Identifying Ways to Support the Informed Introduction of New Health Technologies in Developing Countries

A report to the UK Department for International Development

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PATH

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Abbreviations

AA	Artemether-amodioquine
ACT	Artemisinin-based combination therapy
AL	Artemether-lumefantrine
ART	Antiretroviral therapy
AVI	Accelerated Vaccine Introduction Initiative
BERR	UK Department of Business, Enterprise, and Regulatory Reform
BPR	Business process re-engineering
DDF	Department of Drugs and Food
DG SANCO	Directorate-General for Health and Consumers
DOTS	Directly observed therapy
G-FINDER	Global Funding of Innovation for Neglected Diseases
HSP2	Health strategic plan 2
LMIC	Low- and middle-income
MDG	Millennium Development Goal
MOH	Ministry of health
NGO	Nongovernmental organization
NHSP	National health strategic plan
PDP	Product development partnerships
PRA	Pharmaceutical regulatory authority
R&D	Research and development
TB	Tuberculosis
TWG	Technical working group
UK	United Kingdom
WHO	World Health Organization

Executive Summary

In 2010 PATH received a grant from the United Kingdom (UK) Department for International Development to support a project to examine the factors that affect how new health technology products are introduced and adopted in developing countries. The goal was to increase opportunities for new products to help improve health status in low- and middle-income countries (LMICs) through accelerated product adoption. We hypothesized that achieving this goal requires improved interactions between the global health technology market and LMICs in the adoption of new products. In other words, the market needs to provide products that meet country needs, and countries need to be able to adopt products that meet their needs.

The study had three objectives: 1) To understand the market environment for global health technologies; 2) To understand how countries adopt new health products; and 3) To develop recommendations to support interactions between countries and the health technology market.

This project report has four sections: Section I) Global health technology market and low- and middle-income countries; Section II) Seven principles of country empowerment in the global health technology market; Section III) Three country case studies on health product adoption; and Section IV) Conclusions and next steps.

Section I: Global health technology market and low- and middle-income countries

The past decade has seen increased investment in research and development (R&D) activities for products targeting neglected diseases. In 2005, Moran noted increased investment in R&D for drugs targeted at neglected diseases and predicted that the change would not be a passing trend but a sign of structural changes in global health technology development (Moran 2005). The Global Funding of Innovation for Neglected Diseases (G-FINDER) report, which has surveyed annual investments in neglected disease R&D since 2007, has reported steady investment increases from US$2.56 billion in 2007 to $3.2 billion in 2009 (adjusted to 2007 US dollars) (Policy Cures 2011).

Public-private partnerships for product development, or product development partnerships (PDPs), have become prominent in the R&D for neglected diseases. For example, Moran reported that three-quarters of all identified R&D projects in 2005 were classified as PDPs that involved both large and small private-sector partners (Moran 2005). A PDP in the context of global health is defined as a nonprofit organization established in partnership between the public and private sectors with a mandate to research, develop, and support accessibility of new health technologies that target diseases disproportionately affecting developing countries (Brooks 2010; IAVI 2010).

In addition to PDPs, many public- and private-sector entities, including pharmaceutical companies, academic institutions, nonprofit organizations, and start-up technology companies, are actively involved

in R&D for neglected diseases and other health conditions in developing countries. Increased investment into neglected disease R&D has increased the volume of new products in the pipeline. Not all product candidates will successfully make it to market, but thanks to the increase in pipeline products, the number of products with promising impact on health for developing countries likely will increase in the near future.

For new products to impact the health status of target countries, their health systems need to adopt the products for use by intended populations. To help ensure products reach intended populations and impact public health, researchers, funding and technical organizations, and PDPs have proposed frameworks and pathways to promote access. Efforts to facilitate the introduction and use of new global health technology products are not limited to PDPs. Some efforts focus on advocacy, research, and technical assistance for the adoption of new products by countries. These frameworks, guidelines, and approaches share certain commonalities. A key underlying theme is how to convince countries to adopt new products. Other repeated themes include development of products that fill expressed or perceived needs of countries, dissemination of product information, articulation of users' needs, branding through global endorsements, subsidization through financing support, and supporting procurement and logistics.

The global health technology market and role of national governments

For our study, we defined the global health technology market as the market for new and existing technology products intended to address health demands in the developing world. Roberts and Reich note three potential problem areas in the global pharmaceutical sector: demand-side shortcomings, supply-side shortcomings, and government shortcomings. These shortcomings increase the complexity of the global health market and the difficulty in grasping and engaging with its structure. In this section we focused on the role of LMIC governments in the global health technology market and how to support their interactions with this market, and proposed viewing national governments as consumers of global health technology products.

Specific market and government shortcomings can place national governments in LMICs in a relatively weak position in comparison to other actors in the global health technology market. National governments, as consumers of new global health products, need specific skills and knowledge to ensure they can navigate the market and products with high informational transactional costs. A global or regional mechanism to support governments in building and exercising their skills and knowledge would help empower national governments as consumers.

We proposed the following definition of empowerment of national governments in the context of the global health technology market:

> *Empowerment is a national government's ability to exercise greater control in choosing among global health products to intentionally produce desired health outcomes aligned with the goals of the country's health system.*

This definition implies that empowering governments requires two kinds of global mechanisms: one to advise, inform, and build capacity, and another to monitor and regulate market practices that might increase the potential for consumer detriment. The definition also implies that governments should have the ability to control the list of products from which they choose based on their own health needs and goals.

Section II: Seven principles of empowerment of national governments in the global health technology market

We conducted 24 in-depth interviews with persons involved in the global health technology market and used insights gained to develop a framework to assess the strength of country empowerment in this market. Interview respondents included representatives of donor agencies, academic institutions, nongovernmental organizations, international technical agencies, and product researchers and developers, including PDPs. Secondary data on product development activities were collected through Internet searches and a review of published literature.

Based on the proposed definition of empowerment of national governments in the context of the global health technology market, we proposed seven principles of national government empowerment to reduce the risk of structural detriments in the market (see Table 1).

Table 1. Seven principles of national government empowerment.

Principle	Description
1. Information on Technologies	Standardized information on new and existing health technologies should be systematically made available to countries.
2. Advice Channels	Good-quality advice channels for countries should be easily accessible.
3. Country Capacity Strengthening	Global mechanisms should exist to strengthen country capacity to collect, interpret, and translate relevant information for decision-making.
4. Country Choices	Countries should be able to make technology adoption decisions from a choice set rather than one product at time.
5. Country Networks	Information-sharing networks should exist among countries for exchange of information on product implementation, quality, and trade practices.
6. Country Representation	The interests of countries as consumers of health technologies should be represented in the processes for shaping the global health technology market.
7. Monitoring Market	Global mechanisms should be in place to monitor and regulate practices that would negatively affect incentives for innovation in the global health technology market.

Finally, we have given special consideration to access to information and advice channels for national governments that are especially vulnerable. These governments include those with small populations or that are under conflict or are fragile in other ways. We consider the special attention needed for governments of vulnerable countries a subset of principles 1, 2, and 3.

Section III: Country case studies

An interview-based, qualitative study was carried out to understand the experiences of low-income countries with technology adoption and their interactions with the global health technology market. The research sought to identify the different ways that low-income countries learn about new health products and to describe how they assess, adopt, and integrate new products into their health systems. Additionally, the research sought to understand the range of stakeholders involved in this process and to describe their roles. Finally, the research explored the perspectives of country-level stakeholders on their interactions with the global health technology market and whether specific mechanisms at the global, national, or regional levels support countries in product adoption.

The research involved 40 in-depth interviews with country-level stakeholders in a convenience sample of three low-income countries: Cambodia, Ethiopia, and Zambia. The three countries presented diverse health demographics and health status, socio-cultural backgrounds, and different health systems supported by different sources and mixes of financing.

For the country case study, we define the technology adoption process as the set of activities and actors involved in identifying, assessing, choosing, and integrating health products into health systems. The research did not examine whether or how the adopted technologies were used and the resulting health impact. The researchers used an open-ended interview guide based on a series of ten questions. The instrument allowed for semi-structured, stakeholder-led interviews focused on: the process of technology adoption, the criteria that influence decisions to adopt, the alignment of technology decisions to national health goals, the sources of product information and their availability, the stakeholders who play a role in national-level technology decisions, and the sufficiency of this process for present and future health system needs.

The researchers analyzed the qualitative data using thematic analysis. This report presents seven shared themes to illuminate country-level stakeholder perspectives on the health technology adoption process in their countries and their experiences with the global health technology market. We acknowledge some biases in the collection of data among the countries, such as organizational affiliations of respondents. These methodological issues, along with the small sample size of the study, mean that the research cannot claim to be generalizable to all low-income countries. We also note that the data represent stakeholder opinion. This assumption of the subjectivity of interview data differentiates qualitative research from information-gathering, which often treats stakeholder statements as objective facts. The findings of this study should be seen as a set of issues to be considered when product development partnerships or other new product advocates approach national-level stakeholders. The findings are not intended as a formal guide to adoption, and the researchers acknowledge that any findings herein may be colored by informant perception and subject to change over time. At the same time, the variety of stakeholders interviewed, their long histories of participation in health technology adoption decisions across both public- and private-sector institutions, and their present role as advocates, funders, implementers, and champions of

new health products in their respective countries supports the authenticity of the common themes and opinions derived from the research.

We identified a set of seven shared themes that help define the policies, processes, and pathways the three countries use to assess, adopt, and integrate new health products into their health systems:

1. Ministries of health, their donors, and technical partners in all three countries align their adoption of new health products to existing policies, strategies, and guidelines. It is unclear whether policy alignment is leading the decision to adopt, or the decision to adopt is being justified by policy.

2. Ministries of health in low-income countries access information about new health products through at least four information pathways. These pathways are not mutually exclusive. Global and regional consultations, workshops, and partner-led dissemination are the most important sources of information on new health products. Other sources are readily available if MOH officials have the capacity and initiative to use them.

- Pathway 1: Global and regional consultations, meetings, and workshops
- Pathway 2: Product manufacturers
- Pathway 3: Partner-led interventions at the country level
- Pathway 4: Internal technical working group discussions

3. World Health Organization (WHO) endorsement plays a major role in ministry of health decision-making on adoption. Endorsement can take several forms and is often enough by itself for the ministry to adopt. However, if the technology is controversial within a country, or if a country is a slow adopter, then evidence generated by a local pilot is a key factor in adoption.

4. Ministries of health are primarily concerned with effectiveness, safety, quality, and availability of financing, and the product's relevance in relation to the burden of disease. Cost is also important, although in all three countries, governments will often prioritize quality and potential impact ahead of cost, particularly if products are already linked to a funding stream. Nevertheless, even products meeting all these criteria need a ministry champion to move forward.

5. Ministries of health are generally open to adopting new products that have technical leadership, proof-of-concept (including pilot studies), and financing. Most decisions to adopt health products are ad hoc, with decisions made product by product and program by program. Many stakeholders see this model of technology adoption as acceptable.

6. Regulatory authorities can be important gatekeepers for new health products, but in countries where regulatory authorities are independent from the ministry of health, the relationship between the two institutions may create tensions in the technology adoption process.

7. Mechanisms to conduct health technology assessment may already exist within ministries of health in low-income countries, but it is unlikely that they have the capacity to assess value for money. Stakeholders agree that technology assessment and cost-effectiveness data are vital to planning, but many

were doubtful about the usefulness and sustainability of placing a designated technology assessment unit within the Ministry of Health.

The health sectors of Cambodia, Ethiopia, and Zambia have notable differences. Cambodia is a relatively late adopter of new technology and requires a critical mass of evidence (including pilot studies) before taking new products on board. Zambia adopts products early and historically has moved ahead with products prior to their inclusion on the national essential drugs list and formulary. Ethiopia is in the middle of these two models, with product adoption a sometimes complex process that requires champions at the most senior levels of the Ministry of Health.

Still, the case studies illustrate commonalities across the three countries. The following six themes emerged from the research:

1. There is little evidence in the three countries of proactive, strategic, health systems-oriented planning for new product adoption over the long term. Most health-product decisions are made according to an ad hoc, product-by-product, program-by-program model. National disease-control programs and other vertically organized initiatives tend to have more resources, greater administrative capacity, and increased accountability to funding agencies with regard to strategic planning. Further technology-focused case studies in a larger sample of countries are required to understand whether these factors play a significant role in expediting adoption of particular health products. Nevertheless, interviews suggest that a long-term, systems-oriented approach to new health-product adoption, even in these vertical programs, is still unrealized.
2. Technology adoption decisions in the three countries are presently supported by external parties. This does not mean that external parties determine what products the ministries adopt, rather that information and evidence on effectiveness of new products primarily comes from external parties. WHO, in particular, plays a major role. The global office provides guidance and standards for adoption. Regional offices provide information and links to evidence. Country-level WHO headquarters provide technical assistance toward adoption and implementation. External guarantees by donors and partners for both financing and technical support toward procurement and implementation also greatly facilitate and expedite decision-making. It is likely, too, that any sort of health technology assessment unit or mechanism placed within a ministry of health would require substantial external support.
3. Stakeholders in these three low-income countries have various pathways to obtain information on health products. Global consultations, meetings, and workshops are one important pathway. Technical working groups, nonprofits, technical agencies, and manufacturers provide other pathways for the identification, evaluation, recommendation, and implementation of new health products. These pathways do not provide information systematically or in standardized ways.
4. In the three countries, Millennium Development Goals significantly influenced the structure of national health plans, which in turn influenced both short- and medium-term planning and management around health product adoption. The focus on these global targets, rather than cross-cutting health systems issues, may restrict decision-makers' abilities to consider long-term, health-system-wide product adoption.
5. Many stakeholders in the three countries welcome more country-level health technology assessment, especially in the area of value for money and cost-effectiveness. However, many are not able to conceptualize what a health technology assessment unit would involve or where it would be located. They doubt the usefulness of creating additional layers of bureaucracy and express concern about sustainability if created with external financing. A country-level health

technology assessment mechanism is, moreover, an idea that would require "selling" to the ministry of health because its representatives may feel the current model of health product adoption is acceptable.

