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Discerning Demand:

A Guide to Scale-Driven Product Development and Introduction

The lead author of this report is the Center for Innovation and Impact (CII) at the United States Agency for International Development (USAID). CII incubates new ideas, puts them into practice, and scales effective approaches through partnership and institutional change. Our expertise in innovation, market-based solutions, and digital health helps us accelerate impact against critical health issues.

CENTER FOR INNOVATION AND IMPACT

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To download the latest version of Discerning Demand: A Guide for Scale Driven Product Development and Introduction, please visit www.usaid.gov/cii.

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FOREWORD

Scaling any new product is hard. When you target scale-up in resource-constrained settings, the challenge grows further, especially for commodities not supported by global funders.

The financing landscape has shifted over the last two decades, and there is more potential to increase global health financing by mobilizing private capital from impact investors. At the same time, both bilateral and private funders continue to invest in the research and development of new products as they seek transformative impact. As of April 2023, Policy Cures Research counted 749 products in the pipeline for neglected health priorities.[1]

While new product development is abundant and often celebrated, many resulting products struggle to scale in target markets, especially when there is no global, centralized procurer and a greater reliance on governments as the payer for procurement, delivery, and uptake. Despite significant attention by funders and partners to scale new products—including by funding the companies, pilots, and more—uptake often remains challenging.

We believe product adoption is hampered by demand insufficiently considered early in product development and misunderstood by multidisciplinary global health teams. In particular, funders and investors tend to rely too much on understanding unmet needs instead of accounting for more precise definitions that reflect a product's rollout feasibility and likely success. This publication's focus on discerning demand attempts to untangle how demand is understood by different global health stakeholders. It explores approaches to better align on an understanding of demand and informs ways we can individually and collectively change how we invest our time and resources to generate the health impact we collectively strive for.

This publication offers no easy answers and is not exhaustive. It is not a review of pooled procurement, supply chain and logistics, or market shaping, nor is this a guide on how to generate demand—these topics are well-covered elsewhere. This publication intends to catalyze reflection, discussion, and action on better understanding demand as early as possible during product development. CII welcomes any feedback on the ideas put forth in this publication.

We recognize that an effective but unused health product doesn't make a difference. By being better equipped to assess demand critically, we can be more confident in making tough choices as stewards of product innovations. Doing so can improve how funders, investors, advocates, innovators, countries, and communities invest limited resources to accelerate the availability of new life-saving interventions.

1 This definition includes 21 diseases disproportionately affecting people in low- and middle-income countries, with limited suitable products to prevent or treat the disease or condition, and with no commercial market to stimulate R&D. This figure is based on personal correspondence with Policy Cures Research on April 20, 2023. (Unpublished; updated from previous estimate).

EXECUTIVE SUMMARY

Three primary objectives guide the breadth of content put forth in this publication.

Our first objective is to establish a common understanding of demand for new health products. The global health sector is highly multidisciplinary, with influence from institutions across commercial, non-profit, philanthropic, and public sectors. It is natural that how demand is understood varies depending on the perspectives and agendas of different stakeholders. We've seen the word "demand" often conflated with at least three other terms: need, total market size, and consumption. This conflation leads to misinterpretations that can be counterproductive, especially in multidisciplinary teams. Furthermore, different stakeholders tend to be overly dependent on terms based on their incentives. For example, unmet need is common among influencers such as advocates concerned with the magnitude of a disease burden. Alternatively, other definitions of demand are under-utilized in market access discourse, including total addressable market (TAM), serviceable available market (SAM), and serviceable obtainable market (SOM). We offer four distinct demand definitions to help standardize how stakeholders understand demand and reduce the risk of misinterpretations. We hope that alignment on more precise definitions of demand among different stakeholders can improve decision-making.

Our second objective is to assess available tools and approaches to understand demand at different stages of the product development pathway. Our landscape review synthesizes ten unique tools and approaches used across public and private sectors to understand end-users, markets, and market size. Tools are only as good as the processes set up to use them. While the main report includes a synthesis of tool categories, the Supplemental offers more detail on facilitating a process that appropriately utilizes different tools and methodologies.

Our third objective is to offer recommendations for collective action and individual decision-making. We started with the question, "What is fundamentally challenging with how we currently think about demand?" We brought together leading institutions that make direct investments in new global health products and facilitated a reflection process to test, iterate, and build consensus on Why it has been challenging to understand demand, What product stories exemplify some of these challenges and offer learnings, and What this means for our collective global health goals.[2]

Our iterative approach to understanding the Why culminated in four common pitfalls of trying to understand new product demand in global health.

- **Pitfall 1: Difficulties with accessing timely information on client and provider health journeys in low-resource settings.** Insufficient time, limited funding, and limited consensus on how to get and use information can result in a disconnect between what end-users (patients or providers) want and what global health advocates and innovators think they want. This disconnect influences the product design, how it is delivered, and how it is purchased. Difficulties in understanding what matters to users—preferences, ability to pay, and health system inhibitors or enablers such as procurement behavior—exacerbate this challenge.
- **Pitfall 2: Incomplete understanding of country priorities, financing landscape, and political will.** For funders or innovators operating in multiple countries, there is low visibility into health innovation priorities in and across countries. The ecosystem of health product purchasers can vary substantially from one country to the next, and the financing and political complexity can obscure whose decision matters and where accountability lies. Product developers and their advocates might have limited ability to identify and engage with different country-based decision-makers and influencers. This can be especially challenging when advocates might be seen as at odds with the government.
- **Pitfall 3: Inaccurate demand sizing that leads to overestimation or underestimation.** Challenges include a lack of clear definitions for what is quantitatively sized, incorrect target populations, and limited or no inputs on willingness to pay. Iteration and scenario planning is not widely practiced. Weaknesses in data quality and availability exacerbate this challenge when decisions have to be made with incomplete information.
- **Pitfall 4: Continuation bias and limited opportunities to pivot or stop.** Global health stakeholders tend to prove something is worthwhile rather than consider the possibility of pivoting or stopping. Over time, multiple layers of information through studies, pilots, and proof-of-concepts are generated with limited or unclear changes in meaningful decision-making.

2 See Acknowledgements for full list of technical advisors.

The four pitfalls are informed by a health product retrospective approach and a review of how the commercial sector assesses demand. Four health products—internal condoms, non-pneumatic anti-shock garments, pulse oximeters, and rectal artesunate—were chosen to illustrate the What and exemplify some of the identified challenges as well as offer forward-facing learnings on demand-related considerations. A review of how the commercial healthcare sector assesses product demand in launch plans also revealed practices to amplify in the global health context.

Collectively, these analyses led to the So What, or implications for our collective global health goals synthesized as four individual best practices and five ideas for collective investment.

These **best practices** are behaviors any global health stakeholder supporting new product development or introduction can adopt immediately.

1) **Build stakeholder consensus for a precise definition of demand.** The global health community over-relies on unmet needs. This broad definition overestimates what demand can be feasibly met based on operational realities determined via estimates of SOM. Prioritize which stakeholders should align on which definitions.
2) **Incentivize organizational norms that reward pivots.** Reduce the stakes of discussing what may be interpreted as a failure through supportive leadership that rewards actions that pivot through recognition. Celebrate learnings from pivots as advancements of shared goals to address unmet health needs.
3) **Adapt stage-gating processes.** Encourage the adoption of go and no-go milestones that account for demand considerations through evidence of SOM. Ensure that decision-making processes embrace sunk costs and lead to a change or stop entirely.
4) **Continuously pressure test demand and purchasing signals.** Account for country-based demand-related signals in product development, ideally in a co-creation process with a diverse group of country-based actors who can better inform SAM or SOM. Country-based demand signals should be bottom-up as much as possible, especially where procurement and budget decisions are decentralized

We also recommend five **ideas for collective investment.** For all of these, engaging as early as possible with stakeholders who understand country-specific market dynamics is important.

1) **Enable visibility of market and health system data through existing and non-traditional partners.** Incentivize existing on-the-ground partners to share intelligence with product developers. Distributors, wholesaler networks, and health provider associations know their markets and are an untapped resource in global health.
2) **Pair product developers and innovators with in-country partners who understand market dynamics.** Country-based market information on regulations, policy and financing landscapes, distributor networks, and user preferences can help innovators design tailored go-to-market strategies for specific user segments and thus better meet existing demand.
3) **Support country-based platforms that connect innovators with public and private decision-makers and influencers.** This could be a two-way facilitation process that helps decision-makers understand innovators' capabilities and amplifies payer interest in health product innovation.
4) **Support wraparound services necessary for new product introduction.** Product introduction should include considerations for product and health system enablers. Integration into government-led or payer-led systems is paramount.
5) **Aggregate priorities and demand signals from payers across countries.** For specific health areas, aggregated intelligence on health priorities can help channel investments and minimize ill-timed introductions or missed opportunities.

We spotlight four current examples of these ideas worth tracking: The MATRIX and MOSAIC HIV Prevention projects, SAMRIDH Blended Finance Facility, Pumani device/NEST360 program, and Seasonal Malaria Chemoprevention.

Stakeholders and advocates across health areas are encouraged to consider these ideas in the context of what already exists. Some health areas, such as HIV, malaria, vaccines, and family planning, have specific institutions and coalitions mandated to understand demand as part of broader market assessment efforts. For others, such as maternal and newborn health and non-communicable diseases, these institutions are limited. As the global health field's collective understanding of market dynamics evolves, it is our hope that there will be additional opportunities to learn and further improve how we channel resources.

HOW TO USE THIS PUBLICATION

For the purposes of this publication, demand and supply define what we consider to be market dynamics. These dynamics accelerate or decelerate the availability of quality commodities such as medicines, diagnostics, and devices. While this publication focuses on demand, it builds on other market access resources CII published over the last ten years that serve as complementary references: the IDEA to IMPACT series (2016) and the Market Shaping Primer (2014).

