significant savings for governments and donors. Successes have been achieved across a number of product and disease areas.

One example is in the area of vaccines. Working with the Department for International Development (DFID), the Bill and Melinda Gates Foundation, WHO, GAVI and UNICEF, CHAI helped to secure a 45 percent reduction in the price of pentavalent vaccine, which will result in at least $225 million in savings over five years and allow a greater number of children to be immunized and a greater number of lives to be saved with existing funding. CHAI also helped these partners to secure a 67 percent reduction in the price of rotavirus vaccine, which will result in over $650 million in savings over five years. Finally, CHAI supported negotiations that secured a 56 percent reduction in the price of Inactivated Polio Vaccine, which will result in savings of at least $150 million over five years. Total savings across these three areas are estimated to be more than $1 billion, and will help offset the increasing costs to fully immunize a child, which have been rising with the ongoing introductions of new vaccines.

Gains were also made on viral load testing for HIV. South Africa is the largest purchaser of viral load tests in the world. In partnership with South Africa's National Health Laboratory Service (NHLS), UNAIDS, the Global Fund and the President's Emergency Plan for AIDS Relief (PEPFAR), CHAI worked with pharmceutical firm Roche to negotiate a reduction in the price of viral load testing. The agreement will benefit not only the 2.6 million people on treatment in South Africa, but also millions more receiving Antiretroviral Therapy (ART) across sub-Saharan Africa and beyond. Prices were reduced on average by more than 40 percent, and the agreement is expected to save more than $150 million over the next five years.

In order to achieve and sustain market-shaping success, CHAI engages directly with country partners. Doing so, CHAI ensures the timely development of and rapid patient access to high-quality health commodities. For example, despite widespread availability of pediatric ART fixed-dose combinations (FDCs) in 2008, uptake remained low in most countries. What was required, beyond the simple availability of the products in the market, was a rapid, time-limited focus on the key elements of product uptake: adoption, product registration, procurement, uptake planning and execution, and uptake monitoring. In countries such as Uganda, where this approach was used, pediatric FDC uptake increased from 17 percent of eligible children to 100 percent over just two years.

Many other partners use innovative approaches to help shape markets. UNITAID is a global health initiative that is in part financed by a solidarity levy on airline tickets. Working with partners like CHAI, UNITAID helps to identify market shortcomings for life-saving commodities and support time-limited, targeted interventions to facilitate greater access to those commodities. These interventions can take a number of different forms, including helping to accelerate market entry of improved products, supporting demand-side activities to help countries adopt better technologies and create a global market for those technologies, and fostering market competition to drive down prices. Gains from interventions, such as reduced prices and increased availability of more cost-effective products, help to bring down overall treatment costs and ensure other large donors utilize their funds more efficiently. UNITAID's approach is catalytic and has led to important results. For example, UNITAID's support jump-started the pediatric ARV and diagnostics markets and helped more than 125,700 children gain access to treatment by the end of 2006, up from 71,500 in 2005. By 2012, 647,000

children under 15 years of age were receiving ARV's.

The future of market shaping

There is a constant need to innovate in response to emerging market forces and changing market conditions. Flexibility to adapt to new constraints is critical, as is the need to put in place mechanisms that are themselves sustainable and resistant to market fluctuation.

Partners such as DFID will continue to play a critical role in market shaping, with an emphasis on maximizing the impact of each pound that they spend to improve the lives of poor people. DFID funds pioneering market-shaping work for essential health commodities such as medicines, vaccines, diagnostics and contraceptives, which helps organizations and governments allocate their funding more efficiently and enhances access for those most in need. Moving forward, DFID also recognizes the need to develop relationships with emerging powers like China, India, South Africa and the Persian Gulf, while still building and strengthening relationships with other entities. DFID expects that collaborating with emerging powers will help to make development assistance more effective; enhance the development impact of investment in poorer countries and regions; respond better to global challenges; and help develop an international system that more aptly reflects the needs of poor countries.

The next few years of market-shaping work at CHAI presents an opportunity to expand on lessons learned and address new challenges where they arise. We at CHAI hope to use market shaping to have an impact that is sustainable, responsive, and ultimately works us out of a job.

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