6. Many stakeholders in the three countries do not feel that health technology adoption is the key access issue. Rather, stakeholders perceive the access bottleneck to be capacity to finance and implement after product adoption. This view may reflect the fact that national-level stakeholders are tasked with implementation and do not have a broad perspective on new product pipelines. However, there are many examples of products that ministries of health have adopted quickly and easily but that remain unavailable to end users. Most low-income countries face severe financing and systems constraints and are subject to donor conditions and priorities. Many stakeholders believe that procurement, delivery, and integration remain the biggest challenges to new technology access, rather than the assessment and adoption process.

This qualitative study in three countries was carried out to understand the experiences of low-income countries with technology adoption and their interactions with the global health technology market. As the study was designed to be exploratory, and the sample size was small and not representative of all low-income countries, the findings must be interpreted with caution. They do, however, provide a starting point for understanding how low-income countries learn about new health products, the process by which they assess, adopt, and integrate new products into their health systems, and their interactions with the global health technology market. The findings also help identify questions for future research on technology adoption and the global health technology market.

Introduction

In 2010 PATH received a grant from the United Kingdom (UK) Department for International Development to support a project to examine the factors that affect how new health technology products are introduced and adopted in developing countries. The goal was to increase opportunities for new products to help improve health status in low- and middle-income countries (LMICs) through accelerated product adoption. We hypothesized that achieving this goal requires improved interactions between the global health technology market and LMICs in the adoption of new products. In other words, the market needs to provide products that meet country needs, and countries need to be able to adopt products that meet their needs.

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Section I: Global health technology market and low- and middle-income countries

Investments in global health technology product development

The past decade has seen increased investment in research and development (R&D) activities for products targeting neglected diseases. This investment has intensified with growing awareness of the mismatch between the need for new health technologies to address disease burden in developing countries and the private sector's general lack of willingness and interest to invest in meeting those needs (Widdus 2005; Brooke 2010; IAVI 2010).

Neglected diseases primarily affect poor people in low-income countries and, until recently, had been traditionally perceived as a low priority for R&D investment by both the public and private sectors, despite their public health importance (Caines 2004). However, the R&D investment landscape for neglected diseases has been steadily improving in the last decade. In 2005, Moran noted increased investment in R&D for drugs targeted at neglected diseases and predicted that the change would not be a passing trend but a sign of structural changes in global health technology development (Moran 2005). The G-FINDER report, which has surveyed annual investments in neglected disease R&D since 2007, has

reported steady investment increases from US$2.56 billion in 2007 to $3.2 billion in 2009 (adjusted to 2007 US dollars) (Policy Cures 2011).

While private-sector R&D funding steadily increased from 2007 to 2009 (Policy Cures 2011), major portion of it often happens in the context of public-private partnerships for product development or product development partnerships (PDPs). For example, Moran reported that three-quarters of all identified R&D projects in 2005 were classified as PDPs that involved both large and small private-sector partners (Moran 2005). A PDP in the context of global health is defined as a nonprofit organization established in partnership between the public and private sectors with a mandate to research, develop, and support accessibility of new health technologies that target diseases disproportionately affecting developing countries (Brooks 2010; IAVI 2010). Health technologies targeted by such PDPs encompass different technology product groups, such as drugs, vaccines, new medical devices, and diagnostics. Although PDPs are a relatively recent addition to global health assistance, they have gained prominence since 2000 with increased funding from private foundations such as the Bill & Melinda Gates Foundation. The Gates Foundation was the largest funder of PDPs in 2008 and 2009, accounting for about 50 percent of PDP funding (Ziemba 2005, Grace 2009, Guzman 2010). A product developer landscape report by BIO Ventures for Global Health reported 26 unique PDPs for global health technologies in its 2012 report (Ponder 2012).

In addition to PDPs, many public- and private-sector entities, including pharmaceutical companies, academic institutions, nonprofit organizations, and start-up technology companies, are actively involved in R&D for neglected diseases and other health conditions in developing countries. For example, according to Jeff Bernson, director of the Monitoring and Evaluation Department at PATH, the international nonprofit organization had about 130 candidate products or related projects in its 2010 portfolio of technologies, many funded through mechanisms other than PDPs. Government entities, such as the US National Institutes of Health and UK Medical Research Council often fund their own research and external researchers and developers working to develop global health technology products (Policy Cures 2011).

Increased investment into neglected disease R&D has increased the volume of new products in the pipeline. The 2010 G-FINDER report identified 122 candidates in PDP development pipelines. Cohen and colleagues reported 97 products in clinical development as of July 2009 (Cohen 2010). Another article reported that in 2009, PDPs had nearly 150 biopharmaceutical, diagnostic, and vector control candidates in various stages of development (IAVI 2010). While these numbers do not match because of differences in definitions and types of products examined, the reports clearly confirm a lot of technology investment activity. Not all candidates will successfully make it to market, but thanks to the increase in PDP pipeline products, it is likely that the number of products available with promising impact on health for developing countries will increase in the near future.

Frameworks of health product introduction and adoption

For new products to impact the health status of target countries, their health systems need to adopt the products for use by intended populations. According to Frost and Reich, potential barriers to adoption include financial resource constraints, limited capacity of public health systems, lack of political commitment to distribute and deliver products and services, international trade and patent disputes, and cultural attitudes toward diseases and products to remedy or prevent disease (Frost 2008).

To help ensure products reach intended populations and impact public health, researchers, funding and technical organizations, and PDPs have proposed several frameworks and pathways to promote access. For example, Frost and Reich proposed an access framework that organizes key processes into four categories (architecture, availability, affordability, and adoption) and four phases of access (product development, introduction, scale-up, and sustaining access) (Frost 2008). The Stop TB Partnership and the World Health Organization (WHO) jointly published a framework in 2007 for the adoption, introduction, and implementation of new tuberculosis (TB) control technology (WHO 2007). Similarly, the Malaria Vaccine Technology Roadmap working group published its roadmap (MVTR WG 2006).

Efforts to facilitate the introduction and use of new global health technology products are not limited to PDPs. Some efforts focus on advocacy, research, and technical assistance for the adoption of new products by countries. For example, the Hib Initiative and the GAVI Alliance's Accelerated Vaccine Introduction Initiative (AVI) have focused their assistance on country decision-making in introducing new vaccines.

Product developers and advocates are improving their understanding of the issues that affect country access to new health technologies and are increasing efforts to coordinate their actions. In 2008, 12 PDPs formed the PDP Access Steering Committee to facilitate information-sharing in the area of product access. Brooks and colleagues defined access in a PDP context as "a set of coordinated activities needed to ensure that the products developed will ultimately have an equitable public health impact (Wells 2010)." Building on the definition, the committee reviewed access strategies used by various PDPs and organized a symposium in July 2010. The committee found that PDPs largely lack definitions of success for their access work, and PDPs varied in the degree of comprehensiveness and the approach for their access strategies. It also found that many PDPs consider the provision of technical support to a country's decision-makers to be an important activity to facilitate access to new products but acknowledged that they had limited capability to reach all countries that might benefit from their technologies (Wells 2010). The symposium report concluded with four proposed areas of activities to improve coordination among PDPs and their partners: the analysis of access options, information-sharing among PDPs related to access, the establishment of joint research or implementation projects, and the convening of conferences and working groups (Concept Foundation 2009).

These frameworks, guidelines, and approaches share certain commonalities. A key underlying theme is how to convince countries to adopt new products. Other repeated themes include development of products that fill expressed or perceived needs of countries, dissemination of product information, articulation of

users' needs, branding through global endorsements, subsidization through financing support, and supporting procurement and logistics.

Characteristics of the global health technology market

For our study, we defined the global health technology market as the market for new and existing technology products intended to address health demands in the developing world. At the simplest level, a market is a place, system, or a process where parties engage in the exchange of goods, services, and information by barter, often between goods/services and money. Roberts and Reich analyzed the global market for pharmaceuticals from the perspective of both market failures and government failures. They noted that the concept of market failure derives from economic theory about perfect competition, which assumes market characteristics such as perfect information on products for buyers and sellers, no entry and exit barriers, homogenous products, and no transaction costs. They classified problems in the global pharmaceutical sector into three groups: demand-side shortcomings, supply-side shortcomings, and government shortcomings, as summarized here (Roberts 2011).

Demand-side shortcomings

- Buyers have limited knowledge and information, which may result in reliance on brand names, judgment of quality by observable characteristics, and reliance on sellers in decision-making.
- Buyers confront subsidized prices. In the perfect competition model, product prices reflect actual product costs, while in the global health market, some products are heavily subsidized.
- Buyers fail to consider external effects, where the adoption of public health goods by a buyer might influence others positively or negatively.

Supply-side shortcomings

- Limited price competition, which includes patent-based monopoly, oligopoly, and regulatory barriers to entry into the market.
- Product differentiation through advertising and marketing efforts to establish brand loyalty, which may unfairly influence buyer's decisions.
- Unfair trade practices, such as bribes, demand for exclusive market access, and intentional supply of substandard products.

Government shortcomings

- Government failures to set appropriate priorities.
- Government failures in the design of policies, so that they cannot achieve their intended objectives.
- Government failures to implement policies that have been adopted.

These market shortcomings and government shortcomings increase the complexity of the global health market and the difficulty in grasping and engaging with its structure. For example, buyers' limited knowledge and information may place them in a disadvantageous position in the market. In this section

we focused on the role of LMIC governments in the global health technology market and how to support their interactions with this market.

Role of national governments in the global health technology market

Ideally, a national government should make its own independent decisions to choose health products that best meet its national health needs in the context of its national priorities and health systems goals, (Widdus 2005; Hunter 2004) but other factors are at play. Chalkidou and colleagues describe how product adoption decisions are often driven by historical norms, priorities of foreign donors, and lobbying pressure (including corruption) (2010). Product developers, including PDPs, are likely to act as lobbyists for their own products in the national decision-making process; wanting to promote the public health impact of the products they develop (Wells 2011). Recognizing the importance of adoption decisions by national governments, they develop explicit or implicit access strategies for their particular products (Wells 2010).

While "adoption" is often treated as an event, past studies have shown that it is actually a lengthy process. For example, Meyer and Goes in 1988 proposed that decision-making in the assimilation of innovations involves three stages with nine steps (Table 2) (Meyer 1988). When a government goes through the stages of knowledge-awareness, evaluation-choice, and adoption-implementation for a new product, the process creates an interaction between the government and the global health technology market. Product developers might influence how government decision-makers and influencers learn about new products through marketing. International technical organizations might host a workshop or conference to discuss new products. Donor agencies might help the government develop proposals for product acquisition or support clinical trials. Throughout the process, the government needs to manage interactions with various actors and navigate the complex global health technology market to produce the desired outcomes.

Table 2. Meyer and Goes model of decision-making stages in the assimilation of medical innovations.

Knowledge–Awareness Stage
1. Apprehension: Individual organization members learn of an innovation's existence.
2. Consideration: Individuals consider the innovation's suitability for their organization.
3. Discussion: Individuals engage in conversations concerning adoption.
Evaluation-Choice Stage
4. Acquisition proposal: Adoption of equipment embodying the innovation is proposed formally.
5. Medical-fiscal evaluation: The proposed investment is evaluated according to medical and financial criteria
6. Political-strategic evaluation: The proposed investment is evaluated according to political and strategic criteria
Adoption-Implementation Stage
7. Trial: The equipment is purchased but still under trial evaluation.
8. Acceptance: The equipment becomes well accepted and frequently used.
9. Expansion: The equipment is expanded, upgraded, or replaced with a second-generation model.

National governments as consumers of health technology products

In this context, we propose to view national governments as *consumers* of global health technology products. While the term consumer is generally reserved for individuals, the concept also applies to public-sector bodies using goods and services (Europe Economics 2007).

When a public-sector body, such as the national government, seeks goods and services for the benefit of its citizens, it is considered to be acting as an instrument for people to act collectively (Europe Economics 2007). The ultimate consumer of a health product is usually the individual user (patient or health provider). However, most products in the global health technology market require some form of government sanction (e.g., approval or regulation) for use by the intended target population. These consumers will be exposed to products that are allowed or sanctioned by the government for use through the national health system. In this setting, the public-sector body is considered an agent of the principal (the intended individual consumers of the product). If the alignment of interests between the agent and the principal is clear, the government is considered an aggregate consumer in the global health technology market. A bad government decision about product adoption can create negative consequences for all individual consumers within the system. An important point is that public adoption processes tend to involve multiple stakeholders and formal and informal processes, as suggested in the medical innovation process by Meyers and Goes; consequently, the public process can be quite complicated. Also, a public body's decision to use a product does not translate to actual use by 100 percent of individuals under its jurisdiction (Europe Economics 2007). An example is vaccination—the decision by the public body to use a vaccine is unlikely to translate into 100 percent vaccination coverage. Many additional processes affect actual use by the end-user (including, for example, financing, supply chain operations, opportunity costs, social marketing, etc.)