This publication is comprised of two parts: a primary report and an accompanying Supplemental. The Supplemental includes a landscape review of common quantitative and qualitative tools used to assess demand, examples of these tools and methodologies, additional market access resources, and expanded retrospectives.

Although this publication offers insights and resources for anyone who works on market access predominantly in low-resource settings, funders, investors, and innovators are the primary audiences. The primary report consists of three main sections. **(1) Demystifying Demand** posits common misinterpretations of demand in global health contexts, offers four definitions to help bring alignment, and explores underlying motivations and biases of different stakeholders toward the relevance of certain definitions over others. **(2) Summary of Learnings** synthesizes findings from three analyses: common pitfalls of understanding demand for new global health products, four product retrospectives and their learnings, and common practices the commercial sector uses in understanding and accounting for new product demand. **(3) Insights and Actions to Support Innovators** proposes four best practices for individual behavior and five ideas for collective investment. To exemplify these ideas in action, we highlight four ongoing projects (as of 2023) that are worth tracking and learning from. All recommendations are a culmination of the extensive research conducted, group discussions, and iterations.

1. DEMYSTIFYING DEMAND

1.1. Incongruous Understandings of Demand

Understanding demand is complex. For one thing, demand is rarely understood independently of supply and the interrelated market dynamics. The five factors that inform market shortcomings and therefore the demand for and use of a specific product are Affordability, Availability, Assured Quality, Appropriate Design, and Awareness.[3] Stakeholders may perceive demand differently depending on their role, incentives, and information within a given market.

Varying stakeholder perspectives often lead to different interpretations of how to define and estimate demand. Moreover, demand is dynamic: assumptions made about demand in one stage of the development process can change drastically over the 10 to 20 year period it might take to move a product from inception to full-scale launch. Throughout development, the individuals who are key to advancing the product to market will also change. As a result, terms that should be distinct are often conflated. We have identified three common misinterpretations of how demand is understood.

Demand equals need or burden of disease. Innovations in global health are typically driven by the acknowledgment of a specific problem, usually related to health inequity. While it can be easy to assess need based on epidemiological data, such as a specific number of individuals suffering or dying from a disease, that need does not necessarily translate to demand. Need is agnostic of the buyer's interest, willingness to pay, and user acceptance, whereas demand accounts for these factors.

Demand equals total market size. Total market size typically refers to a subset of those affected by the burden of disease. However, the affordability, awareness, and acceptability of a product can hamper or expand demand, thereby making it distinct from the total market size.

Demand equals consumption. Consumption can be affected by many different scenarios, such as adherence, product misuse, or supply chain considerations (e.g., expiry risks). Demand can be greater than consumption when accounting for access attributes such as awareness and availability.

1.2. Consensus on Demand Definitions

To improve understanding of demand among multidisciplinary teams, we propose alignment on four precise definitions of demand. These definitions are most relevant to stakeholders estimating demand for new health products across multiple geographies.

It is best to review these different definitions at the start of any project to avoid confusion. Figure 1 provides a visual representation of where each definition falls along the product development continuum.

To make these definitions as tangible as possible, we provide a working example of each in response to a hypothetical new adult COVID-19 vaccine, assuming one vaccine dose per adult.

1) **Unmet Need:** An estimation of demand based on the number of at-risk or sick populations not being served by an intervention or treatment. This number is often expressed in incidence, prevalence, or the number of total events. This number could also include target populations not satisfied with what they use now and who might prefer a better alternative; these are often known as "switchers" in market sizing exercises. A working example would be the total number of adults defined by an age across several countries who could benefit from a COVID-19 vaccine, accounting for any known contraindications.

3 The Market Shaping Primer (2014).

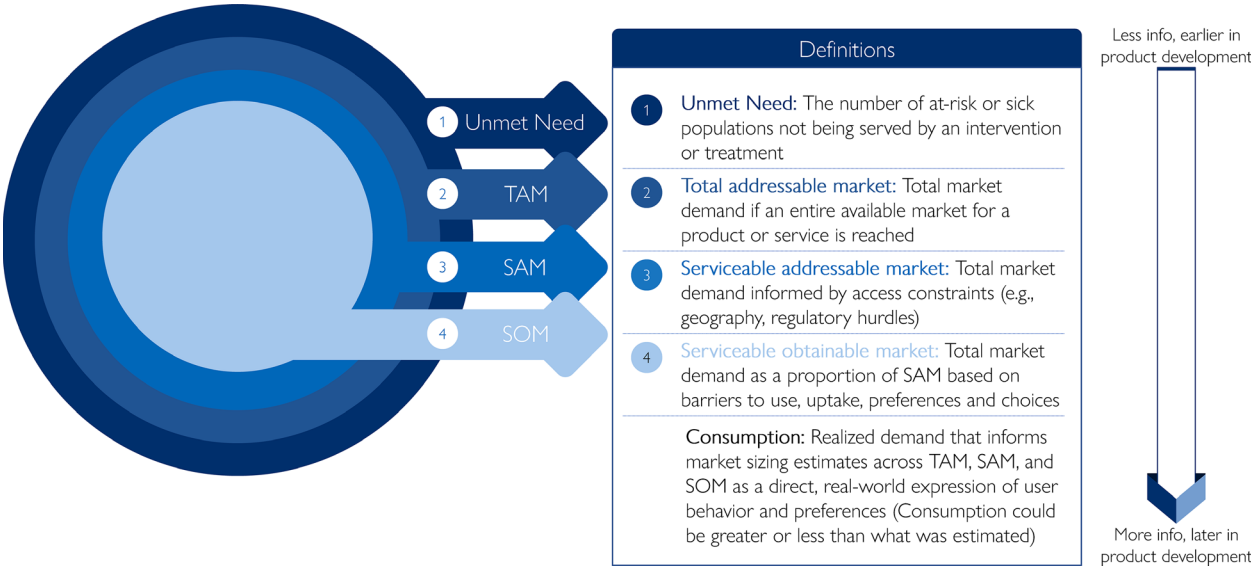
2) **Total Addressable Market (TAM):** An estimation of total market demand if the entire available market for a product or service is reached. This figure is independent of whether a new product is able to reach end-users and so assumes no competition. Building on the previous example, this could be the number of adults in a target geography (e.g., target countries or regions).

3) **Serviceable Available Market (SAM):** An estimation of demand that considers constraints to the total addressable market, such as geography and access challenges. This is a subset of TAM and assumes the new product is not hindered by competition. Building on the previous example, this figure could be limited to a few target countries where regulatory hurdles are likely to be overcome and only include adults with target user demographics within these countries (e.g., adults aged 18 to 75 years old living in urban settings).

4) **Serviceable Obtainable Market (SOM):** An estimation of demand that considers what portion of the serviceable available market will realistically be captured, accounting for barriers to use and uptake such as awareness, affordability, availability, and acceptability based on preferences and choices. SOM is often a short-term target that accounts for operational realities and the product company's ability to adapt or disrupt them. Building on our example, SOM would be a subset of SAM as it might account for the company's marketing budget, understanding of distributor networks or other supply chain considerations, and the competitive landscape (e.g., other vaccines, preferences for alternative solutions). These factors inevitably reduce SAM to a more realistic fraction of the market a new product might achieve. For the COVID-19 vaccine example, this number would be the adults aged 18 to 75 years old in urban settings in the target countries with supportive regulations who are reachable with reliable cold chains and are willing to take a vaccine.

Actual consumption, also referred to as realized demand, might ultimately be greater or less than what was forecasted and is a vital input to inform future market sizing estimates (across TAM, SAM, and SOM) because it is a direct, real-world expression of user behavior and preferences. Realized demand is the actual quantity of products consumed by end-users within a set timeframe and geography. The realized demand can either validate original assumptions used for market sizing, show alternatives (e.g., other types of potential users), or suggest that substantial pivots need to be made. Forecasting TAM, SAM, or SOM for new products could be informed by historical consumption data of similar or proxy products.

Figure 1: Visual representation of four precise definitions of demand

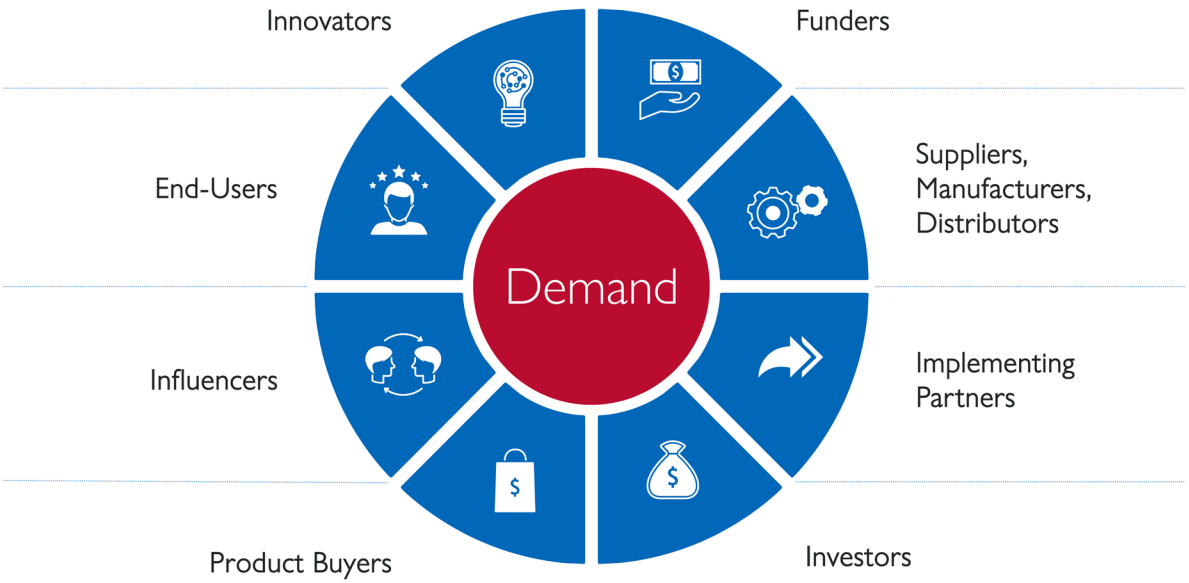


Informed by: Steenburgh, Thomas J., and Jill Avery. "Marketing Analysis Toolkit: Market Size and Market Share Analysis," Harvard Business School Background Note 510-081, February 2010; (Access Fee). Sekhri, N.; Levine, R.; Pickett, J. "A Risky Business Saving Money and Improving Global Health through Better Demand Forecasts," Center for Global Development. Washington, DC, USA, 2007.

1.3. Stakeholder Perspectives That Inform Demand

We have identified eight perspectives that inform product demand.

Figure 2: Eight perspectives that inform product demand



As each perspective tends to be overly dependent on specific definitions, misalignment is common. For example, there might be broad consensus among innovators, implementing partners, investors, and funders on regulatory hurdles to overcome but disagreement on who the expected product buyer is (whether the procurer is a multilateral institution, a public sector entity, or other). In this situation, unmet need or TAM might be clear, but SOM much less so.

When considering demand for new products, it is important to understand perspectives and incentives among different stakeholders and how those might evolve. The complexities of balancing and prioritizing stakeholder perspectives are exemplified in product retrospectives in Section 2.2. For this section, we lay out common biases that influence how relevant certain demand definitions are to different stakeholders. These are intended to be directional, not absolute. We hope that any stakeholder reading this publication is aware and mindful of these likely biases when engaging in multidisciplinary collaborations typical of most global health product introduction efforts.

Innovators. Innovators are often incentivized to have a broad target market. They tend to rely heavily on **unmet need** in order to maximize reach and secure funding from funders or investors to ensure product scale. As products develop, innovators often face pressure and expectations from other stakeholders. Frequently, they do not have the resources to understand more than **TAM** unless they get support from funders or investors to engage with stakeholders with that information.

Funders. Funders of product development can be optimistic in their perception of a product's potential market size. Social impact funders also care about equity. Funders can be biased in how they perceive demand for products when they are also the key advocate. As such, they may overestimate based on **unmet need and TAM**. They typically work across multiple countries and may rely predominantly on country-based partners for information on market dynamics and health system priorities and capacity. Their understanding of demand may therefore be obscured by the relationships they have with different country-based stakeholders—including implementing partners, government agencies, and private sector stakeholders—and their related interests in maximizing resources to fulfill unmet needs.

Suppliers, Manufacturers, and Distributors. This group of stakeholders is incentivized by accurately estimating expected volume, which informs margins at various levels of the supply chain and operational planning. Manufacturers and distributors prefer knowing **SOM** or, ideally, realized demand to minimize surpluses and optimize operational plans, from customs clearing to last-mile delivery. Limited demand forecasts and market size information increases risks for new suppliers and increases costs.

Implementing Partners. Implementers often have significant knowledge of local needs and preferences. Their scope of work is often limited to time-bound grant deliverables or specific projects. This limits bandwidth for generating intelligence that could inform or support new product development and introduction. They are likely to rely more on **SOM** because they typically work directly with end-users or those who serve them. They may also be influenced by limited funding cycles and therefore overstate **unmet need** to advocate for resources and stretch impact targets.

Investors. Investors are generally interested in return on investment or, at a minimum, breaking even on their investments. Investors are incentivized to be highly sensitive to overestimating demand as doing so may directly impact their financing outcomes. They are likely inspired by **unmet need or TAM** but will be primarily interested in **SAM** to understand market potential. They may underestimate the funding required to generate intelligence that would inform **SOM**.

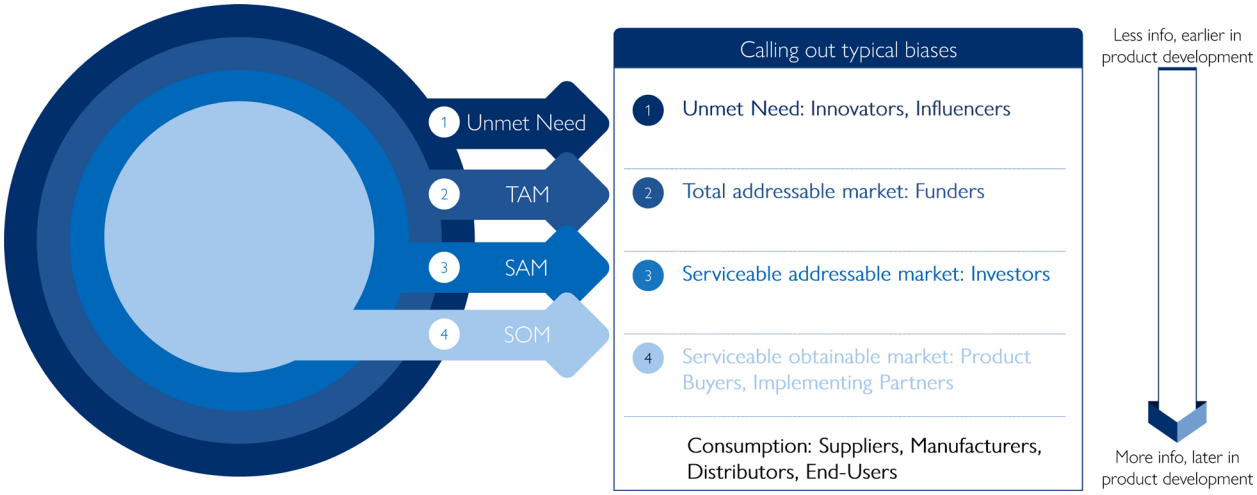
Product Buyers. Product buyers are also known as payers or purchasing actors. These can be private (e.g., out-of-pocket payments or insurance companies) or public (e.g., government financing). Private and public buyers care about cost and value, although the balance between the two depends on incentives and resources. Public buyers often rely on separate procurement agencies and, as such, operate in a complicated political economy with varied incentives that can shift over time, including cost, quality, source of supply, lobbying, and guidelines. Private buyers, whether insurers or consumers, may be motivated by factors like government, healthcare professionals (lay or certified), and social circle (family, friends, media). Buyers are likely predominantly interested in **SOM**, followed by realized demand.

Influencers. Influencer stakeholders include normative bodies (e.g., WHO) and advocates (e.g., civil society). Healthcare providers might be influencers as well if patients defer to their opinions to change behavior. Influencers typically have an agenda that may or may not align with operational realities or practicalities such as buyer potential, consumer constraints, or preferences. Advocacy perspectives can overestimate or underestimate demand depending on their agenda and appreciation for the broader health system context and purchasing decisions. Influencers tend to rely on **unmet need** because they focus on the magnitude of the problem, although some focus on **TAM or SAM**, informed by an understanding of demand and supply considerations closest to users.

End-Users. End-users such as patients or health providers (when they are needed for product use) often have the most acute sense of a product's value for new adoption or switching potential based on their awareness of what the product is intended to do, their means to pay for it, and who they are influenced by. Accepted norms can hugely influence end-user acceptance of any product, particularly if their job changes as a result or there is peer support. On the one hand, their preferences manifest in realized demand. On the other, their preferences may be unfulfilled if there is misalignment between what they want and what they can feasibly access. These unfilled preferences could then inform other demand definitions including **TAM, SAM,** and **SOM.**

The below schematic illustrates the demand definitions most relevant to different stakeholders. This is not an absolute but rather a representation of common demand definitions used by each stakeholder group.

Figure 3: Demand definitions most relevant to different stakeholders



2. SUMMARY OF LEARNINGS

Aligning on how demand is defined is the first step toward closing the gap in understanding and accurately assessing demand. Our analysis uncovered four common pitfalls implicated in global health.

2.1. Common Pitfalls of Understanding Demand

Difficulties with accessing timely information on patient and provider health journeys in low-resource settings. We cannot overstate the importance of understanding country-based providers and the patient journey when considering demand. Understanding takes time, funding, and consensus on approaches. It is often not possible to get the necessary information quickly enough to inform product design, launch planning, and other critical milestones. Understanding who procures and who uses often gets conflated. This inhibits adequate understanding of the patient journey and healthcare provider workflows, preferences, and operational realities. These difficulties also limit understanding of health system requirements to validate a product's value and support introduction, including distribution networks, supply chain considerations, financing, and service delivery needs. This can result in a disconnect between what end-users (whether patients or providers) want and what global health advocates and innovators think they want. Difficulties in understanding what users care about—preferences, ability to pay, and health system inhibitors or enablers—deepen this disconnect.

> *"Many stakeholders are currently not included in the innovation conversation but influence product scale-up."*
>
> *- Funder*
>
> *"It's hard to know who has skin in the game and whose opinion matters. The users understand the benefits but don't have control."*
>
> *- Funder*
>
> *"The global health community is too focused on delivering new products when, in reality, it will be very hard for those products to displace what is already available from a cost-effectiveness perspective. We don't invest enough in testing the true value of a product"*
>
> *- Funder*

Incomplete understanding of country priorities, financing landscape, and political will. Establishing the financing landscape and buyer ecosystem of target countries is an important component of successful product development and uptake. For funders or innovators operating in multiple countries, there is low visibility into those priorities in and across countries. It can also be difficult to understand what innovation purchasers are willing to pay for. Lack of early engagement with government decision-makers and influencers across functions such as health, finance, and regulatory inhibits product developers. Product developers and their advocates have limited ability to identify and engage with different country-based decision-makers and influencers.