Although the concept of consumer is closely linked to the concept of buyer and often these words are used synonymously, we make a distinction between these terms in considering the global health technology market. The buyer is an entity or individual that buys products, but being a buyer does not imply that the buyer is also the user of the product. On the other hand, the consumer is a user of the product but not necessarily the buyer. The product could be bought by a third party and given to a consumer. These third-party buyers in the global health technology market include nongovernmental organizations, bilateral and multilateral donors, and global health initiatives. Buying decisions by donors might happen independently of use decisions by governments. Sometimes, donor-funded projects or nongovernmental organizations buy and use new products through their service provider networks. In these cases, the entities are acting as both consumers and buyers in the global health technology market.

Identifying national governments as consumers also means that they face both demand-side shortcomings and government shortcomings, according to the classification by Roberts and Reich.

Characteristics of global health technology products

Specific market shortcomings and government shortcomings (such as lack of access to information, limited price competition, and weak implementation) can place national governments in LMICs in a relatively weak position in comparison to other actors in the global health technology market. For example, if governments do not have access to information on alternative products or full information about the product under consideration, they might decide to adopt an inappropriate product.

In the economics literature, the concept of "consumer detriment" is used to consider negative outcomes on consumer welfare. Consumer welfare is measured by consumer surplus, which is the difference between what a consumer is willing to pay for a product and what a consumer has to pay (Europe Economics 2007). A report on consumer detriment commissioned by the Directorate-General for Health and Consumers of the European Union (DG SANCO) identified two types of consumer detriments: personal detriment and structural detriment. Personal detriment means negative outcomes for individual consumers, while structural detriment means aggregated loss of consumer welfare due to market or regulatory failure (Europe Economics 2007). In the case of the global health technology market, characteristics that place national governments in a weak position (relative to other actors) lead to structural detriments. In the next section, we present a set of principles aimed at reducing structural detriments of the global health technology market.

Another way to consider detriment in a market was presented in a report prepared for the UK Department of Business, Enterprise, and Regulatory Reform (BERR). The report considered three types of detriment: appropriateness detriment, price detriment, and quality detriment. Appropriateness detriment means that consumers may not adopt the most appropriate product given their particular tastes and preferences. Price detriment occurs when consumers do not choose the product at the lowest price available to them. Quality detriment is when consumers adopt a product that is not of the quality they assumed beforehand (ESRC/BERR 2008). (*In this context, we modified the report's wording slightly, replacing the word "purchase" with "adopt" to be consistent with our definition of consumer.*) While avoidance of all three detriment types is relevant in the global health technology market, avoiding one detriment may mean compromising another. A country needs to be aware of trade-offs in its choices.

Consumers need information on products that they are interested in to gauge potential for experiencing detriments. Yet, the degree of information-gathering effort may vary significantly across products. Consumer goods can be classified into four categories based on the degree of consumer information-gathering effort required to observe potential utility of products: ordinary goods, search goods, experience goods, and credence goods (Dulleck 2011).

Ordinary goods (such as ballpoint pens) have well-known characteristics and consumers know where and how to get them. *Search goods* (such as computers) need to be inspected to observe their characteristics before a consumption decision. *Experience goods* (such as music CDs) have unknown characteristics that consumers can only measure through experience. *Credence goods* (such as a service provided by a car mechanic and high-end skincare products) have characteristics that consumers can only observe after

experiencing them; consumers cannot judge the type or quality of the good they receive before consumption, and they cannot even judge the quality and need after the experience (Dulleck 2006). Most new global health products are search or experience goods. Some products can be considered credence goods because countries rely on expert opinions in assessing their need, and measuring the health impact of the product is often difficult. Consumers must spend resources to gather and assess information when dealing with search, experience, and credence goods. The process of information gathering and assessment will create transaction costs. High informational transaction costs increase information asymmetry between sellers/manufacturers and consumers and create opportunities for detriment.

To ensure that national governments, as consumers of new global health products, are able to navigate the global health technology market and products with high informational transactional costs, and thus reduce the risk of structural detriments, they need specific skills and knowledge. A global or regional mechanism to support governments in building and exercising their skills and knowledge would help empower national governments as consumers. In high-income countries, for example, national government agencies regularly organize educational and dissemination events such as workshops and seminars to educate and disseminate information on products to sub-national government agencies.

According to Hunter and Garnefeld's literature review in 2008, consumer empowerment is generally defined in two ways (Hunter 2008). In the first definition, consumer empowerment gives power through resources, such as greater information or greater understanding. Second, the concept is defined as a subjective state, indicating the consumer's perception of increasing control (COI 2006). While the second definition is attractive in that it places importance on a country's subjective assessment of its state of empowerment, we consider the first definition to be more practical in analyzing the current state of the global health technology market.

As discussed earlier, information asymmetry and high informational transaction cost are factors that contribute to consumer detriment. Therefore, a key element for avoiding consumer detriment should be the availability of and access to product information by consumers. As proposed by Brennan and Coppack, we also believe that consumer skills need to be developed to collect, analyze, and process information (Brennan 2009). The BERR report indicated that consumer empowerment requires laws and institutional arrangements to advise, inform, and educate (ESRC/BERR 2008). National governments need a range of capabilities to access and analyze information to support decision-making when considering new and existing global health technology products. In some cases, institutional mechanisms would be critical to support countries in gaining necessary skills in the global health technology market.

The notion of structural detriment also suggests the importance of regulatory and institutional arrangements to monitor and regulate market practices that increase the potential for consumer detriment. Empowerment of national governments, therefore, should not be limited to information skills and capacity-building, but should also include global or regional mechanisms to monitor and regulate the practices of actors in the market.

Another important element of the definition of consumer empowerment is presented by Wathieu and colleagues, who argued that the ability to control (i.e., to expand as well as to constrain) the composition of a set of choices is a key determinant of the experience of empowerment (2002). When consumers are overloaded with options to choose from, the conflict which arises from the overload will lead consumers to defer choices. This suggests that simply enlarging the set of options alone does not increase the level of empowerment. This also requires a process whereby consumers can specify and express their preferences and adjust the choice options accordingly. For example, when national governments are presented with diagnostics products that encompass all price ranges and all laboratory set-ups, the choice set might become overwhelming for the governments to handle. However, if the government can articulate their preferences in price ranges based on their ability to purchase and maintain, then the choice set can be narrowed down to a more reasonable number of options.

Based on these arguments, we propose the following definition of empowerment of national governments in the context of the global health technology market:

> *Empowerment is a national government's ability to exercise greater control in choosing among global health products to intentionally produce desired health outcomes aligned with the goals of the country's health system.*

This definition implies that empowering governments requires two kinds of global* mechanisms: one to advise, inform, and build capacity, and another to monitor and regulate market practices that might increase the potential for consumer detriment. The definition also implies that governments should have the ability to control the list of products from which they choose based on their own health needs and goals.

Section II: Seven principles of empowerment of national governments in the global health technology market

We conducted 24 in-depth interviews with persons involved in the global health technology market and used insights gained to develop a framework to assess the strength of country empowerment in this market.

Interview respondents included representatives of donor agencies, academic institutions, nongovernmental organizations, international technical agencies, and product researchers and developers, including PDPs. All respondents were either directly involved in product development and advocacy or indirectly involved through funding, conducting related research, or advising countries on related subjects. Table 3 summarizes their background. The research team initially identified respondents through personal contacts or published literature. We also asked interviewees who they considered to be involved

* These mechanisms might be initiated regionally considering factors such as financial and technical resource availability, economic development, and sociocultural and political factors, but ultimately all LMICs should have equitable access to such mechanisms.

and knowledgeable in the global health technology market. Secondary data on product development activities were also collected through Internet searches and a review of published literature.

Table 3. Interview groups.

Interview groups	Number of interviews
Donor organizations	7
International technical agencies	5
Product developers, product development partnerships, suppliers, and advocates	9
Researchers and academics concerned with product R&D and adoption	3
Total	24

The researchers used an open-ended interview guide based on a series of six questions. The interview guide allowed for semi-structured, respondent-led interviews focused on the following key issues: the respondent's experience related to the global health technology market; perspectives and experiences on how countries are informed, advised, and educated on new product information; and perspectives on moving toward a broader, strategic technology adoption process. The interviews were not recorded, but researchers kept detailed notes of each session. Interview data have been kept confidential, and respondents' names are not used in the report.

As noted in the previous section, we defined the concept of country empowerment in the global health technology market as:

> *A country's ability to exercise greater control in choosing among global health products to intentionally produce desired health outcomes aligned with the goals of the country's health system.*

Based on this definition, we propose seven principles of national government empowerment to reduce the risk of structural detriments in the global health technology market.

Seven proposed principles of country empowerment

We developed a set of seven principles of national government empowerment in the context of the global health technology market. In developing these principles, we drew from concepts of consumer empowerment presented in the BERR in 2008 and the analytical framework on consumer detriment from the report commissioned by the DG SANCO in 2007 (as presented in the previous section). The principles were informed by insights gained through interviews with global opinion leaders.

The seven proposed principles are presented in the

Table 4, which is followed by a detailed description of each principle.

Table 4. Seven principles of country empowerment.

Principle	Description
1. Information on Technologies	Standardized information on new and existing health technologies should be systematically made available to countries.
2. Advice Channels	Good quality advice channels for countries should be easily accessible.
3. Country Capacity Strengthening	Global mechanisms should exist to strengthen country capacity to collect, interpret, and translate relevant information for decision-making.
4. Country Choices	Countries should be able to make technology adoption decisions from a choice set rather than one product at time.
5. Country Networks	Information-sharing networks should exist among countries for exchange of information on product implementation, quality, and trade practices.
6. Country Representation	The interests of countries as consumers of health technologies should be represented in the processes for shaping the global health technology market.
7. Monitoring Market	Global mechanisms should be in place to monitor and regulate practices that would negatively affect incentives for innovation in the global health technology market.

Principle 1: Information on Technologies

> *Standardized information on new and existing health technologies should be systematically made available to countries.*

The appropriateness, accessibility, and quantity of information about new products form a core concept supporting the first proposed principle. Consumer empowerment is primarily defined as giving consumers power through resources such as increased information or better understanding of products (Frost 2008). To be empowered, countries also need access to appropriate information and understanding of the products they are considering for use.

New global health products are primarily search or experience products. It takes more effort to gather information on these products than for ordinary products to determine their potential benefits. Information on new products tends to be less complete than on existing products, and their history of use is often insufficient for countries to make decisions regarding adoption. In addition to incompleteness of information, inconsistency in type and format of product information further aggravates the burden of information collection and translation.

Our interviewees identified the kind of information they felt countries should consider, including technical specifications, technical performance measures, such as efficacy and effectiveness, cost/price, procurement processes and procedures, and operational implications.

Increasing the availability of and access to such information alone is not sufficient. Our interviews also showed that such information is often incomplete and inconsistently presented to countries by product developers and/or advocates, making it difficult for countries to translate information into decisions. This

situation implies that the information should be presented in a standardized and accessible manner to reduce the information transaction costs.

Wide variations in the product information required by countries create a burden on suppliers—product developers, manufacturers, dealers, and advocates. Interviews with product developers also indicated that standardization in presenting information would create practical benefits for them as they do not invest in understanding each country's information needs.

Principle 2: Advice Channels

> *Transparent and neutral advice channels for countries should be easily accessible.*

A key market driver of empowerment is the establishment of consumer advice channels to provide support to less skilled consumers (Chalkidou 2010). To support countries in adopting new global health technology products, advice channels should be available and easily accessible. Such advice channels need to be easy to identify to reduce the informational transaction costs of searching for them. Interview respondents also supported the importance of advice channels. Three respondents who worked with the development of standardized product information packages all observed that, even if standardized information is available on a group of comparable, countries often require technical assistance in interpreting such information to make adoption decisions.

It is critical that these advice channels be trustworthy. In economics, the "principal-agent" problem refers to the difficulty of giving incentives for agents to act on behalf of the principal (Dulleck 2006). When countries perceive that incentives for advice channels are more aligned with the supplier side of the market, the countries are not likely to trust the advice channels. The supply side may perceive the same problem when the incentives are aligned with countries. The neutrality of advice channels in global health is important. Advice channels need to maintain transparency and independence from vested commercial and technical interests in the eyes of both countries and product suppliers. Such channels also need to establish a long-term relationship with both sides to build confidence.

The perception of bias in advice channels could create a barrier to entry into the global health technology market for innovators, thus discouraging them from investing in the research and development of innovative products. This disincentive could cause a long-term detriment because countries will have fewer choices in technology innovations.

Respondents often discussed the role of WHO as an advice channel to countries. While some respondents saw WHO as an exemplified advice channel trusted by countries, some argued that WHO might not always act in a neutral way, especially at the country level, influenced by individual technical officer's knowledge of emerging products and professional interests, the role that WHO played in development of particular technologies, and/or WHO's organizational goals.