> *"There is a gap in understanding between countries' innovation agendas and what is being developed, and a need to better bridge the gap of what countries want with what is being developed."*
>
> *- Funder*
>
> *"We don't have a great view of the political influencers and decision-makers in-country and misunderstand what is going on. Even if we think demand is well-understood and prepared for, if the country champions are not engaged, and budgets not identified, then introduction is unlikely to occur."*
>
> *- Investor*

Inaccurate demand sizing that leads to overestimation or underestimation. Precision on definitions of demand must inform what is being quantitatively estimated. An ongoing issue is the incorrect segmentation of target users based primarily on demographics such as age and gender while excluding life stages and behavioral drivers. A lack of high-quality, robust inputs for modeling, such as consumer research to understand preferences and willingness to pay, is also a challenge. Difficulties exist with demand forecasting, given the high level of uncertainty in the data and limited opportunities for iteration.

> *"Demand forecasts are very dependent on what people want. Is demand sizing done for advocacy or for operational purposes? The unspoken agenda needs to be made more clear."*
>
> *- Implementing partner*

> *"New product adoption often depends on the budgeting processes in health facilities; demand is driven by how much funding they have and if something isn't commonly available, they might order extra. But this wouldn't reflect an accurate need or a priority. It is common to overlook these micro-level nuances that lead to overestimated needs."*
>
> *- Funder*

Continuation bias and limited opportunities to pivot or stop. Continuation bias among global health stakeholders leads to multiple iterations of evidence generation through investments in pilots, proof-of-concepts, and other studies that do not always lead to pivots in decision-making, including the potential to stop. There is limited use of stage-gating processes or other forms of governance that ensure accountability as it relates to decisions made by those both paying for and using the product. Sometimes it can be better to embrace sunk costs collectively and stop investments.

> *"Funders overinvest in the optimistic case but need to acknowledge the uncertainty and move away from a point estimate; we need room to expect worse outcomes."*
>
> *- Funder*

> *"Funders push products that are complete failures, then quickly disassociate from the product and leave it to the countries to explain. There needs to be a shared responsibility to acknowledge what happened!"*
>
> *- Implementing partner*

2.2. Product Retrospectives and Learnings

We identified four product-specific retrospectives that exemplify some of these pitfalls. These retrospectives were selected to reflect diversity in market archetypes (new vs. generic), buyers (funder vs. government or other), disease areas (maternal, newborn, child health), and product types (diagnosis, prevention, treatment). They were prioritized based on technical advisory group feedback and the feasibility of generating retrospective insights across at least four different perspectives: buyers, innovators, adopters, and implementing partners. While the product retrospectives exemplify the pitfalls, our intention is not to judge an individual product as a failure or a success. Rather, these retrospectives are intended to offer forward-facing learnings applicable to any new product. Expanded retrospectives of each product, including references, are available for download in the report Supplemental (Section 4).

Figure 4: Overview of four product-specific retrospectives across product retrospectives

Fast Facts (Note: Sources noted in retrospectives)	Internal Condom (IC)	Non-Pneumatic Anti-Shock Garment (NASG)	Pulse Oximeter (PO)	Rectal Artesunate (RAS)
Health Area	Family planning and HIV prevention	Postpartum hemorrhage (PPH)	Oxygen	Severe malaria
Market Archetype	New product with few suppliers	Niche product; crowded PPH market	Generic/commodity; many suppliers	Generic/commodity; not crowded market
CII Global Health Innovation Index	Transformative	Incremental	Incremental	Incremental
Expected Buyer/Procurer	Global Fund, PEPFAR, UNFPA	Limited government procurement; some private sector procurement	Local government, private providers, global donors	PMI, MMV, and GFATM, some country funding
Funder	USAID, KfW Dvt Bank, UK Foreign, Commonwealth & Development Office	CHAI, UNICEF, UNFPA; studies funded by USAID PRH, MacArthur Fdn., BMGF, Laerdal Fdn.	USAID, Unitaid, Wellcome Trust, BMGF, GAVI, World Bank, Global Fund, WHO, CEPI, FIND	Studies funded by WHO and Unitaid
Countries	FC2 is available in more than 54 countries globally	Scale-up strongest in Africa; small quantities procured in 90+ countries	Available in 100 countries around the world	Registered in 20 countries, all in Africa
Manufacturers	Female Health Company, Cupid Limited, HLL Lifecare	LifeWrap International in China (About 80%-85% of market), VISSCO in India	Many (e.g., Acare Tech, Masimo, Nonin, Edwards Lifesciences, Phillips)	Strides Pharma and Cipla (both prequalified)
Intended Delivery Setting	Public clinics and hospitals, mostly for HIV prevention	Primarily in public and private-sector hospitals, some health centers and remote maternal care sites	Primary, secondary, and tertiary facilities	Community healthcare workers
Cost	$0.31-$0.50 per condom	Product cost is about $40-$75 with shipping	About $25-$50 for fingertip device, $100-$250 for handheld device	Less than $1 per suppository
Uptake	Less than 2% of women of reproductive age using contraceptive methods	Low, in peak years can be about 10K-15K units per year; historically has been lower	50%-70% of health facilities in LMICs lack functional pulse oximeters	About 2M-3M suppositories annually; dependent on funder commitments and WHO guidance

INTERNAL CONDOM RETROSPECTIVE

Internal condoms (ICs) are single-use contraceptive devices inserted into a woman's vagina before sexual intercourse. Though the product was originally designed as a contraceptive method, the internal condom was positioned as an HIV prevention tool in response to the increasing number of women that were being infected by HIV. As the only woman-initiated method for HIV prevention, uptake in LMICs affected by HIV was expected to be high. However, the internal condom faced numerous challenges, including no clear funding champion, a misunderstanding of end-user preferences and needs, insufficient funding for demand activation activities, and inaccurate comparisons to the male condom.

The PATH Woman's Condom (WC) was designed by global health stakeholders to offer an internal condom that addressed concerns with acceptability identified through the use of FHC products. Despite addressing many end-user concerns, the WC—priced at $0.80—was undesirable to price-conscious public sector payers because it was more expensive than other internal condoms. No purchases were ultimately made through global health funders or government payers as originally anticipated. PATH attempted to pivot its go-to-market strategy from the public to the private sector, targeting customer segments with disposable income willing to pay for a better consumer experience. Yet due to the lack of marketing investments required to reach and entice the target population, this strategy resulted in limited orders. We have synthesized four learnings sparked by the demand-related challenges in this story.

Key Learnings

Allocate funding to demand-activation activities. Limited funding was allocated early on for customer segmentation, marketing, and other demand activation relative to the male condom and other HIV prevention and FP interventions. For new products, especially those for which there might be a strong stigma, significant funding needs to be allocated upfront to inform end-users and train healthcare workers. Funding should be sustained beyond the initial scale-up to increase awareness and normalize use.

A strong value proposition relative to alternatives must be established and updated over time. The lack of a clear perceived value proposition for the internal condom in comparison to new HIV prevention methods led to decreased interest among advocates and buyers for the product. More broadly, the lack of champions for multi-purpose products weakened advocacy for the internal condom. Identifying Key Opinion Leaders and funding champions early on is essential for activating demand in later stages of product development. This is especially true when new products and

treatments are in the pipeline and end-users will be faced with many options to choose from. If these funding champions are not readily available, funders should consider whether pursuing the later stages of product development is a worthwhile investment.

Inappropriate demand sizing and customer segmentation is an ongoing issue. Initial demand estimates for the internal condom were based on comparisons with the male condom despite significant differences in needs and preferences between women and men. This led to overestimations of potential demand. Efforts to expand internal condom use were stymied by misguided promotional efforts that inadvertently stigmatized the product and its users. Demand sizing processes need to account for updated assumptions, and these, in turn, should update product introduction strategies, including pivots as needed. Changes in target customers need to inform decisions on whether further investments in product promotion are worthwhile, with accompanying funding commitments when decisions conclude that additional promotion is justified.

It was difficult to meet both user and payer needs. While it met usability concerns, PATH WC could not meet the price expectations of global payers, especially in comparison to other, more affordable products at the time. If a product does not meet target payer expectations, then innovators should explore alternative go-to-market strategies to reach intended clients, adapt the product, or deprioritize further development.

NON-PNEUMATIC ANTI-SHOCK GARMENT RETROSPECTIVE

For women experiencing severe postpartum hemorrhage (PPH) in rural LMIC contexts, mortality and severe morbidity are determined by how soon they can reach appropriate care. The non-pneumatic anti-shock garment (NASG) is a lightweight first aid device designed to stabilize women during instances of severe postpartum hemorrhage until care is available. It reduces blood flow to the uterus, prolonging life up to 48 hours. The garment is washable and reusable up to about 150 times and does not require extensive training to use. NASG studies helped generate support in the global health community, with the WHO including NASG in its guidelines on PPH treatment. While subsequent studies have demonstrated that NASG is not by itself a life-saving product, the WHO has not updated its PPH guidelines for NASG.

Recognizing the unique role of the NASG as a stabilizing tool, CHAI leveraged its partnership with the UN Commission on Life-Saving Commodities to spur interest in scaling NASG, chiefly through market-shaping interventions. CHAI partnered with the Safe Motherhood Program and the NASG manufacturer to design a volume guarantee. They successfully lowered the price and increased the product's durability. The volume guarantee was accompanied by funder support for an integrated maternal health program led by CHAI, which included training and mentorship, referral system solutions, and community-based data system strengthening.

While market shaping catalyzed a spike in procurement in 2015, volumes decreased over the following years. Additionally, NASG has struggled to generate the funder and country buy-in needed for scale-up due to challenges with funding, conveying its relative value proposition, and functioning within the constraints of weak health systems. Three demand-related learnings stand out from this retrospective.

Key Learnings

Innovators need support to develop a go-to-market strategy informed by expected payers as early as possible. NASG innovators and advocates invested significant resources to demonstrate NASG's efficacy and effectiveness. However, they lacked a go-to-market strategy that implicated intended payers and decision-makers. Without a go-to-market strategy that ensures it is framed and perceived as intended by target audiences, NASG scale-up has been slower than expected and sporadically funded. Early payer engagement can help inform a product's value proposition and potential market sizing. This is particularly key for niche products.