Principle 3: Country Capacity Strengthening

> *A global mechanism should exist to strengthen country capacities to collect, interpret, and translate relevant information for decision-making.*

As discussed earlier, "knowledge-awareness" is the first step in the three decision-making stages of technology adoption by an organization. This step requires the adopting organization to possess the capacity to collect and process relevant information. The four country reviews of evidence-based decision-making on medical technologies by Thatte and colleagues illustrate differences in country capacity to undertake such tasks (2009). Capacity-building efforts should therefore be designed to address varying needs. Capacity is needed to process product information and other stages of technology adoption such as the evaluation-choice and adoption and implementation stages.

A single organization or agency cannot conduct all necessary capacity-building activities, which encompass many different geographical and demographic conditions, disease profiles, and technology product characteristics. Often, PDPs provide countries with technical assistance to build capacity for collecting and using information not specific to PDP-supported products. However, their efforts are usually restricted to a limited set of target countries where they are operating (MVTR WG 2006). Interviews with PDP respondents indicated that their project scope is defined by the project agreement with donors and that expending their project funding for broader capacity-building efforts requires explicit agreement with donors, which is often not easy to obtain. In addition to PDPs, international agencies and global health projects in arenas such as maternal and child health and disease advocacy provide various degrees of capacity-strengthening support.

Given the involvement of multiple organizations, coordination among them is critical to ensure consistency. Identifying a set of minimum standards for market knowledge and skills might be helpful as one way to ensure consistency. Consumer detriment arises not only from market failure but also from irrational consumer behavior (Wathieu 2002). Global health technical assistance is often organized around specific health conditions or topics. A country might exhibit a strong preference for prioritizing health issues that receive well-organized technical assistance or funding support rather than health issues that affect significant proportions of the population, and that preference might well influence the product adoption process. This tendency indicates that country capacity-building efforts for product adoption should not be limited to a specific health issue or dominated by a disease program. Rather, such efforts should be targeted to build capacity to consider broader health system needs.

Principle 4: Country Choices

> *Countries should be able to make technology adoption decisions from a choice set rather than one product at time.*

As proposed by Wathieu and adopted as part of our country empowerment definition, country empowerment is built on the notion of consumer choice. While it is difficult to determine the optimal

number of products available in the market that constitute a "choice," (Hunter 2008) a lack of variety can produce monopoly effects. Monopoly effects can reduce a country's power to negotiate prices, which can cause price detriment. In addition to the risk of price detriment, lack of choice means limiting a country's ability to compare different product sets, which, in turn, can lead to appropriateness detriment.

Some health products require high switching costs—the cost to switch from a product in current use to a new one. For example, adopting a sophisticated diagnostic device may later make it difficult to introduce future products with superior attributes because countries could consider the costs of switching related to acquisition, training, and changing policies and guidelines. Some PDP interview respondents complained that a recent successful launch of an innovative diagnostic product made it difficult to launch their near-market products despite their appropriateness to certain low-resource settings and lower cost of ownership compared to the just-launched product. Therefore, information should not be limited to currently available products. Information on product pipelines, expected release dates, and technical attributes could be useful in guiding choices about product adoption.

Principle 5: Country Networks

> *Information-sharing networks should exist among countries for exchange of information on product implementation, quality, and trade practice in support of adoption decisions.*

Useful product information for countries should not be limited to technical features and implementation processes. Particularly in the case of health technology products, systematic exchange of country experiences would help other countries consider adoption. In reviewing literature on the diffusion of innovation in health service organizations, Greenhalgh and colleagues highlighted the important influence of inter-organizational networks (2007). These networks influence decisions about adopting innovative products in both facilitative and obstructive ways. Information on positive and negative experiences with products is communicated through networks. When a network of countries supports adoption of products, the network could also increase collective bargaining power to prevent quality and price detriments.

Principle 6: Country Representation

> *The interests of countries as consumers of health products should be represented in the processes for shaping the global health technology market.*

Global health partnerships involving technical agencies, donors, procurement agencies, and product developers have significant impact on shaping the global technology market through tools such as technical guidelines, policy recommendations, quality endorsement, and price negotiations.[3{IAVI 2010}] Despite the potential impact, the countries that are (or will be) the consumers of these new products are often underrepresented in the governance structure and processes of global health partnerships. A study of public-private partnerships for product development by Ziemba found frequent underrepresentation of less-developed countries in the governance structures of global partnerships (2005). Without proper

representation of a country's interests as a consumer of new products, such partnerships might overlook country's interests during the decision making processes. Global health partnerships often attempt to influence country decision-making through allocation of funding and design of project activities that they support, as illustrated in a case study by Cruz et al (Cruz 2011). Ensuring representation of developing-country interests at the global level would be important in shaping such influence.

Selecting country representatives for this purpose also needs to be carefully considered. Interview respondents commented that LMIC representatives in their product development or demonstration projects functioned as facilitators of project implementation and experts in local contexts rather than truly representing government's interests. LMIC representatives included in global governance structures are often political or technical elites in their countries. Their interest or willingness should be aligned not only with interests of the technical expert communities, but also with the need to represent a broad spectrum of their country's population and other nonrepresented countries. Global and regional advocacy groups could also support the representation of country interests.

Principle 7: Monitoring the Market

> *Global mechanisms should be in place to monitor and regulate market practices that would negatively affect a country's interests in the global health technology market.*

Practices of product developers and manufacturers, donors, international technical agencies, and nongovernmental organizations might negatively affect a country's interests in adopting technologies. For example, price subsidization of a particular product by a donor agency or preferential endorsement of a particular product by an international agency might coerce a country to make an adoption decision that is not aligned with country priorities. Global or regional mechanisms should be established and strengthened to monitor and regulate such practices.

So far, our consideration of market principles has focused on the avoidance of detriment from existing or near-market products. We also need to consider future potential detriment arising from current-day market practices. Certain market practices also create real or perceived barriers to entry by new entities interested in the research and development of global health technologies. For example, a strong collaborative relationship between a PDP and a global technical partnership tasked to endorse products might be effective in facilitating country adoption of a product. But this collaboration might be perceived as an entry barrier and reduce incentives for other developers to enter the market. Any disincentive to innovate might stall investment into research and development. Other barriers include excessive subsidization of a product by a donor, bundling of new products with other necessary commodities, the high initial cost of obtaining global endorsement, and perceived or real corruption between countries and incumbent developers or suppliers. Market practices should be monitored to assure that they will not deter future investment by innovative developers and manufacturers.

Special consideration for vulnerable countries

In addition to these seven principles, special consideration should be given to access to information and advice channels for national governments that are especially vulnerable. These governments include those with small populations or that under conflict or are fragile in other ways.

In the global health technology market, and specifically in interactions with PDPs, some countries possess characteristics that put them at a further disadvantage in accessing production information. PDPs and other product researchers and developers conduct demonstration projects or clinical trials that provide opportunities to introduce new product information and build country capacity in conducting and analyzing research. They tend to select countries with large market potential (large population size), a stable government, strong technical capability, and a reputation as an early adopter of demonstrations and clinical trials (MVTR WG 2006). Many interview respondents agreed with the tendency and justified their need to ensure the best use of project resources by focusing on high-potential countries. However, PDPs and other product development initiatives are often important sources of product information and capacity strengthening. Countries less likely to be selected for demonstration projects and clinical trials thus may be disadvantaged in accessing information even though they may have greater health needs per capita basis than do the high-potential countries. We consider the special attention needed for governments of vulnerable countries a subset of principles 1, 2, and 3.

Conclusions

The past decade has seen increased public and private investment in R&D activities for products targeted for health needs in LMIC. Increased investment has resulted in more new products in the pipeline. To create public health impact, countries need to adopt and use these new products.

> *"I understand the importance of country ownership but building their capacity takes time. In a meantime, we know that we can save lives by using this product." (Respondent from PDP)*

We noticed during our interviews with global-level opinion leaders that respondents often shifted their roles during the interviews between country advocate and product advocate, which sometimes created implicit contradictions in their statements. Many respondents have worked with countries on product adoption issues, and they conceptually believe in country ownership of adoption decisions. At the same time, they have also worked with specific health products or interventions and are keen to see their successful and speedy adoption by countries. While they agree with the principle that countries should make their own decisions on product adoption, they also believe that product champions should seek to influence countries to adopt specific products. The interests of some respondents seem to be more aligned with the products or health issues on which they work, and less well-aligned with the need to increase a country's ability to make independent decisions on product adoption.

As a step to toward improved alignment with the need to increase countries' decision-making ability, we have proposed the idea of national governments of LMICs as consumers of the global health technology

market. Country empowerment as consumers is critical for avoiding three types of detriments associated with adoption of health products—price detriments, appropriateness detriments, and quality detriments. Empowerment of national governments requires two kinds of global mechanisms: one to advise, inform, and build capacity of governments and another to monitor and regulate market practices. We proposed a set of seven principles to assess and monitor strengths of country empowerment in the global health technology market:

Seven principles of country empowerment:

- Principle 1: Information on Technologies
- Principle 2: Advice Channels
- Principle 3: Country Capacity Strengthening
- Principle 4: Country Choices
- Principle 5: Country Networks
- Principle 6: Country Representation
- Principle 7: Monitoring Market

These principles should be subjected to careful scrutiny by researchers and stakeholders in the market and revised as our understanding of the market evolves.

Section III. Country case studies

Objectives

An interview-based, qualitative study was carried out to understand the experiences of low-income countries with technology adoption and their interactions with the global health technology market. The research sought to identify the different ways that low-income countries learn about new health products and to describe how they assess, adopt, and integrate new products into their health systems. Additionally, the research sought to understand the range of stakeholders involved in this process and to describe their roles. Finally, the research explored the perspectives of country-level stakeholders on their interactions with the global health technology market and whether specific mechanisms at the global, national, or regional levels support countries in product adoption.

Background

The research involved 40 in-depth interviews with country-level stakeholders in a convenience sample of three low-income countries: Cambodia, Ethiopia, and Zambia. (The World Bank reclassified Zambia as a lower-middle-income country on July 1, 2011. However, the research was done prior to the reclassification.) Originally, the research was to be Africa-based, with Ghana as the third case-study

country. Unfortunately, the researchers could not secure institutional sponsorship for a visit to Ghana in time for the study. The research team instead chose Cambodia as a third case study to examine differences between Africa and Asia in how administrative processes, health systems, and available financing mechanisms influence the process for adopting health technology.

Table 5 shows the range of health problems faced by the case-study countries. Ethiopia has the largest population of the three, followed by Cambodia and Zambia. Like other countries in sub-Saharan Africa, Ethiopia and Zambia struggle with endemic malaria and high mortality rates from childhood pneumonia, diarrhea, maternal causes, and neonatal complications. Zambia has a high prevalence of HIV/AIDS (13.5 percent), whereas HIV/AIDS prevalence in Ethiopia is under two percent (UNAIDS 2010). Both countries have underperformed in indicators related to maternal health, major childhood illness, water and sanitation-related diseases, and uniformity of access to health services and technologies (WHO 2009). By contrast, indicators in immunization coverage, malaria, and HIV/AIDS in Ethiopia and Zambia have improved over the past ten years, partly due to the presence of strong vertical programs with access to large amounts of dedicated external financing (WHO 2009). The Health Extension Workers program in Ethiopia, started in mid-2000, has increased access to health services throughout the country (USAID 2008). A pilot study improving support for community health workers in Zambia is under way (Government of Zambia 2011). Still, the logistical and administrative challenges of providing health services to remote areas mean that many rural Ethiopians and Zambians remain underserved.

Cambodia's health indicators are, in almost all categories, markedly better than those in Ethiopia and Zambia, but the country still falls far below regional averages for Asia in most categories. Malaria has a significant prevalence along Cambodia's border regions, but mortality from the disease remains low. Japanese encephalitis and dengue fever also are important infectious diseases. The HIV/AIDS epidemic has been concentrated among high-risk populations, and while Cambodia still has one of the highest prevalence rates in Asia, control efforts have managed to bring prevalence rates under 0.5 percent (UNAIDS2010). Antiretroviral therapy (ART) coverage is high (UNAIDS 2011). Tuberculosis (TB) prevalence far exceeds that of Ethiopia and Zambia, and the country is classified twenty-first on WHO's list of 22 high-TB-burden countries (WHO 2010). An intensive push to implement a TB control strategy known as Directly Observed Therapy−Short Course (DOTS) has improved TB detection and treatment success rates markedly. A government health sector review in 2007 found considerable improvement in infant and child mortality rates, but also found the maternal mortality ratio—the fourth highest in Asia—to be stagnating (WHO 2009). Additional challenges include human resource management, socioeconomic disparities in health status, and aid ineffectiveness due to fragmentation of donor support (Government of Cambodia 2008).

Table 5. Health statistics for Cambodia, Ethiopia, and Zambia (WHO 2009).

Indicator	Cambodia	Ethiopia	Zambia
Under-5 mortality rate (probability of dying by age 5 per 1,000 live births)	91	119	170

Indicator	Cambodia	Ethiopia	Zambia
Maternal mortality ratio (per 100,000 live births)	540	720	830
Births attended by skilled health personnel (%)	44	6	47
Contraceptive prevalence (%)	40	15	34
Unmet need for family planning (%)	25	34	27
Prevalence of HIV (adults aged ≥ 15 years per 100,000 population)	755	1,907	15,087
ART coverage among people with advanced HIV infection (%)	67	29	46
Prevalence of tuberculosis (adults aged ≥ 15 years per 100,000 population)	664	579	387
Tuberculosis treatment success under DOTS (%)	93	84	85
Distribution of causes of death in children <5 years (%): malaria	1	7	17
Children aged <5 years who received any antimalarial treatment for fever (%)	0	10	58
Total population (millions)	**14.4**	**83.1**	**12.0**

The three countries also have different health systems supported by different sources and mixes of financing. Ethiopia's government is a federal system with nine regional states and two city administrations. These are further divided into 611 districts. The health system is decentralized, though policymaking is still centralized. In 1993 Ethiopia published its first health policy document in 50 years, setting out a 20-year vision for the health sector. The policy focused on fiscal and political decentralization, expanding primary health care, and encouraging partnerships and the increased participation of nongovernmental organizations (NGOs) (Wamai 2009). This policy is implemented in five-year cycles under the health-sector development program framework.

The Ethiopian government recently completed a countrywide reform known as business process re-engineering (BPR). The goal of BPR is to implement clear policies, strategies, and programs "liberating Ethiopia from the existing backward socioeconomic condition and attain a middle-income country position (Ethiopian MOH 2009)." BPR restructured the federal Ministry of Health (MOH) away from vertical programs to three cross-cutting directorates: agrarian, pastoralist, and urban. Restructuring within the MOH is ongoing as officials respond to the BPR reform. Donors provided 43 percent of total health expenditure in Ethiopia in 2006, up from 10 percent in 2002 (Global Fund 2010).

The primary mission of Zambia's national health strategy is "to provide cost-effective, quality health services as close to the family as possible (Government of Zambia 2005)." The mission reflects ongoing efforts to create decentralized chains of referral, planning, and decision making that start at the community level. Zambia's health system was decentralized following the national decentralization

policy of 2003 to shift planning and resource allocation decisions to district health management teams. Decentralization was meant to empower district teams to plan, budget, and implement health services with a degree of independence from the central MOH. In practice, authority is often deferred to the central government. Strategic planning is done in five-year cycles at the national level and two- to three-year cycles at the district level. Donors account for a substantial proportion of Zambia's health financing. By 2005, 43 percent of health spending came from donor funding, up from 15 percent in 2001 (Goldsbrough 2007). More than 40 percent of all health expenditure has been directed to HIV/AIDS-related vertical programs (Amico 2010)

Zambia also plays host to several pilot studies and clinical trials for new products and delivery mechanisms. The University of Alabama's Center for Infectious Disease Research in Zambia and Boston University's Center for International Health and Development in Zambia both have large clinical-trial portfolios receiving substantial amounts of financing from the National Institutes of Health, although it remains unclear how, if at all, clinical trials translate into policy. Zambia is also the site of innovative HIV/AIDS service-delivery mechanisms, along with being a benchmark country for best practices in TB medication, artemisinin-based combination therapy (ACT) for malaria, and misoprostol introduction for medical abortions.

Cambodia's health system was decimated by civil war starting in the late 1970s, destroying much of Cambodia's health workforce, medical education and laboratory systems, and health care infrastructure. Following the 1991 peace accords, the government attempted to meet short- to medium-term health needs by contracting with NGOs to provide both a basic package of health services and to support government provision of services. The government also decentralized the health system from provinces to districts, with population-based "operational health districts" acting as a system of referral (Men 2005). Following the first national health strategic plan from 2003 to 2008, the government established the second national health strategic plan from 2008 to 2015 (HSP2). This plan is unique in that it spans seven years, as opposed to the typical five years, taking the country up to 2015, the target year for reaching the Millennium Development Goals (MDGs).

HSP2 highlights MDGs as key milestones of the strategic framework. HSP2 is focused on the reduction of: maternal, newborn, and child morbidity and mortality; morbidity and mortality due to HIV/AIDS, malaria, TB, and other communicable diseases; and the burden of noncommunicable diseases (Government of Cambodia 2008). The US Agency for International Development, the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Bank, the Australian Agency for International Development, the United Nations Population Fund, and the Asian Development Bank are major partners providing health sector funding, with external resources for health representing 22 percent of total health expenditure in 2006 (WHO 2009). Additionally, Cambodia has a very high level of private, out-of-pocket spending, which accounts for approximately two-thirds of all health expenditures. Cambodia also uses innovative health equity funds—district-based, externally financed schemes—to increase access to health services for poor people, and also uses a community-based health insurance program (Grundy 2009).

Methodology

In this section, we define the technology adoption process as the set of activities and actors involved in identifying, assessing, choosing, and integrating health products into health systems. The research did not examine whether or how the adopted technologies were used and the resulting health impact. We began the research with the hypothesis that there are three broad models at the country level for technology adoption: 1) the sequential (ad-hoc) model; 2) the program-based model; and 3) the broad-health systems model in which product adoption is considered across health program areas. We hypothesized that few low-income countries presently make use of the third model or think about the technology adoption process in the context of long-term planning objectives. We assumed that most countries were making ad hoc, product-by-product decisions, but also wondered whether programs that were well-financed by global funding agencies were more strategic in their decision-making. We also sought to examine the role of product developers (including pharmaceutical companies), donors, and global technical agencies in promoting and influencing the adoption of new products.

Data collection

Study respondents included representatives of government, provider groups, technical agencies, international and local NGOs, donors, and donor-funded program staff (Table 7). All stakeholders had experience with the health technology adoption process and decision-making. The research team initially identified stakeholders whose areas of expertise were in specific program areas, in particular those related to malaria, maternal health, and reproductive health. These program areas were identified as being strongly reliant on product-centered interventions. However, we found that each program area was organized and financed quite differently. Malaria interventions were generally financed by donors and implemented vertically. Maternal and reproductive health interventions were less likely to be the subject of national control programs and were more likely to have diverse and less dependable sources of funding. When we studied Cambodia, TB was substituted for malaria as the program example as TB is more prevalent there than in either of the African case-study countries.

Over the course of the interviews our research focus widened beyond these program areas. Stakeholders were interested in talking about a range of health products—from diagnostics and medicines for opportunistic infections to information technology, nutritional supplements, and child health devices. The researchers allowed the stakeholders to move away from the original program areas and discuss anything that might shed light on how newly developed products have been adopted in the past, how existing products are launched in new contexts, and how product-dependent interventions are introduced and used to support the case for adoption.

The researchers used an open-ended interview guide based on a series of ten questions. The instrument allowed for semi-structured, stakeholder-led interviews focused on: the process of technology adoption, the criteria that influence decisions to adopt, the alignment of technology decisions to national health goals, the sources of product information and their availability, the stakeholders who play a role in

national-level technology decisions, and the sufficiency of this process for present and future health system needs. The interviews were not recorded, but the researchers kept detailed notes of each interview. Interview data have been kept confidential, and stakeholder names are not used in the study reports. The interview transcripts were coded using the first three letters of the country, a signifier of the stakeholder group (Table 6), and a unique number for each interviewee. These codes are used throughout this section of the report to cite quotes from respondents.

Table 6. Interview stakeholder groups.

Stakeholder groups	No. of Interviews	Cambodia	Ethiopia	Zambia	Transcript Code
National Ministry of Health officials and regulatory authorities	10	7	1	2	GOV or REG
Donors	5	1	1	3	DON
International technical agencies	4	2	2	--	TA
International NGOs	10	2	2	6	INGO
Donor-funded project officers	4	--	3	1	PO
Health professional organizations	3	--	1	2	PROF
Technical staff from local NG0s	4	3	--	1	NGO
Total	40	15	10	15	

Data analysis and limitations

The researchers analyzed the qualitative data using thematic analysis. First, each researcher analyzed his or her interview transcripts and identified recurring themes. Next, the research team reviewed the findings together in May 2011. During this meeting the team discussed differences and similarities among the countries and agreed upon shared themes. This report presents seven shared themes to illuminate country-level stakeholder perspectives on the health technology adoption process in their countries and their experiences with the global health technology market.

Some biases existed in the collection of data among the countries. The Cambodia research included more national MOH officials, whereas securing MOH interviews in Ethiopia and Zambia was difficult. The Ethiopia data had more donor-funded project representation, while the Zambia data included more international NGO staff.

In Ethiopia and Zambia, the researchers sought to compensate for fewer MOH interviews by ensuring that stakeholders from technical agencies and NGOs were Ethiopian and Zambian nationals with a long history of working within their respective health systems. In most instances, stakeholders in these categories were former MOH workers, starting initially as clinicians (doctors, nurses, midwives, and

pharmacists) and then moving into the civil service. These stakeholders, while having in-depth experience with the adoption of certain products, may view the present situation through the lens of their past experience and may not reflect current MOH thinking. The Cambodia data, by contrast, may contain bias in that MOH sources may be more likely to describe how things should work as opposed to how things do work.

Some response biases were also shared among countries. National-level stakeholders are naturally concerned with the implementation of specific programs and projects. Many did not speak about the technology adoption process without reference to specific cases and examples. Moreover, the primary interest of many of these stakeholders was in adoption at lower levels of the health system. For them, technology adoption is about adoption by providers and patients. The concept of national adoption, therefore, was difficult to convey and often had to be "overexplained" to stakeholders to elicit an answer. The same can be said about the concept of health technology assessment, which most stakeholders only understood after a great deal of explanation by the interviewer. These methodological issues, along with the small sample size of the study, mean that the research cannot claim to be generalizable to all low-income countries.

As a final research observation, we note that the data represent stakeholder opinion. This assumption of the subjectivity of interview data differentiates qualitative research from information-gathering, which often treats stakeholder statements as objective facts. The findings of this study should be seen as a set of issues to be considered when product development partnerships or other new product advocates approach national-level stakeholders. The findings are not intended as a formal guide to adoption, and researchers acknowledge that any findings herein may be colored by informant perception and subject to change over time. At the same time, the variety of stakeholders interviewed, their long histories of participation in health technology adoption decisions across both public- and private-sector institutions, and their present role as advocates, funders, implementers, and champions of new health products in their respective countries supports the authenticity of the common themes and opinions derived from the research.

Results

From our interviews and analysis, we identified a set of seven shared themes that help define the policies, processes, and pathways the three countries use to assess, adopt, and integrate new health products into their health systems.

1. Ministries of health, their donors, and technical partners in all three countries align their adoption of new health products to existing policies, strategies, and guidelines. It is unclear whether policy alignment is leading the decision to adopt, or the decision to adopt is being justified by policy.

In all three countries, stakeholders stated that discussions about technology adoption usually take place within the framework of national health policies, strategic plans, and guidelines. While there were mixed feelings among stakeholders in all three countries about the quality of these health frameworks and their

usefulness for long-term planning, the national planning documents were thought to be relevant to country needs and tied to global standards and best practices. Stakeholders felt that countries had a clear sense of mission and objectives and, especially in the cases of Ethiopia and Zambia, usually insisted that interventions involving health product adoption explicitly spell out their relationship to national policies, strategies, and plans.

> "For you to advance your interest, you need to fit whatever you are doing into the National Health Strategic Plan…. You justify rapid diagnostic tests for malaria (RDTs) in terms of malaria indicators, like proportion of children with malaria identified within 24 hours, because this is in the National Malaria Strategic Plan and the national malaria guidelines. So when it comes to new technologies, you make a case for them using the indicators and goals already set up by the Ministry of Health."
> [ZAM-PO-1]

In Zambia, for example, stakeholders frequently quoted from key national policy documents during interviews. This included not only the National Health Strategic Plan (NHSP) or the National Malaria Strategic Plan but also acts of parliament such as the National Pharmaceutical Act of 2004 (in the case of the adoption of generic ACTs and ARTs) and the Termination of Pregnancy Act of 1972 (in the case of the adoption of misoprostol). As one stakeholder said: "You have to tie everything to a document. This guarantees political will. If new guidelines are outside policy, the Ministry of Health will not approve." [ZAM-PROF-1] Some stakeholders also noted the need to quote from global resolutions, such as the Cairo Programme of Action or the WHO Global Strategy on Reproductive Health. Every stakeholder, regardless of program area, could cite and link technical decisions to an array of legal and policy decisions.

Although NHSPs and other strategic policy documents play an increasingly important role in health sector planning, these documents often do not make direct linkages between the adoption of new health products and the realization of policy objectives and goals. In a PATH study reviewing the national health plans of 13 African countries, the authors found that, apart from information and communication technologies, national health plans rarely linked the adoption of new health products to national health system goals or articulated the need for health technology assessment (Msaaki 2011). Similarly, in the three country case studies, it was unclear whether national planning documents and policies *led* to adoption decisions or, alternatively, were simply used to *justify* such decisions.

Stakeholders in all three countries could cite examples of product-dependent interventions being delayed if there were changes to product indications, for example, when a product required a prescription, and the intervention sought to shift product delivery to community health workers. The study found far fewer examples of products being turned away. Only one Zambian stakeholder recalled an instance in which Chinese partners wished to introduce a new artemether-amodioquine (AA) as a parallel public-sector treatment for malaria and registered the drug with the Pharmaceutical Regulatory Authority (PRA). The MOH, however, refused to change guidelines and so artemether-lumefantrine (AL) remained the public-sector product of choice. In this rare instance of the public sector rejecting an effective treatment, and the Zambian stakeholder was unsure of the rationale behind the decision. Instead, the stakeholder noted: "The

MOH rarely says 'no' to new programs, although they increasingly ask all stakeholders to buy into the National Health Strategic Plan." [ZAM-DON-2]

Instead, the key problem felt by many stakeholders in Ethiopia and Zambia is that new products are adopted without considering whether a country has systems to implement and efficiently use the products or a plan for how products might be integrated into the health system.