Clarity on a product's value proposition is integral to understanding and acceptance. NASG was introduced into a service delivery process that already includes multiple interventions to prevent and treat PPH. Compared to first-line treatment protocol products, NASG has a narrower use case as a first-aid device for stabilization. Its relatively high initial investment cost, combined with reliance on and continuous need for other PPH interventions, has deterred buyers. Despite its framing as a complementary tool, its value proposition has not been widely understood or accepted. For instance, the NASG should not be compared to uterotonics, but to the transport options (or lack of) women have to get

to the care they need sooner. In settings where women have delayed access to critical care, the NASG application makes it more likely that they will survive. Its niche and focused use case have been under-appreciated. NASG illustrates the need for new products to demonstrate a clear value proposition to decision-makers relative to preferred standards of care and in the context of the health system.

Funding for health system interventions must accompany product rollout. Funders supported both a volume guarantee to lower the price and improve the durability of the NASG as well as health system strengthening interventions to integrate the product. However, interest in scale-up has been slower than expected among potential payers. The limited support for NASG scale-up reflects a wider challenge in scaling maternal health products: advocacy to date has produced an impact that has not been sustained, and uptake of commodities has been subpar. Expanded access to new and existing maternal health commodities would benefit from a coalition approach that harnesses resources and convening power to drive change.

PULSE OXIMETER RETROSPECTIVE

A pulse oximeter (PO) is a non-invasive and relatively low-cost device that measures blood oxygen saturation and pulse rate. POs can range from basic fingertip devices to more robust, medical-grade handheld devices. POs have the potential to lower mortality and morbidity across a number of disease areas if their use prompts immediate action to provide needed therapy. POs quickly became the standard of care in HICs for surgical purposes, while LMICs lagged behind in uptake. In 2008, the WHO endorsed the PO as a mandatory monitoring tool during anesthesia as part of their Safe Surgery Saves Lives and Patient Safety Pulse Oximetry initiative. Unfortunately, this did not lead to a coordinated, global effort to widely expand access to POs for vital screening and diagnostics outside of a surgical context in LMICs.

The COVID-19 pandemic exposed significant gaps in oxygen access across most countries, particularly LMICs. In 2021, a stakeholder partnership was formed to launch an emergency task force chaired by Unitaid, which mobilized over $700 million in grants to help LMICs procure oxygen supplies. While resource mobilization in response to COVID-19 has catalyzed an unprecedented availability of POs across many low-resource settings and more global awareness about the value of the devices for monitoring and screening, PO utilization is still lower than needed. Key challenges remain in understanding PO demand. These challenges include limited funding and a fragmented buyer ecosystem, lack of information on end-user needs, no clear country-based programmatic champion, lack of quality assurance pathways, limited awareness among health workers, and lack of perceived value among clinical health providers.

One notable challenge recognized and being responded to is that current versions of POs are prone to inaccurate readings on darker skin tones, limiting their applicability in sub-Saharan Africa and parts of Asia. In 2022, researchers at UCSF launched the Open Oximetry Project to improve access to safe pulse oximeters worldwide by sharing data and creating new standards and technologies for oximeter validation that better account for skin color. In collaboration with global partners such as WHO, UNICEF, and PATH, this project supports ongoing efforts to develop tender and procurement guidance and a performance validation mechanism for global and national agencies to identify high-quality POs. Additional innovations in the PO space, even after improved accuracy for darker skin tones, are unlikely to solve the aforementioned system challenges facing current POs unless there is a clear use case and demonstration of value-add, particularly related to the immediacy of action that saves lives.

Future innovations in PO devices must demonstrate improved cost-effectiveness across various clinical applications relative to current diagnostic practices with multiple devices or current POs, improved quality of care, or a quantifiable health impact. Ongoing efforts (e.g., Unitaid's Tools for Integrated Management of Childhood Illnesses) are generating evidence on PO utilization, health impact, durability, and cost-effectiveness in primary healthcare settings, as well as post-market surveillance of the durability and use of POs in field settings. We have synthesized four learnings sparked by the project challenges in this demand story.

Key Learnings

Robust financing options to help local governments purchase at scale are lacking. Governments have been able to acquire POs via donations as part of the COVID-19 response without integrating them into their annual budget, a temporary and unsustainable acquisition strategy. Globally led co-financing options are needed to help local governments

purchase high-quality POs at scale, integrate them into the national budget and health systems, and fund operational costs, maintenance support, and healthcare worker training. The Global Fund is leading this effort by allowing countries to use Global Fund resources for PO procurement and other oxygen needs.

New devices require clear use cases and value-add. Planned or proposed innovations in POs lack a clear use case and do not address health system challenges related to insufficient quality assurance pathways, lack of co-financing options, health worker awareness, and quality data inputs for demand forecasting. There is a need to evaluate the use case and value-add based on current demand challenges before funding the innovation of any new global health products.

Demand forecasting should be more informed by bottom-up information that includes financing considerations. Many national governments lack accurate estimates of their current PO needs. In addition, top-down estimates and the inability to capture willingness and ability to pay limits accurate forecasting based on the SOM. More accurate estimations are necessary from the ground up based on the type of PO, different service delivery levels of the health system, or a demonstrated willingness and ability to pay.

A clear regulatory framework and independent quality assessments are necessary. Independent pathways are lacking to validate and evaluate monitoring tools like POs, leading to the wide availability of low-quality devices in LMICs that do not meet minimum technical specifications. Independent performance validation is needed to indicate to buyers which devices are of high accuracy and durability and will not create additional costs for the health system in clinical errors or replacement devices.

RECTAL ARTESUNATE RETROSPECTIVE

For children under age six with severe malaria, the risk of death is greatest in the first 24 hours. In rural settings, many children die from severe malaria due to long travel times to reach care at health facilities. Rectal artesunate (RAS) is a pre-referral treatment for severe P. falciparum malaria in children under age six intended to fill this gap and prolong the life of children until they can receive injectable artesunate followed by a three-day course of artemisinin combination therapy. In 2006, RAS was recommended by the WHO for pre-referral treatment of severe malaria in remote areas when injectable artesunate is not available.

After the WHO's recommendation, multiple studies looked further into the efficacy of RAS in the field. In response to study findings that RAS actually increased negative outcomes for children above age six, the WHO updated its guidance to only recommend RAS for children under age six with severe malaria who live over six hours away from a referral facility.

Meanwhile, many countries procured non-prequalified RAS for introduction and scale-up as early as 2009. From these country pilots, common challenges emerged when implementing RAS at scale, the most common of which were incomplete referrals from communities to facilities, insufficient training of health workers across levels of care on RAS administration, and difficulties forecasting, supplying, and storing RAS.

Acknowledging these challenges, global funders supported efforts to demonstrate the efficacy of RAS in the field and to understand how to overcome these challenges. A study conducted in Zambia showed RAS' success at reducing mortality of severe malaria when combined with health system changes. However, to generate implementation guidance, RAS needed to be successful in the hard-to-reach community-based settings where expected to have the most impact. To this end, Unitaid launched the CARAMAL project, a project led by CHAI in a consortium with Swiss TPH and UNICEF in Nigeria, Uganda, and the DRC to deliver guidance on effectively operationalizing RAS in the field to overcome the known challenges. In parallel, Unitaid funded Medicines for Malaria Venture to undertake activities to address supply-side barriers—including market entry of WHO prequalified RAS products.

The CARAMAL study generated significant evidence to inform operational guidance on care and treatment for children in hard-to-reach communities across three community health system settings. The study also showed that when RAS is implemented in complex conditions without supportive health systems, the delivery of the product may result in less access to appropriate care and worse health outcomes, raising alarm. Following the release of the CARAMAL study results, the WHO recommended that countries review the conditions of current RAS use and halt further expansion of RAS implementation until further technical guidance can be provided on how to deploy RAS responsibly. We have synthesized four learnings sparked by the project challenges in this demand story.

Key Learnings

The assessment of health system limitations is often minimal. Early pilots on RAS did not assess health system readiness despite evidence of RAS effectiveness in the context of a system able to ensure referrals, transportation, and quality of care at referral sites. RAS effectiveness depends on a continuum of care across different health system levels (e.g., primary and referral facilities). Countries were procuring RAS before it was prequalified, yet no studies that assessed the effectiveness of RAS introduction in real-world settings existed. As soon as recommendations exist for products with identified dependencies on other health system attributes, it is worth investing in implementation studies that assess operational limitations or enablers sooner than later to inform policy and introduction plans. Funders and advocates should evaluate the minimal viable environment required to ensure the product works accordingly.

The true state of community health systems in low-resource settings must be better understood and acknowledged. The RAS patient journey depends on strong community health systems that enable community health workers, caregivers, and patients to navigate a multi-step and multi-setting process to properly diagnose severe malaria, administer a correct RAS dosage, and complete follow-on referral care in a health center. For new interventions at the community level, like RAS, it is important to understand the current sophistication of community health systems, including information on patient journeys between health system levels. Acknowledge when they may not suffice or make investments to raise the standard of care so that the product can have the intended effect.

An overemphasis on solving supply-side barriers exists. Global health funders invested significant time and resources in attaining prequalified RAS suppliers. These efforts responded to gaps identified by the global community at that time.[4] While important, addressing supply barriers alone did not increase access in most cases. Innovators and funders need to watch for the risk of underinvesting in overcoming demand-side barriers, including investment in health system strengthening by funders and organizations with a comparative advantage in that space.

When forecasting niche health products, consider and manage uncertainty. Accurate forecasting of RAS demand can be complicated by a lack of reliable data on the target population, the unpredictability of severe malaria incidence, poor data on RAS consumption, and availability, distribution, and capacity of community health workers. Forecasting accurately is also compounded by the difficulty of disentangling the occurrence of severe malaria versus other severe febrile illnesses that commonly affect children in rural areas. Reducing uncertainty for niche products can occur through investments in data systems so that consumption, incidence, and patient care data can be monitored. Such data can be integrated into iterative forecasts that inform scenarios. Investments should prioritize data collection and use at the community level and ensure process and outcome indicators are trackable across community- and referral-level care. Any uncertainty or updates in new data can inform new conclusions.

4 See product retrospective for complete timeline.

2.3. Key Learnings Across Retrospectives

We extracted six cross-cutting learnings from the product retrospectives.

Figure 5: Six cross-cutting learnings across product retrospectives

1) **A clear product buyer strategy must be developed early on and continuously reassessed, with stage-gating based on payer insights.** Early in development, innovators should develop a payer strategy as part of their critical path. If there is a lack of interest from expected payers, product supporters should (i) adapt the product to what payers signal they are willing to pay for, (ii) explore alternative payer models such as the private sector or a dual market strategy for HICs and LMICs, or (iii) accept that the product may not succeed if it cannot reach intended end-users. Stage gates should exist to reallocate funding or adapt decision-making.
2) **A product's value proposition must be clear to decision-makers and payers in the context of other solutions.** In markets with multiple solutions, especially when upfront investment costs are high or where no funders exist, innovators must clearly articulate a product's value relative to alternatives and standard of care. Focusing on price, user acceptability, or target population size without considering the success or failure of alternative solutions is insufficient. Further, as new solutions emerge, a product's value proposition may need to be repositioned accordingly in that context.
3) **Uncertainty of data when developing forecasts can influence investment pivots or pauses.** Forecasting demand for health products in LMICs is frequently hindered by the limited availability of data on disease incidence or prevalence and populations, poor data surveillance systems, and limited visibility on health system assets or operational considerations like the number of facilities with the availability of needed medical products. Innovators and their advocates must identify ways to manage uncertainty through propagation, such as iteration and scenario planning based on revised assumptions. There should also be transparency about when data is lacking. Uncertainty should be a catalyst to update conclusions about when and how to invest and pivot, including potential pause.
4) **Health system limitations may inhibit product adoption and limit a product's perceived value.** Innovators and their advocates should consider to what extent their product's success relies on the capacity of different health system attributes, such as the health workforce, supply chain, policy environment, and information systems. The robustness of health systems often differs significantly between and within LICs and MICs. Assess health system enablers and inhibitors as part of a due diligence process. Not meeting health system requirements degrades the perceived value of a product. The value may downgrade further if similar products that are easier to implement exist.

5) **In-country Key Opinion Leaders (KOLs) and champions must be engaged from the start of product development.** KOLs and champions are essential for activating demand in the later stages of product development; they are also important for understanding LMIC contexts, political will, patient journeys, and user needs in the earlier stages of development. KOLs can represent a diverse range of interests, for example, regulatory, policy, procurement, and distribution across public and private sectors. Prioritize identifying KOLs early and continuously reassess, reengage, and maintain communication throughout product development. If no product champions exist, it is likely a sign that there will be limited success and uptake, and the product should be redesigned or deprioritized.

6) **When introducing new products or expanding use to new settings, education and awareness for end-users is critical.** At the time of introduction for new products or existing products in new settings, earmark resources for the education, marketing, and awareness of end-users. Without these investments, product misuse can occur, stigma can develop, misinformation can spread, and adoption is unlikely. Proactively use end-user engagement to inform product design and definitions of ideal characteristics. Target product profiles are useful to transparently spell out use cases and operational considerations that most clearly reflect SOM. For products that need specific training and education for users to use the product effectively, innovators should consider the necessary funding as early as possible in product development.

2.4. Highlighted Practices from the Commercial Sector

Private sector healthcare companies, notably in pharmaceuticals, biotech, and medical devices, are incentivized to rigorously evaluate products at multiple decision points based on evidence that suggests a high likelihood of commercial success alongside health impact for patients. The sector is also mindful of feasibility considerations and associated costs. Product development and launch plans rigorously include assessments of TAM, SAM, and SOM for investment decisions. Companies invest in a market access strategy informed by engagement from a wide range of stakeholders across regulatory, policy, payer, and end-user perspectives as early as preclinical stages. Their practices can offer valuable learnings.

Three glaring differences between global health and commercial product development sectors are worth noting: incentives, marketing budgets, and target end-users. Incentives in global health are not linked strictly to profit-minded shareholders, instead complicated by the many agendas between different types of stakeholders and sub-stakeholders within those groups—funders are not a homogenous group, nor are investors or public purchasers. One advisor summarized a notable challenge well: "In industry you look for data that might kill a product, but in global health you look for data that will keep your grant going."

Secondly, new products for global health priorities are rarely accompanied by marketing budgets. In contrast, the commercial sector invests significantly in research to understand the many influences on expected demand, followed by marketing investments necessary to activate and generate demand. Investments in marketing strategies (bolstered by a vibrant market access consulting and data analytics industry that engages target KOLs) informs if a product will make it through.

Finally, commercial actors can choose the type of end-user most likely to pay for and use their products. Their consumer research and payer insight capacity fiercely focuses on SOM, customer segmentation, and target selection based on profitability. In contrast, most global health stakeholders, particularly funders and innovators, are primarily driven by impact and equity concerns. Getting products to people not served by the status quo, especially those who may be difficult and costly to reach, is the north star of global health.

Commercial actors are perceived as non-traditional partners for global health funders, particularly innovators. In fact, pharmaceutical companies often receive scrutiny for not doing more when it comes to equitable access. Nevertheless, they can be valuable partners who can unlock resources and knowledge and expand access. Many commercial companies share access goals with global health funders, with their experiences offering useful lessons. We posit that while the market environment facing global health stakeholders is fundamentally different, more attention to these practices could help optimize relatively limited global health resources. We extracted four key practices from our review of the commercial sector that are worth considering for global health products.

Accept sunk costs as past expenses and make go-forward decisions based on incremental return on investment. Focus less on cumulative investment over time, acknowledging that prior expenses are now sunk cost, and develop

approaches to maximize return on the next dollar invested, including assessing the opportunity cost. A portfolio approach that invests in multiple ideas but only selects a targeted few to move forward could de-risk the chance of failure.

Understand payer and end-user economics early. Assess the complete ecosystem of stakeholders as early as the preclinical stage. For patients, this should include data-driven customer segmentation based on more than just demographic data typically limited to age, gender, and urban/rural setting—it should also include behavior insights through rigorous consumer research (See Supplemental Section 1). For providers, this should include stratification based on their preferences, economics, and value in patient care. For key opinion leaders, this should include mapping of engagement pathways. Seek to understand the evidence payers and regulators expect as early as possible. Articulate a clear value proposition for payers early on to help them understand the costs and benefits of the product.

Leverage partnerships to bring the right capabilities. Be mindful of when it makes sense to build versus buy the required capabilities and on-the-ground connections, considering partnerships where efficiency is higher or where there is a greater likelihood of a favorable outcome. Build multidisciplinary teams or invest in collaboratives devoted to finding strategic partnerships for products in later stages of development to support go-to-market activities, including registration, procurement, and delivery.

Plan scale-up early on. Develop introduction and scale-up plans early in clinical development and reassess continuously. Establish checkpoints at a regular cadence to reevaluate introduction and scale-up preparedness. Agree on investment or funding decisions conditional on product milestones and scale-up progress.

3. INSIGHTS AND ACTIONS TO SUPPORT INNOVATORS

This publication strives to offer insights and actionable ideas that will ultimately accelerate the availability of new life-saving interventions. We provide two types of recommendations to advance this goal. **Best practices** are recommended behaviors to improve how activities and investments are designed and executed. **Ideas to support** are recommended investments that can help optimize the use of limited resources for new product development and introduction. All recommendations are rooted in the baseline need to engage early and regularly with stakeholders who have lived experiences in and with target markets.

3.1. Changing Behavior: Four Individual Best Practices

1) **Apply and advocate for the use of standard definitions of demand.** Complex market factors and varying stakeholder perspectives often cause people to define and perceive demand differently. We recommend that stakeholders align on precise demand definitions before starting work, moving away from an over-reliance on unmet needs and toward serviceable obtainable market sizes. Explicitly and transparently revisit the use of different demand definitions as a product advances through development stages.
2) **Incentivize organizational norms that reward pivots.** Continuation bias and work environments that disproportionately reward product development can inhibit identifying what is needed for product uptake. This behavior dampers the potential to pivot to alternative interventions or stop entirely. It is crucial to cultivate an organizational or team culture of critical reflection, recognizing when activities fall short or do not go as planned, and adapting. To promote this culture, we suggest including reflections on successes and shortcomings on routine team agendas, regardless of how big or small, to reduce the stakes of discussing what may appear to be a vulnerable topic or interpreted as a failure. Additionally, supportive leadership can model adaptive behavior and reward actions that pivot through recognition. Incentivize pivots based on evidence of demand signals so that resources do not continuously flow into products that lack them. Celebrate learnings from pivots as advancements of shared goals to address unmet health needs.
3) **Adopt stage-gating processes.** Despite known, addressable issues that impede uptake, many products are continuously funded and advanced through development. Check the data that undermines rather than supports a particular innovation. We recommend adopting decision-making processes with clear go/no-go milestones that account for demand-related considerations through evidence of SOM. Decision-making processes should embrace sunk costs and lead to a change or stop. Continued investment in product development should be conditional on progress against these milestones. Funders and investors can co-design these stage gates with key stakeholders, including innovators. An effective stage-gating process can benefit from visibility into the histories of similar products paused so that they can be quickly resurfaced as needs evolve (e.g., Wolbachia as a form of vector control). Milestones can change over time if necessary and inform pivots in product launch plans.
4) **Continuously pressure test country-driven demand and purchasing signals.** Global health product development often suffers from insufficient or unclear buy-in signals from local governments and purchasing actors. The lack of clarity may stem from shifting political and economic priorities. We recommend co-defining milestones with key country-based stakeholders responsible for regulatory, purchasing, policy, financing, or contracting functions. Including these perspectives will lead to greater clarity on SAM or SOM.