> "Adopting new products is one thing, but actually integrating them into the health system is an entirely different process. A product that is not so appropriate to the health system can fairly easily move through the adoption process, but then getting it integrated into a health system that cannot support it is very difficult."
>
> [ETH-PO-1]

For example, magnesium sulfate was adopted by Zambia in 2004 within a year of addition to the WHO Essential Medicines List. By 2006 it was on every national policy document of relevance, including the essential drug list, the formulary, standard treatment guidelines, and guidelines for pregnancy, childbirth, postpartum, and newborn care. Yet some stakeholders noted that magnesium sulfate remains unavailable at both the primary and secondary health levels due to both supply chain and financing problems. In many places, the drug has never even been in stock. Similarly, one stakeholder in Ethiopia noted that misoprostol, registered in 2010 and placed on the national essential drug list, has been out of stock in health centers due to lack of funding to purchase the product and supply chain problems. [ETH-PROV-1] Both Ethiopian and Zambian stakeholders could cite examples of products, including contraceptive devices, drugs, and diagnostics, which have been adopted but are continually stocked out at the primary level.

Finally, some stakeholders pointed out that when it came to planning beyond the four to five years delineated in most national planning documents, countries were often overly focused on meeting specific MDG targets and on adopting products based on whether they will help them reach those targets. They felt that the MDGs had ultimately detracted from integrated, long-term planning and encouraged vertical, indicator-targeted health interventions at the expense of the system as a whole.

2. Ministries of health in low-income countries access information about new health products through at least four information pathways. These pathways are not mutually exclusive. Global and regional consultations, workshops, and partner-led dissemination are the most important sources of information on new health products. Other sources are readily available if MOH officials have the capacity and initiative to use them.

> "I was at this meeting in Zambia in 1994. It was about reproductive health. They were supposed to be discussing adopting technology, but the meeting ended up being about, 'OK, what's out there? Can we pay for it? How can it work logistically?' And I remember one woman getting up in the meeting at one point and saying: 'I've heard about this thing called the female condom. Does anyone know anything about it?'…. For everyone else in the room, it was the first time they had heard of it."
>
> [ZAM-DON-3]

Pathway 1: Global and regional consultations, meetings, and workshops

Stakeholders from all countries reiterated that information on new health products is readily available via WHO and partner-sponsored consultations and workshops. Such meetings are a critical source of intelligence even if the meeting is about a more general

health issue, such as child survival or cervical cancer, rather than the product itself. In Ethiopia, one stakeholder gave the example of a senior MOH official attending a partner consultation in the US and learning about a neonatal resuscitation product. The official returned to Ethiopia determined to have the product integrated into public-sector training. Similarly, the WHO African Regional Office has sponsored global consultations and meetings on male circumcision, emergency obstetric care, cervical cancer, postpartum hemorrhage, and other topics, with country-level WHO offices providing technical support and advice toward specific adoption decisions. The MOH and its partners in Zambia often send representatives to WHO meetings and workshops. Stakeholders frequently cited those gatherings as vital forums for sharing information and evidence on new technologies. WHO forums were also important sources of information for the Cambodian national TB program.

Pathway 2: Product manufacturers

> "Manufacturers can try to influence programs by providing funding to show resistance to existing drugs or to support the demonstration of new drugs so that programs will have evidence to present to the Essential Drugs Committee."
>
> CAM-GOV-2

In all three countries, some stakeholders were able to provide examples of pharmaceutical companies or distributors bringing information about their products directly to the MOH. In Ethiopia, for example, stakeholders said the manufacturer of the Implanon® contraceptive implant visited senior MOH officials and provided information about the product. The MOH adopted the implant, which is being implemented in a pilot program through the MOH Health Extension Worker program. Similarly, Novartis spent several years engaging the MOH in Zambia regarding Coartem® treatment and held meetings and consultations to promote the drug with the support of WHO.

In Cambodia, a stakeholder gave the example of laboratory companies approaching the National Institute of Public Health directly with catalogs and information. Also in Cambodia, a stakeholder mentioned that pharmaceutical companies or their distributors sometimes approach private providers, many of whom also work in the public sector. Yet another Cambodian stakeholder pointed to examples of manufacturers presenting evidence to the MOH of ineffectiveness or resistance to existing drugs to make a case for the adoption of their new products.

Many stakeholders felt that it was not typical for manufacturers or distributors to bring new health products directly to the MOH and noted that technical partners frequently bring information on behalf of the manufacturer. A stakeholder in Zambia suggested that private-sector companies may take the lead on communication regarding bulk, generic supplies of essential, non-branded drugs for use in health facilities. However, dissemination of information on new, innovative products, including those emerging from PDPs or those that will require special financing, were typically led by the nonprofit sector and technical agencies such as UNICEF and WHO.

Pathway 3: Partner-led interventions at the country level

The willingness of implementing or technical partners to take on new health products and introduce them at the country level is also a key information pathway. Family Health International, for instance, championed Sino-implant contraceptives and the Shang Ring male circumcision device in Zambia, bringing these to the attention of the MOH, assisting with quality and safety testing at its US-based laboratory, advocating for adoption, and supporting registration and pilot-testing. Likewise in Cambodia, the US Centers for Disease Control and Médecins Sans Frontières have played important roles in introducing and promoting new diagnostic and laboratory technologies for HIV and TB, providing Cambodian officials with information about innovative products. Across all three case-study countries, the Concept Foundation, Ipas, Population Services International, and Venture Strategies Innovations have provided information to ministries of health for both misoprostol and Medabon® (misoprostol/mifepristone) packets for postpartum hemorrhage and medical abortion. Several pharmaceutical companies are involved in the misoprostol and Medabon® initiatives and must submit their products for registration to national regulatory authorities. However, without partners' advocacy, dedication to proof-of-concept, and information dissemination, it is unlikely that these products would have moved forward through the adoption process.

Pathway 4: Internal technical working group discussions

The final pathway of information flow occurs within country-level technical working groups (TWGs). TWGs discuss, evaluate, and mediate new interventions and products at the country level, thereby representing key country-level forums in learning about new products and disseminating this information. They also serve as a coordinating mechanism in different program areas, with the goal to facilitate technical decision-making. These groups are led by MOH officials and donors and include key partners. They exist both within national disease control programs (e.g., diagnostics TWGs within national malaria control programs, or an ART TWG within national HIV/AIDS programs) and more generally across program areas of the MOH (e.g., TWGs on nutrition, safe motherhood, child survival, information technology, medical devices, and health financing). Following the 2007 Malaria Indicator Survey, the Ethiopian MOH decided to shift from a monospecies malaria rapid diagnostic test to a multispecies test. The malaria TWG engaged in extensive discussions about which test to select and drew on information about potential products and their characteristics provided by WHO and the Geneva-based nonprofit Foundation for Innovative New Diagnostics. A TWG may serve as a forum to disseminate information via other pathways or as an independent pathway. However, new health products frequently need buy-in from a TWG to move forward.

Stakeholders in all three countries noted that it was not common for the MOH to take the initiative and search out new products independently. A Cambodian stakeholder mentioned one example of the National Institute of Public Health initiating a needs assessment of diagnostic technologies and identifying the absence of spectrum photometers as a critical health product gap. Most frequently, external sources generated and delivered information.

Some stakeholders also pointed out that even if the MOH takes the initiative, few tools and platforms exist to enable a simple and efficient search for new products. All three ministries of health have access to computers and the Internet, but connections are not always reliable and awareness of search engines and online information clearinghouses may be limited. In Cambodia, several stakeholders pointed out that while they know there is information on the Internet about health products, the process of searching, reviewing, and interpreting information is a time-consuming task.

Finally, country clinical trials offer an additional potential pathway for information. Clinical trials, however, are not the same as pilot or implementation studies. They only represent an effective pathway for information if there are clear mechanisms to communicate data generated by in-country research and if those conducting a trial have the skills to effectively translate research findings into policy. In Zambia, a country that frequently hosts clinical trials, many stakeholders noted the lack of a national forum for the broad dissemination of in-country research, let alone for the translation and packaging of clinical research data into clear, policy-relevant findings. Indications suggest that the Zambian MOH is moving in this direction, but stakeholders noted that many clinical trials carried out in Zambia fail to feed into national policy. While trials are sponsored by the MOH and often include public-sector local researchers, most data emerging from the trials do not pass to the MOH in a way that is meaningful in decision-making. This finding is important for those PDPs supporting clinical trials. Generating information on clinical effectiveness in-country may not, in fact, feed into country-level adoption, unless trials include within their dissemination plans a strategy for presenting data that supports decision-making.

3. WHO endorsement plays a major role in MOH decision-making on adoption. Endorsement can take a number of forms and is often enough by itself for the MOH to adopt. But if the technology is controversial within a country, or if a country is a slow adopter, then evidence generated by a local pilot is a key factor in adoption.

The role of WHO regional offices in disseminating information and evidence has already been mentioned, as has the technical support for decision-making provided by WHO country offices. Additionally, WHO global endorsement is a key factor in all three countries in terms of decision-making about inclusion of a product in national guidelines, policies, and plans, though the nature of this influence is not always predictable (Wells 2011). By endorsement, we mean the inclusion of the international nonproprietary name of a product on the WHO Model List of Essential Medicines and, if applicable.

WHO prequalification of the product is under its trade name. Endorsement might also include the presence of the technology in WHO recommended guidelines. Low-income countries require product registration by their national regulatory agencies and, if possible, independent laboratory confirmation of the identity, safety, and quality of the product. However, WHO endorsement as described here is an important factor in the willingness of most MOHs and their corresponding regulatory authorities to include new products in national guidelines, policies, and plans.

> "With Coartem®, the Ministry of Health took the most expensive option because it had the greatest effect. The Global Fund was not in the game at that point, so the ministry had to procure itself. But the drug was brought to it by Novartis and WHO, with WHO assurance that the price would come down eventually. The formulary was not 100% convinced, but precedence of accepting WHO took over, and they went with Coartem®."
>
> ZAM-INGO-6

In Zambia, many stakeholders said new health products could move toward adoption on the basis of WHO endorsement and prequalification, plus evidence of safety and effectiveness in other countries. In the case of ARTs, in particular, the country was deeply reliant on the validation of medications through the prequalification process. Local evidence was rarely required for ARTs because, stakeholders pointed out, universally accepted, prequalified WHO "gold standard" ARTs can guide MOH selection. In addition, stakeholders noted that for AIDS, children are a vulnerable population, leaving no time for three-year local pilots or extensive country-level evidence-gathering. For these and other vital products, stakeholders gave examples where the MOH encouraged the Pharmaceutical Regulatory Authority to prioritize dossiers of drugs that were prequalified by WHO.

Perhaps the best example from Zambia is the adoption of Coartem® (artemether-lumefantrine, or AL) as a treatment for malaria. Zambia decided to move ahead in November 2002, prior to WHO prequalification, following consultations with both the manufacturer and WHO. The country made the decision knowing that: 1) The WHO global office had already changed its malaria guidelines and listed AL on the List of Essential Medicines in 2002; 2) Zambian national malaria guidelines had also been shifted to reflect AL as a first-line treatment; 3) WHO was expected to prequalify Coartem® within months, and at that time, Coartem® was the only available AL product on the market; 4) Epidemiological evidence had shown high levels of resistance to existing drugs, creating a sense of urgency; and 5) WHO was negotiating price reductions with Novartis. In 2003 Zambia became one of the first countries in Africa to adopt Coartem®, and the experience helped establish Zambia as an early adopter of many subsequent health products.

> "Weekly supplementation of iron for pregnant women was successful. German Development Cooperation demonstrated the effectiveness in a small-scale demonstration project, but the government said the sample size was too small. USAID supported a bigger demonstration project, and now it will be incorporated into the national program."
>
> CAM-DON-1

While WHO endorsement is an important factor in country adoption of new products, other products often require additional local evidence, especially on implementation feasibility. The MOH may expect pilot studies to troubleshoot operational challenges for product categories that are completely new to a country or that are considered controversial or challenging to deliver. In all three countries, pilot studies and demonstration projects of product-dependent interventions are commonplace.

Pilot studies, for example, were often required for new reproductive health products due to social, cultural, political, and human resource concerns. In both Ethiopia and Zambia, the nonprofit Venture Strategies Innovation brought the use of misoprostol for the prevention and treatment of postpartum hemorrhage to the attention of the MOH and the TWGs. In Ethiopia, Venture Strategies Innovation

partnered with the social marketing organization DKT to pilot-test misoprostol. One key partner was concerned about the safety of delivering misoprostol through the Health Extension Worker program. The pilot results were presented in a variety of forums nationally and regionally and discussed within the TWGs, and the product was registered in June 2010.

In Zambia, the decision to adopt Depo-Provera, an injectable contraceptive, depended on the ability of partners to demonstrate its feasibility, acceptability, and safety in the local context. Global media reports of racial biases and safety concerns led the Zambian government to ban Depo-Provera in the early 1980s (Solo 2005). In 1996, after lobbying from WHO, the MOH and its partners conducted the "Enhancing Contraceptive Choice and Improving Quality of Care" pilot study. This study piloted WHO's contraceptive introduction strategy and included two injectable contraceptives—Depo-Provera® and Noristerat®—in the method mix. The pilot study, implemented across Copper Belt Province, lasted five years and generated extensive evidence on Depo-Provera acceptability and delivery in both rural and urban settings. A three-year campaign was then launched, using local evidence and strong advocacy by community groups, and Depo-Provera was finally registered for broad use and adopted in 2004. Since proof-of-concept was demonstrated for this product, it has been far less difficult to secure MOH buy-in for subsequent injectable contraceptives.

In this instance, WHO worked across global, regional, and country offices, providing policy guidance, evidence, and country-level technical support toward eventual country adoption. It is important, however, to distinguish between WHO's global influence and its regional and country-level roles. While the guidelines, standards, and validations provided by the WHO global office form the basis for many country-level product adoption decisions, WHO cannot provide substantive country-level financing, nor does it act as an implementing agency. WHO regional and country offices help to generate and disseminate evidence for decision-making and provide critical information and technical support for countries considering WHO-endorsed products. WHO global endorsement facilitates a country's consideration about whether to include new products in national guidelines, policies, and plans, but it plays a lesser role in determining country-level *access*.

4. Ministries of Health are primarily concerned with effectiveness, safety, quality, and availability of financing, and the product's relevance in relation to the burden of disease. Cost is also important, although in all three countries, governments will often prioritize quality and potential impact ahead of cost, particularly if products are already linked to a funding stream. Nevertheless, even products meeting all these criteria need a ministry champion to move forward.

In each of the three countries, stakeholders across all program areas emphasized that the MOH was concerned primarily with whether products were safe, effective, of high quality, and able to address an existing and pervasive health problem. It also helped to have a guarantee of financing in place to procure new products, such as those to be implemented within well-funded vertical programs. Many stakeholders in the three countries mentioned that a clear financing source—such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria—could have a positive effect in expediting MOH willingness to buy into a new product. Likewise, if adequate financing was not available, or if financing was to be provided out of a

general basket of funds, some stakeholders felt that governments might hold off on decision-making. Zambia, for instance, has adopted and is rolling out its cervical cancer screening and treatment programs, but questions about whether to include human papillomavirus immunization in this program are unresolved, partly due to questions about financing. Should the vaccine be provided through immunization funding or HIV/AIDS funding? While health products that cut across program areas (HIV/AIDS and reproductive health, for example) might seem better equipped to achieve the larger goal of health systems integration—thus improving value-for-money—they also require countries to make difficult choices regarding funding streams, administrative responsibilities, and program boundaries. These choices, likewise, may have additional indirect costs attached. For products that slot neatly into obvious vertical programs, cost may be less of an issue because funds exist not only for product procurement, but also for structures supporting product implementation and administration.

The cost of products was also more important to some countries than others. In Ethiopia, one stakeholder gave the example of the national regulatory authority questioning the need to register new brands (of condoms, for example) that were cheaper than other existing products already registered in the country. In Cambodia, cost was a deciding factor in whether a drug ended up on the national essential medicines list, especially if comparable products were available. The committee responsible for the essential medicines list functioned as a gatekeeper in this context. The EML was updated every two years with support from WHO. If comparable products were available, cost considerations became a major factor in whether a product made the list.

In Zambia, by contrast, cost was an issue for bulk purchases of mass-sourced generic products, like those that were part of basic health center kits and that were procured through ordinary tender procedures. Cost, however, often was a secondary consideration for new essential health products directed at targeted programs. In those instances, the MOH occasionally chose products that demonstrated the highest level of effectiveness and quality over cheaper products of slightly lesser effectiveness if a financing source could pay for it. One example addressed questions about whether to procure Tenofovir 3TC or Tenofovir FTC for ART. One stakeholder stated: "3TC is cheaper by $1 per dose. So you can imagine that 300,000 doses will equal a cost savings of $300,000. But the MOH sees that the evidence shows FTC as more effective. So they made the strategic decision to stay with the higher-priced product." [ZAM- INGO-5] This decision was made easier by the availability of Global Fund procurement funds. A similar decision was made with regard to second-line ART therapy. Unlike first-line therapies now available as generic products, the MOH has decided to remain with branded therapies by Abbott for second-line ART therapy. Likewise, the MOH in Zambia is committed to sticking with Coartem®, even though a cheaper drug has been both WHO prequalified and locally registered.

Even effective and well-financed products, however, require a point person at the MOH to ensure adoption. Stakeholders in all three countries emphasized the need for a champion advocating for product adoption from within the MOH and within the TWGs, regardless of the effectiveness, safety, quality, and cost of the new product. Without that, adoption would either not proceed at all or would move forward at such a slow pace that the product would likely become irrelevant by the time it was adopted. In Ethiopia,

many stakeholders noted that product adoption required support at the most senior levels of the MOH (Roberts 2011). The minister of health, a malaria researcher with strong connections in the global health community, was described by stakeholders as being open to "big ideas" and "innovations" in health and providing a "facilitating environment" to new products and interventions. The support of the minister or other senior MOH officials was described as essential for product adoption.

> "It is important to have someone at the ministry who knows what is involved and who is in a better place to advocate."
>
> ZAM-NGO-1

Reproductive health products presently enjoy an extremely receptive environment in Zambia due to the initiative of an active and well-connected reproductive health unit leader who also is spokesman for the MOH. This individual was mentioned by almost every stakeholder as a critical champion for misoprostol, Medabon® misoprostol-mifepristone copackaging, female condoms, nonpneumatic antishock garments, and several new technologies associated with cervical cancer. Several stakeholders also suggested that had this individual not been in a position of influence within the MOH, it was likely that reproductive health would have remained neglected in Zambia. Together with the policy window created by renewed interest in the Safe Motherhood Initiative in 2007, the presence of a high-level champion at the MOH has meant that piloting reproductive health products in Zambia now can move forward quickly, and the adoption of safe and effective products is more likely to be guaranteed.

In Cambodia, stakeholders often pointed to the national TB program manager as a strong champion of introducing new products into the country. The manager is well-recognized globally as a member of the WHO Strategic and Technical Advisory Group for TB and has keen interest in and knowledge of innovative products. Stakeholders mentioned that his global status and exposure to new research allowed him access to information on new health products. Coupled with Global Fund funding ensuring strong administrative capacity, the presence of a champion ensures that TB is prioritized and the TB program well-administered in Cambodia.

5. Ministries of health are generally open to adopting new products that have technical leadership, proof-of-concept (including pilot studies), and financing. Most decisions to adopt health products are ad hoc, with decisions made product by product and program by program. Many stakeholders see this model of technology adoption as acceptable.

As the previous findings suggest, stakeholders believe that ministries of health are generally open to adopting new products. Many stakeholders, however, do not see health technology decisions being made in the context of long-term, integrated strategic planning. Cambodia, Ethiopia, and Zambia all emphasize health systems strengthening as an important component of present and future health strategies. However, countries are often under pressure by the global health community to prioritize vertical programs because these interventions are better funded, have better administrative capacity, and have more stringent reporting requirements (Buse 2002). The case-study countries lack the financial and human resources, capacity, and time to assess their health technology choices in terms of long-term value.

> "We think the process is OK … We are mindful that we don't become a dumping ground. But we are happy to adopt and take on new technologies. If they are exceptionally good, we appeal to the Pharmaceutical Regulatory Authority. If guidelines are followed and proper steps taken, there is usually no problem."
> [ZAM-GOV-1]

Product adoption, therefore, is often conducted ad hoc and considered program by program and product by product to address targeted needs. Low-income countries are less likely to think proactively in terms of what product adoption will mean in 20 or 30 years. In many countries the health sector frames its work based on four- to five-year strategic plans.

In the three countries addressed in this report the health sector is largely donor dependent, and many donors finance projects in three- to five-year project cycles. While not ideal, ad hoc technology adoption models may make sense in circumstances when long-term revenue and available resources cannot be easily projected 10, 15, or 20 years down the road.

Most stakeholders in the three countries did not see this ad hoc, reactive technology adoption process as a problem. Indeed, government stakeholders in Cambodia and Zambia felt that the present system of planning, involving TWGs, NHSPs, and dedicated action plans, was sufficient for meeting national health goals.

6. Regulatory authorities can be important gatekeepers for new health products, but in countries where regulatory authorities are independent from the ministry of health, the relationship between the two institutions may create tensions in the technology adoption process.

All new drugs and vaccines require local registration by a national regulatory authority before the MOH will consider them. Some regulatory authorities, such as that of Cambodia, are under the jurisdiction of the MOH. Others, such as those in Ethiopia and Zambia, are quasi-independent.

Regulatory authorities in low-income countries are often understaffed and overworked. Manufacturers not infrequently send in substandard registration applications. In Zambia, the PRA estimates that at least half of the dossiers coming in for new products are incomplete and need to be sent back. They also face pressure from the MOH to register products quickly in instances of emergency procurement. Despite these difficulties, regulators in Zambia have managed to reduce clearance times on dossiers and to eliminate backlog. Prior to 2004, the agency had a staff of two and a three-year backlog of dossiers. Now, the agency has tripled in size and has an internal policy to try to keep the evaluation process to less than one year. In Ethiopia, following BPR reform, regulators are trying to conduct the premarketing phase in four months, though other stakeholders point out that the current process takes two years.

> "The MOH always has immediate needs … They always say: 'It's an emergency!' So we are put under pressure. There are often 40 dossiers a week on the desk from the tender committee, and they want it straight away … Now there are already 4,000 products on our register. And they want to procure something else that is not on the register because it is cheap! We are treating medicines like we are buying cars."
> [ZAM-REG-1]

The degree of oversight by regulators on decisions to adopt new products varies by country. In Cambodia, the Department of

Drug and Food (DDF) is part of the MOH, and the Essential Drug Board is under the DDF's jurisdiction. The DDF thus could influence decision-making on the cost of drugs, the rationale for their inclusion on the national list of essential medicines, and other issues related to national adoption. In Ethiopia, the BPR reform led to a greater mandate for the country's regulatory authority. Not only does the agency license products, it also now licenses providers and facilities. The regulatory authority can request information on quality, safety, and bioequivalence, visit manufacturing facilities to ensure compliance, and analyze samples at its lab. It is not involved in MOH decisions to adopt products, which it sees as a separate process. Zambia's PRA also carries out registration activities based on objective and internationally established regulatory standards such as safety, quality, and indication. The agency is adamant that it plays no role in MOH decisions to adopt products.

The relative weakness of some regulatory agencies compared to the MOH did not hinder their ability to slow the introduction of new products if regulatory procedures were not followed. Stakeholders in Zambia could cite instances of a regulatory authority holding up products if the MOH or partners tried to take shortcuts on procedure. For example, if authority for indicating product use shifts from doctors to another group of health workers, the product must be reregistered, even if only used for a pilot study. The same is true if product distribution shifts from prescription-based to over the counter. New distribution methods for health products are common pilot projects brought to the MOH by partners. The MOH and partner organizations feel pressure to move quickly on such projects because they are accountable to donors. However, both NGO and PRA stakeholders pointed to instances in which "leaning on the PRA" to speed up the change in indication for such pilots had the opposite effect.

7. Mechanisms to conduct health technology assessment may already exist within ministries of health in low-income countries, but it is unlikely that they have the capacity to assess value for money. Stakeholders agree that technology assessment and cost-effectiveness data are vital to planning, but many were doubtful about the usefulness and sustainability of placing a designated technology assessment unit within the MOH.

The concept of a health technology assessment unit was difficult to convey to stakeholders in the case-study countries. Many could not grasp exactly what such a unit would do. Some stakeholders doubted the rationale behind expanding MOH bureaucracies that already struggled with efficiency. Stakeholders thought that the impetus for such an agency would largely be external and would require a long-term financial commitment by a donor.

Other stakeholders pointed out that existing units not operating to capacity could carry out health technology assessments. They believed that an assessment unit would simply duplicate tasks and roles already assigned elsewhere. Others wondered where the unit would obtain the necessary data to do its work since

> "The capacity to do [assessment] is there, but the service is not provided … They need people to teach them and give them evidence to do these kinds of analyses. There is already a health economics department at the university. There is already the formulary committee. Therefore the MOH, plus the treasury and other stakeholders, should be able to find a way to produce this information. People just need the opportunity. We don't need a new unit. It's better to just take existing people and use them better."
>
> [ZAM-INGO-6]

health information systems at the country level were generally weak. These concerns echo research by Chalkidou and colleagues that found low-income countries lacking in both the institutional capacity and the flexible, sustained financing mechanisms to support health technology assessment (2010).

Several stakeholders in Zambia gave the example of the pharmacy unit at the MOH. The unit sits under the Directorate of Clinical Care and Diagnostic Services but is responsible for addressing drug-related issues across all ministry directorates. As one stakeholder stated, "Now the pharmacy people run from TWG to TWG, but they don't have a role at the policy level, and they don't really have any leadership. They have to go to Clinical Care or Public Health first, and then they can go to the permanent secretary. They don't have a direct line. They have huge amounts of responsibility but no authority." [ZAM-PROF-2] Another said, "I've always told the pharmacy people that if someone asks you to do something, you should ask: 'What is the added value?' Don't just jump in and do it. But they respond to emergencies. They are just reactive. They don't find time for planning." [ZAM-INGO-6] Stakeholders had a general sense that that the MOH could be better at utilizing its existing personnel according to skills and job roles, rather than creating new institutions.