3.2. Five Ideas for Collective Investment & Spotlights

Our review revealed five mutually-reinforcing investment ideas that can help multidisciplinary groups. Engaging early with stakeholders who understand country-based market dynamics is important for all of these. Understanding what can drive SOM or realized demand is much harder than understanding supply, purely because there is a need to reach and work with so many different country-specific stakeholders. These investment ideas are collective tactics that may streamline and reduce necessary transaction costs.

1) **Enable visibility of market and health system information through existing and non-traditional partners.** Those involved in product development may be limited in their ability to understand health system readiness and the market dynamics of target countries for new products, either due to a lack of resources or networks. Funders routinely fund implementing partners (e.g., non-government or for-profit organizations) with country-based staff with deep expertise in local markets. We recommend incentivizing implementing partners to collect and share market intelligence to benefit innovators early in development. Additionally, invest in forming non-traditional partnerships and ensure end-users are central to development governance processes. Local distributor and wholesaler networks, professional health provider associations, and end-users have valuable market intelligence with untapped potential for product decision-making. More investments should be channeled to rely on and leverage these types of partners. *The MATRIX and MOSAIC spotlight is most relevant to this recommendation.*
2) **Pair product developers and innovators with country-based partners who understand market dynamics.** Small, early-stage innovators often lack the expertise and capabilities to fully understand in-country commercial and market dynamics. We recommend supporting innovators—either directly or through expert partners—with non-financial resources and technical assistance to facilitate a better understanding of local market information that can inform tailored go-to-market strategies. These resources can include stakeholder analysis on influencers versus decision-makers, regulatory and policy pathways, private versus public purchasing actors, distributor networks, and user preferences. *The SAMRIDH spotlight is most relevant to this recommendation.*
3) **Support platforms for innovators to engage early with local governments and other key private sector stakeholders.** Innovators often struggle to understand, let alone integrate into, country agendas and budgets. They may have limited access to political relationships in the public and private sectors. We recommend supporting governments to either build on or develop platforms that bring visibility to needs, priorities, and financing potential for innovators. Multi-sectoral convenings between private and public actors can facilitate connections and signal how products and services are valued. This could be a two-way facilitation process that helps decision makers understand innovators' capabilities and amplifies payer interest in health product innovation. *The PUMANI and NEST360 spotlight is most relevant to this recommendation.*
4) **Support wraparound services necessary for new product introduction.** New innovations can be short-lived when the surrounding environment is ill-equipped for long-term support and sustainable maintenance after introduction. We recommend treating product introduction as a platform rather than a single product. Introduce products in the context of other critical infrastructure necessary to sustain the use of the product over time, such as consumables and maintenance and health system enablers like adequate staff, training, and financing. Key to delivering this is aligning payers (government, funder, and others) intentionally along the chain of needs. This alignment is critical so that government partners are not stranded when funder interests change, which happens more often than admitted. *The PUMANI and NEST360 spotlight is most relevant to this recommendation.*
5) **Aggregate the priorities and demand signals from payers across countries.** Innovators frequently struggle to understand countries changing emphases and environments, leading to untimely introductions and missed opportunities. Global health stakeholders also desire information from multiple countries, which can be challenging to achieve in settings with limited funds, staff, and transparency. We recommend investing in efforts that aggregate intelligence on health innovation priorities across countries. Ideally, this information is regularly updated, but even as a snapshot, such aggregated signaling would enable innovators and advocates to prioritize new ideas in response to clear priorities. *The SMC spotlight is most relevant to this recommendation.*

Many of these ideas are supported in some health areas, and they are mutually reinforcing. For instance, outputs from a country-based innovation platform (Idea 3) could inform a database of aggregated demand signals (Idea 5). Go-to-market strategies informed by local experts (Idea 2) can be tested and validated by intelligence from existing and non-traditional in-country partners (Idea 1). Where are these ideas already working for the health areas you care about most? Which may warrant more attention?

We describe four ongoing projects as spotlights worth tracking to exemplify these recommendations. We recognize that these spotlights may touch on multiple ideas, but we have highlighted one for brevity and emphasis.

SPOTLIGHT: MATRIX AND MOSAIC

Exemplifying idea for collective investment 1: Enable visibility of market and health system information through existing and non-traditional partners

USAID has led the R&D of safe, effective, and affordable biomedical HIV prevention products and technologies for women over the last 20 years. USAID has sought to identify, understand, and remove barriers to new product introduction, access, and usage and convene global, national, and subnational stakeholders to expedite product launch and scale-up while strengthening local partner capacity. In reflecting and building on these multi-decade R&D efforts, USAID realized that impact from product development and access investments was inhibited due to prevailing information gaps about the financing, market and regulatory landscape, and user preferences and acceptance. In response, USAID's HIV Research program staff took a radically different approach when designing MATRIX and MOSAIC in 2019.

MATRIX and MOSAIC are two large-scale five-year HIV prevention programs that support a platform of biomedical product choice to the end-users and inform PEPFAR funding strategies. The two programs focus on two different ends of the product development pathway: MATRIX focuses on advancing the R&D of innovative HIV prevention products, while MOSAIC focuses on innovative and adoptable approaches to facilitate the introduction and access of soon-to-market prevention products.

The projects focus on understanding the value proposition of new products and applying that intelligence to target investments. They incorporate information about end-user preferences, regulatory pathways, and market dynamics at various stages of product development. This approach exemplifies our recommendation to ensure any information on health system readiness and user preferences is shared with product developers as early as possible and ongoing.

MATRIX adopts a rigorous product portfolio assessment to prioritize product investments based on criteria that indicate the likelihood of PEPFAR adoption. The criteria used are supported further by the product's potential for value creation (based on the expansion of product choice, the eligible target population, the expected efficacy and safety profiles), the probability of technical and regulatory success, the anticipated attractiveness and accessibility to potential users, and the ease of introduction and scale-up. MATRIX product developers receive support from several cooperatively coordinated hubs to address these criteria. For example, the Business Market Dynamics and Commercialization Hub (BACH) under MATRIX helps product developers refine their go-to-market strategies, develop their business cases and access plans, and identify complementary resources to advance products to market. Additionally, the MATRIX Design to Delivery HUB engages end-users and stakeholders through participatory research to gather insights on preferences and perspectives of HIV prevention products, ultimately aiming to support product development that aligns with the needs and desires of those using the products. As a product in MATRIX progresses through product development to market availability, MOSAIC works closely with all in-country stakeholders to accelerate product introduction and access.

Both projects strategically engage with country-based stakeholders to derive early insights into product acceptability and health system readiness. For example, MATRIX ensures that early-stage clinical trials occur in sub-Saharan African countries, and leadership includes country-based research investigators. MOSAIC not only supports youth advocates in an official advisory capacity to inform user acceptability, but it also facilitates unprecedented opportunities to convene traditionally disparate stakeholders at local and global levels—end-users, regulatory bodies, policy leaders, and product developers. These convenings provide a platform for multidisciplinary stakeholders to align priorities, share concerns, and troubleshoot.

Time will tell whether the new approaches under MATRIX and MOSAIC will improve results. Significant uncertainty on available funding and potential funding policy shifts makes it impossible to accurately plan. However, the intention is for both projects to mitigate against the challenges commonly identified too late and optimize the chances of new products being used at scale.

SPOTLIGHT: SAMRIDH

Exemplifying idea for collective investment 2: Pair product developers and innovators with local partners who understand market dynamics

SAMRIDH is an example of pairing innovators with partners with go-to-market commercial expertise. SAMRIDH is an India-based blended healthcare financing facility that works with USAID and global and in-country partners to support Indian healthcare innovators. Selected innovators receive business advisory and financing support through SAMRIDH's public and private sector stakeholder network. This network helps provide access to market intelligence, financial resources, and technical know-how to optimize product development and introduction for innovators. At the time of publication, SAMRIDH has supported over 35 businesses with more than $13 million in USAID grants that leveraged 10 times the investment from debt financing (e.g., loans) from private sector financial partners. Grant funding de-risked the investment from private sector partners by ensuring cash flow.

In addition to business advisory and investment support, SAMRIDH organizes cross-cutting initiatives to foster an inclusive innovator environment in India. For example, SAMRIDH organizes knowledge-sharing sessions for innovators on best practices for selling to the public sector through the Government e-Marketplace and facilitates partnerships with Atal Innovation Mission, the government's flagship initiative to create and promote a culture of innovation and entrepreneurship.

As an example of SAMRIDH's impact, SAMRIDH supported a small group of Indian innovators who developed a low-cost medical device to address non-communicable diseases in low-resource settings. Before working with SAMRIDH, the innovator initially oversized the addressable market for their device based on inaccurate assumptions about the payer (assumed public sector would pay for a low-cost option) and product adoption behavior (assumed displacement of existing devices). This overestimation amounted to a misunderstanding of the SAM and SOM for this medical device (see definitions in Section 1.2). The Indian public sector had strict requirements for medical devices not met by the low-cost option and little interest in switching products in low-resource settings already saturated with low-cost options. Together, these resulted in a much smaller obtainable market for the product than anticipated.

SAMRIDH equipped the innovator with financing and business advisory support to iterate and refine its value proposition for target customers, cultivate a market strategy to better position the product against competitors, define new growth avenues for the product (i.e., private sector in LMICs outside India), and understand how to engage buyers in those markets.