> "If the Ministry of Health were to have a unit, then it would help linking up recommendations, actions, and policies. We have 'technical assistance-this' and 'technical assistance-that,' but it has to be mainstreamed and integrated and part of the MOH culture. It has to translate into programming. All of this has to come from within the MOH. But you need a catalyst, and this catalyst can be external. It's just that once it starts, it has to be integral to the MOH."
>
> [ZAM-DON-1]

Despite doubts about the usefulness and feasibility of a dedicated technology assessment unit, stakeholders across the three countries commented on large gaps in the data for decision-making. Strikingly, they noted a paucity of information on "value for money" and cost-effectiveness.

In Zambia delivering cost-effective health care is the primary mission of the NHSP, yet no office within the MOH is engaged in generating this information. The type of data a health technology assessment unit could potentially generate would be greatly appreciated and widely used by technical partners, donors, and the government, provided that the data could be packaged in a way that makes clear its links to policy.

Of the stakeholders interviewed in Zambia, the two donor representatives and the representative of a donor-funded program were most supportive of the need for having the MOH generate and own such data. Other stakeholders also saw the need for health technology assessment data but wondered why an assessment unit necessarily had to be part of the public sector. These stakeholders felt that perhaps such a body would be better located either nationally or regionally in the nonprofit sector. Two stakeholders wondered if an assessment unit might be best placed at WHO's Regional Office for Africa as this office already has access to global-level information on new and existing health products and as the leverage to ask for and support country-level generation of evidence. An assessment unit located within the MOH may have less access to data if it hasn't been empowered to demand it.

Conclusions

> "This is an enabling environment. I have worked in the health field here for 15 years. The last three years have been the most exciting. Partners are valued, and there is an open door."
>
> [ETH-PO-2]

The health sectors of Cambodia, Ethiopia, and Zambia have notable differences. Cambodia usually waits to adopt new health products until the product has moved from the WHO List of Essential Medicines into all relevant national-level policy documents. Cambodia is a relatively late adopter of new technology and requires a critical mass of evidence (including pilot studies) before taking new products on board. Zambia adopts products early and historically has moved ahead with products prior to their inclusion on the national essential drugs list and formulary. The MOH takes an active role in lobbying the PRA for expedited registration. MOH openness to new ideas and interventions has meant that the country has been the site of many pilot and demonstration projects and clinical trials. Ethiopia is in the middle of these two models, with product adoption a sometimes complex process that requires champions at the most senior levels of the MOH.

Still, the case studies illustrate commonalities across the three countries. The following six themes emerged from the research:

1. There is little evidence in the three countries of proactive, strategic, health systems-oriented planning for new product adoption over the long term. Most health-product decisions are made according to an ad hoc, product-by-product, program-by-program model. National disease-control programs and other vertically organized initiatives tend to have more resources, greater administrative capacity, and increased accountability to funding agencies with regard to strategic planning. Further technology-focused case studies in a larger sample of countries are required to understand whether these factors play a significant role in expediting adoption of particular health products. Nevertheless, interviews suggest that a long-term, systems-oriented approach to new health-product adoption, even in these vertical programs, has still not been realized.
2. Technology adoption decisions in the three countries are presently supported by external parties. This does not mean that external parties determine what products the ministries adopt. But information and evidence on effectiveness of new products primarily comes from external parties. WHO, in particular, plays a major role. The global office provides guidance and standards for adoption. Regional offices provide information and links to evidence. Country-level WHO headquarters provide technical assistance toward adoption and implementation. External guarantees by donors and partners for both financing and technical support toward procurement and implementation also greatly facilitate and expedite decision-making. It is likely, too, that any sort of health technology assessment unit or mechanism placed within an MOH would require substantial external support.
3. Stakeholders in these three low-income countries have various pathways to obtain information on health products. Global consultations, meetings, and workshops are one important pathway. Technical working groups, nonprofits, technical agencies, and manufacturers provide other pathways for the identification, evaluation, recommendation, and implementation of new health products. These pathways do not provide information systematically or in standardized ways.
4. In the three countries, MDGs significantly influenced the structure of national health plans, which in turn influenced both short- and medium-term planning and management around health product

adoption. The focus on these global targets, rather than cross cutting health systems issues, may restrict decision makers' ability to consider long-term, health-system-wide product adoption.

5. Many stakeholders in the three countries welcome more country-level health technology assessment, especially in the area of value for money and cost-effectiveness. However, many are not able to conceptualize what a health technology assessment unit would involve or where it would be located. They doubt the usefulness of creating additional layers of bureaucracy and express concern about sustainability if created with external financing. A country-level health technology assessment mechanism is, moreover, an idea that would require "selling" to the MOH because its representatives may feel the current model of health product adoption is acceptable.
6. Many stakeholders in the three countries do not feel that health technology adoption is the key access issue. Rather, stakeholders perceive the access bottleneck to be capacity to finance and implement after product adoption. This view may reflect the fact that national-level stakeholders are tasked with implementation and do not have a broad perspective on new product pipelines. However, there are many examples of products that ministries of health have adopted quickly and easily but that remain unavailable to end users. Most low-income countries face severe financing and systems constraints and are subject to donor conditions and priorities. Many stakeholders believe that procurement, delivery, and integration remain the biggest challenges to new technology access, rather than the assessment and adoption process.

This qualitative study in three countries was carried out to understand the experiences of low-income countries with technology adoption and their interactions with the global health technology market. As the study was designed to be exploratory, and the sample size was small and not representative of all low-income countries, the findings must be interpreted with caution. They do, however, provide a starting point for understanding how low-income countries learn about new health products, the process by which they assess, adopt, and integrate new products into their health systems, and their interactions with the global health technology market. As discussed in the next section, the findings also help identify questions for future research on technology adoption and the global health technology market.

Section IV. Conclusions and next steps

To identify challenges and ways to support the informed introduction of new health technologies in LMICs, we set out with three project objectives: 1) To understand the market environment for global health technologies; 2) To understand how countries adopt new products; and 3) To develop a set of recommendations to support better quality interactions between countries and the global health technology market.

In this report, we conceived national governments of LMICs as *consumers* of global health technology products and proposed that these governments need to be more empowered as consumers. Our definition of empowerment of national governments in the context of the global health technology market as:

> *Empowerment is a national government's ability to exercise greater control in choosing among global health products to intentionally produce desired health outcomes aligned with the goals of the country's health system.*

We then developed a set of seven principles of empowerment of national governments in the global health technology market to reduce the risk of structural detriments experienced by the national governments and, thus, improve government-market interactions.

We reviewed three country case study findings and reorganized them in the Table 7 in reference to the seven principles:

Table 7. Seven Principles and Country Case Study Findings

	Principles	**Country Case Study Findings**
1	*Information on technologies*: Standardized information on new and existing health technologies should be systematically made available to countries.	Stakeholders in the three countries learned about new health technologies via four information pathways. Global and regional consultations, workshops, and partner-led discussions were the most important sources of information about new products. Information about new products was not made available systematically via these pathways but in a more ad-hoc manner. Furthermore, the information provided via these pathways was not standardized. For example, in some cases global data on efficacy and safety were made available to stakeholders, whereas in other instances these data were supplemented with country-specific data.
2	*Advice channels:* Transparent and neutral advice channels for countries should be easily accessible.	In the three countries, advice was accessible via technical partners such as WHO, UNICEF, and others. Future research should probe how country stakeholders and suppliers view the "quality" and "neutrality" of this advice. Our limited country data on this topic suggest that stakeholders view these advice channels as neutral in relation to the Essential Medicines List and product catalogues. In contrast, the advice of technical partners may not be perceived as neutral in regard to work on field trials for particular products..
3	*Capacity strengthening*: A global or regional mechanism should exist to strengthen country capacities to collect, interpret, and translate relevant information for decision-making.	In the three countries, our data suggest that systematic investment by global or regional actors to strengthen countries' capacity to collect, interpret, and translate information for decision-making is not occurring. In interviews, some stakeholders identified capacity building in this area as essential, while others felt that current capacity around product adoption decision-making was sufficient.
4	*Country choices:* Countries should be able to make technology adoption decisions from a choice set rather than one product at a time.	In the three countries, technology adoption decisions are usually ad-hoc and made product by product, and program by program. Within a program, decision-making is sometimes made from a choice set (for example, decision-making about which malaria RDT to choose from a set of RDT products). Many country stakeholders perceived this ad-hoc technology adoption process as acceptable.
5	*Country networks:* Information-sharing networks should exist among countries for exchange of information on product implementation, quality, and trade practice in support of adoption decisions.	In the three countries, information was shared between countries, usually at global and regional consultations, meetings, and workshops. These information-sharing opportunities normally occur program by program, or within global, disease-focused initiatives.

	Principles	Country Case Study Findings
6	*Country representation:* The interests of countries as consumers of health products should be represented in the processes for shaping the global health technology market.	Current research demonstrates that the countries that are (or will be) the consumers of new products are often underrepresented in the processes for shaping the global health technology market. In one of the three countries, stakeholders spoke of how a Ministry of Health official's role on a global partnership board helps represent their country's interests and experiences, and assists them in accessing information on products.
7	*Monitoring market:* Global or regional mechanisms should be in place to monitor and regulate market practices that would negatively affect a country's interests in the global health technology market.	Currently this global or regional mechanism is not in place. In interviews, very few stakeholders in the three countries raised the need for such a global or regional mechanism.

We observed signs that aspects of the principles such as "Information on Technologies" and "Country Networks" are being met in the three countries. On the other hand, the three case studies suggested that other principles were weak, such as "Capacity Strengthening" and "Monitoring Market" principles Experiences on "Country Representation" were inconsistent across countries. Our overall impression was that the national governments in the three countries were not empowered consumers of health products and that there is a room for significant improvement in every principle.

To further operationalize these principles, we identified illustrative questions (Table 8) that can be used to assess practices and structures of the global health technology market. Assessment can be used to identify positive experiences of national governments in dealing with the markets, to identify detrimental practices or structures and take actions to address them, and to monitor the practices over time.

Table 8. Illustrative questions to assess practices and structures of the global health technology market.

Empowerment Principles	Illustrative Questions
1. Information on technologies	• Whether well-recognized channels of information exist on health technology products. • Quality of efforts at the global/regional levels to standardize product information by producers/manufacturers, international technical agencies, product advocates, or donors. • Whether information on comparable products is standardized and easy to understand and used by country stakeholders. • Whether information available to countries is limited to technical specifications or also includes information related to product implementation, cost, and human resource and other health system requirements. • Whether global and/or regional mechanisms exist to monitor the quality of information made available to countries.
2. Advice channels	• Whether well-recognized and trusted mechanisms exist for quality assurance and/or endorsement of products. • Whether conscious efforts are made to monitor and support improvement of quality of advice channels. • Whether access to advice channels is easy and requires few resources

Empowerment Principles	Illustrative Questions
	• Whether mechanisms exist for countries to complain about services provided by advice channels.
3. Capacity strengthening	• Whether global channels/mechanisms exist to build knowledge and skills of national governments seeking information on products. • Assess performance of global channels/mechanisms for capacity strengthening. • Whether capacity strengthening efforts consider health system needs or are limited by a specific health issue or dominated by a disease program
4. Country choices	• To what extent national governments control the composition of a set of product choices where multiple products are available and will be available in the near term. • Whether national governments make conscious decisions on the adoption of a product from the choice set they created by considering trade-offs of the three detriments (appropriateness, quality, and price detriments). • Whether there is an explicit choice not to engage in a transaction.
5. Country networks	• Whether country networks exist among interested countries to monitor and exchange information on their experiences with information collection, implementation, and advice channels associated with products. • Assess the level of exchange of information among countries and support provided by global mechanisms or organizations.
6. Country representation	• Assess how representatives of country interests are included in global governance structures of committees, alliances, and partnerships related to health product development, advocacy, and introduction. • Assess advocacy groups or mechanisms at global and regional levels to advocate for country interests in product development, advocacy and introduction. • Assess representation of country preferences, experiences, and concerns related to product adoption in global governance structures.
7. Monitoring market	• Assess whether global/regional mechanisms/structures exist to monitor the level of investment in the global health technology market. • Assess functioning of mechanisms at the global level to monitor barriers to entry in the global health technology market and to take action on identified barriers. • Assess mechanisms to monitor and regulate donor practices that could negatively affect incentives for innovation.

Our seven principles of consumer empowerment for governments and the accompanying illustrative assessment questions represent a major step forward in thinking how national government make decisions in the context of the global health technology market. Validating the effectiveness of the seven principles in empowering national governments and thus increasing aggregated welfare through global health technology products will be an important next step. Future research on the seven principles should include stakeholders in the global health technology market to help refine the principles and the assessment questions and build consensus on the importance of country empowerment. Further research is also needed to validate the effectiveness of country empowerment in helping making explicit trade-off decisions across the three detriments of appropriateness, price, and quality.

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The authors' contributions are as follows:

- **Dai Hozumi** led the global study design and researched and drafted the introduction and global study sections. He also conducted interviews in Cambodia for the country case studies and participated in the development of the county case study section.
- **Laura Frost** led the country case study design, conducted interviews in Ethiopia, and led the development of the country case study section. She also contributed to the design, data collection, and review of the global study.
- **Beth Anne Platt** conducted the country case study in Zambia and co-authored the country case study with Laura Frost. She also contributed to review of the global study section.
- **Tanya Lalwani** led the literature review for the research and contributed to review of all sections of the report.
- **Michael R. Reich** provided strategic advice for the design and conduct of the study, provided guidance for the research and analysis and revision of the report.

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