Many small innovators are in a similar position, lacking the required resources and expertise to do market research, market sizing, competitive positioning, payer analysis, go-to-market strategy, and marketing necessary to introduce and scale a product. SAMRIDH is an example of a multidisciplinary funding mechanism that supports innovators in assessing business needs and accessing market intelligence for strategic decision-making. SAMRIDH's mixed model of mobilizing public and private capital while offering innovators the business support needed could be translatable to other LMICs.

SPOTLIGHT: PUMANI/NEST360

Exemplifying idea for collective investment 3 & 4: Support platforms for innovators to engage with local governments and other key private sector stakeholders early on and support wraparound services necessary for new product introduction

Pumani is a bubble Continuous Positive Airway Pressure (bCPAP) system to treat infants with respiratory distress syn-

drome in the developing world. The system delivers a blended flow of oxygen and room air. Among approximately one million neonatal deaths in LMICs due to preterm birth complications, about 45% can be attributed to respiratory distress syndrome.[5] Conventional bCPAP systems in HICs can be cost-prohibitive to most health facilities in LMICs.[6] As a result, many infants risk inadequately regulated oxygen care that may result in long-term complications such as retinopathy of prematurity and chronic lung disease.[7] In 2007, Rice University's Rice360 Institute for Global Health commercialized and brought Pumani to market in Malawi. Pumani was one of the first bCPAP devices specifically designed for low-resource settings with a more affordable price point.

Pumani, in the context of NEST360, exemplifies recommendations 3 and 4 in its early engagement with country-based commercial and public actors and its product introduction through wraparound services. Early on, Rice360 partnered with 3rd Stone Design to achieve regulatory approval, prototype and manufacture the product, and establish and leverage country-based distribution networks. 3rd Stone Design specializes in helping innovators take their products from design to commercialization. Rice360 realized that despite a need for new medical devices for newborn care in LMICs, many go unused due to weaknesses in the surrounding health system. In response, in 2019, Rice360 launched an international program called Newborn Essential Solutions and Technologies (NEST360).[8] This comprehensive approach includes upstream activities to inform R&D, such as target product profiles, technology landscapes, and key opinion leader engagement; it includes downstream activities to support adoption, including health system planning like regulatory, financing, and quality monitoring. This approach also has implementation support like training, quality improvement, and distributor engagement for product launch strategy. Collaborative, global advocacy efforts accompanied the launch of NEST360 to strengthen the quality of care for small and sick newborns through updated global guidance and targets.[9]

The NEST360 approach proved instrumental in the scale-up of Pumani in the Malawi health system. Pumani is currently in every government, central, and district hospital.[10] While 90% of the devices were donated, the Malawi government supports training, quality improvement, and ongoing maintenance services. From 2022, the Malawi government has committed to using government funding to procure Pumani from the local distributor.

Pumani's iterative go-to-market approach of relying on insights on innovative product introduction from country-based stakeholders and offering wraparound services has ensured that the product successfully integrates into health systems rather than ending up in a product graveyard.

SPOTLIGHT: SEASONAL MALARIA CHEMOPREVENTION (SMC)

Exemplifying idea for collective investment 5: Aggregate priorities and demand signals from payers across countries

Seasonal Malaria Chemoprevention (SMC) is an intervention that reduces the risk of malaria transmission for young children in malaria-endemic settings with seasonal transmission. Since its WHO approval in 2012, the usage of SMC has skyrocketed, increasing protection from about 200,000 children to more than 45 million children. Significant resources were invested early to assess interest among target adopters (country governments), facilitate collaboration between multidisciplinary stakeholders, and iterate on product attributes in response to end-user preferences. As of 2022, coverage of the target population in the Sahel is nearly saturated, and demand has outpaced forecasts.

The success of the SMC demand story exemplifies the importance of our fifth recommendation. Firstly, regional working groups affiliated with the Roll Back Malaria Partnership to End Malaria across West and Central Africa (RBM) played a

5 Ekhaguere OA, Okonkwo IR, et al. Respiratory distress syndrome management in resource limited settings-Current evidence and opportunities in 2022. *Front Pediatr*. 10:961509; Perin J, Mulick A, Yrung D, et al (2022) Global, regional, and national causes of under-5 mortality in 2000–19: an updated systematic analysis with implications for the Sustainable Development Goals. *Lancet Child & Adolescent Health* 6(2): 106-115.

6 Kinshella MLW, Walker CR, et al. Barriers and facilitators to implementing bubble CPAP to improve neonatal health in sub-Saharan Africa: a systematic review. Public Health Rev 41, 6 (2020).

7 Healthy Newborn Network Website. Safe and Effective Oxygen Use for Inpatient Care of Newborns.

8 Nest360 Website. Accessed Nov 16, 2022.

9 These include: Survive and Thrive (WHO and UNICEF, 2019). Standards for improving quality of care for small and sick newborns in health facilities. Geneva: World Health Organization; 2020. Every Newborn Action Plan 2014 (updated in 2020 to include quality care targets for inpatient newborn care for small or sick newborns).

10 Robert Lerose. "The Professor With a Genius For Global Health". Smithsonian Mag. Sep 7, 2017.

critical role in engaging country-level decision-makers to generate interest in and understand inhibitors and enablers of SMC introduction. These working groups facilitated dialogue within and between countries, global funders, civil society, and suppliers. They aggregated intelligence on demand signals (e.g., SOM) to inform suppliers, developed evidence and advocacy materials, and catalyzed large-scale resource mobilization efforts. Close coordination amongst the U.S. President's Malaria Initiative, the Global Fund, and UNICEF as major procurers and providers of implementation support, together with countries placing their own SMC orders, has been critical to ensuring production availability meets country timelines for impactful implementation of this seasonal intervention. SMC is also a rare example of countries borrowing funds from development banks to scale adoption and successfully advocating before prequalification for the Global Fund to fund the product.[11]

RBM, alongside the Malaria Consortium-led Access-SMC project funded by Unitaid in 2015, pooled evidence that demonstrated what it takes operationally to roll SMC out at scale: door-to-door campaigns led to the best coverage and better value given this higher coverage, SMC was acceptable to communities through delivery campaigns led by local community health workers equipped to reduce misinformation and troubleshoot patient concerns, and would not drive up the drug resistance.[12] Access-SMC ensured that manufacturers received information about SOM, consumption data, and qualitative feedback on what would increase product acceptability. Unitaid funded Medicines for Malaria Venture to work with suppliers to adapt the product iteratively in response to user feedback to increase acceptability through developing a dispersible pill that could dissolve in water, blister packaging for easy administration, and product sweetening to improve digestibility among children.[13] Technical support helped countries target SMC deployment to the highest-need areas.

Pooling information iteratively on evidence, expected consumption, and preferences amongst multidisciplinary stakeholders accelerated the availability and use of SMC products. Future demand for SMC is expected to grow due to a variety of factors, such as increased eligibility due to expanded age (for children up to 10), geographies (for countries outside the Sahel), and the need for additional doses that better align with lengthened rainy seasons driven by climate change.[14] This growth to different contexts will require considering how SMC will fit within a broader package of malaria prevention tools (including vector control and other chemoprevention and vaccination efforts) to ensure equitable access to SMC. Continued pooling of information as demand for SMC evolves will be critical.

11 The Global Fund Expert Review Panel approved SMC for procurement in 2016. It was prequalified by WHO in August 2018. Access-SMC Partnership (2020). Effectiveness of seasonal malaria chemoprevention at scale in west and central Africa: an observational study.

12 Ibid.

13 Ding, et al (2019). Adherence and Population Pharmacokinetic Properties of Amodiaquine When Used for Seasonal Malaria Chemoprevention in African Children; Access-SMC Partnership (2020). Effectiveness of seasonal malaria chemoprevention at scale in west and central Africa: an observational study.

14 World Health Organization (2022). WHO Guidelines for Malaria.

CONCLUSION

Understanding demand for new global health products can be a colossal challenge. The breadth of different stakeholders motivated by different incentives can be overwhelming. Our review of how demand is discerned highlights why using precise terms based on stakeholder consensus is invaluable for alignment and progress. We will collectively be better if we can pay more attention to understanding the market conditions necessary to enable a product's likely reach rather than just how it can address an unmet need.

In this effort, we brought some of the largest funders and investors in global health together to reflect on what we observe as common pitfalls. We extracted insights from product retrospectives and considered broader implications for the hundreds of new products coming down the pike. While recognizing key differences, we think there are practices from the commercial biotech and pharmaceutical sectors that the global health sector can pay attention to.

Our review and iterative analyses led to nine mutually reinforcing recommendations that we believe are worth amplifying and adopting: four individual best practice behaviors and five ideas for collective investment. These behaviors—using definition precision, rewarding pivots, stage-gating, and using and pressure testing demand signals—are not silver bullets but are designed to catalyze a change in how we think, collaborate, and invest our limited resources. Many ideas for collective investment are already taking place across different health areas, as exemplified in the spotlights. But we need to do more. We need to invest more in working with diverse groups of local stakeholders who can speak to user needs and market dynamics. Collectively, we need to facilitate connections between these local market experts and those responsible for product development and manufacturing as early and iteratively as possible to improve decision-making. We must get comfortable with pivoting, pausing, or discontinuing a product's development.

We encourage readers to consider these recommendations in the context of other market access resources for global health products, referenced in the accompanying Supplemental. The Supplemental also includes a broader list of resources for product introduction designers and implementers, including a landscape review of commonly used quantitative and qualitative approaches to assess demand, advice on making the most of those tools, and expanded product retrospectives.

Finally, this publication's focus on demand was intentional, as it is laden with assumptions and misconceptions. However, we recognize that understanding demand is necessary but insufficient on its own and that there are many other critical, interrelated components to launch new global health products. We hope that our insights on ways to understand, use, and collaborate around demand can advance those efforts and ultimately help translate R&D discoveries into life-saving health products that reach communities most in need.

ANNEX

1.1. Methodology and Approach

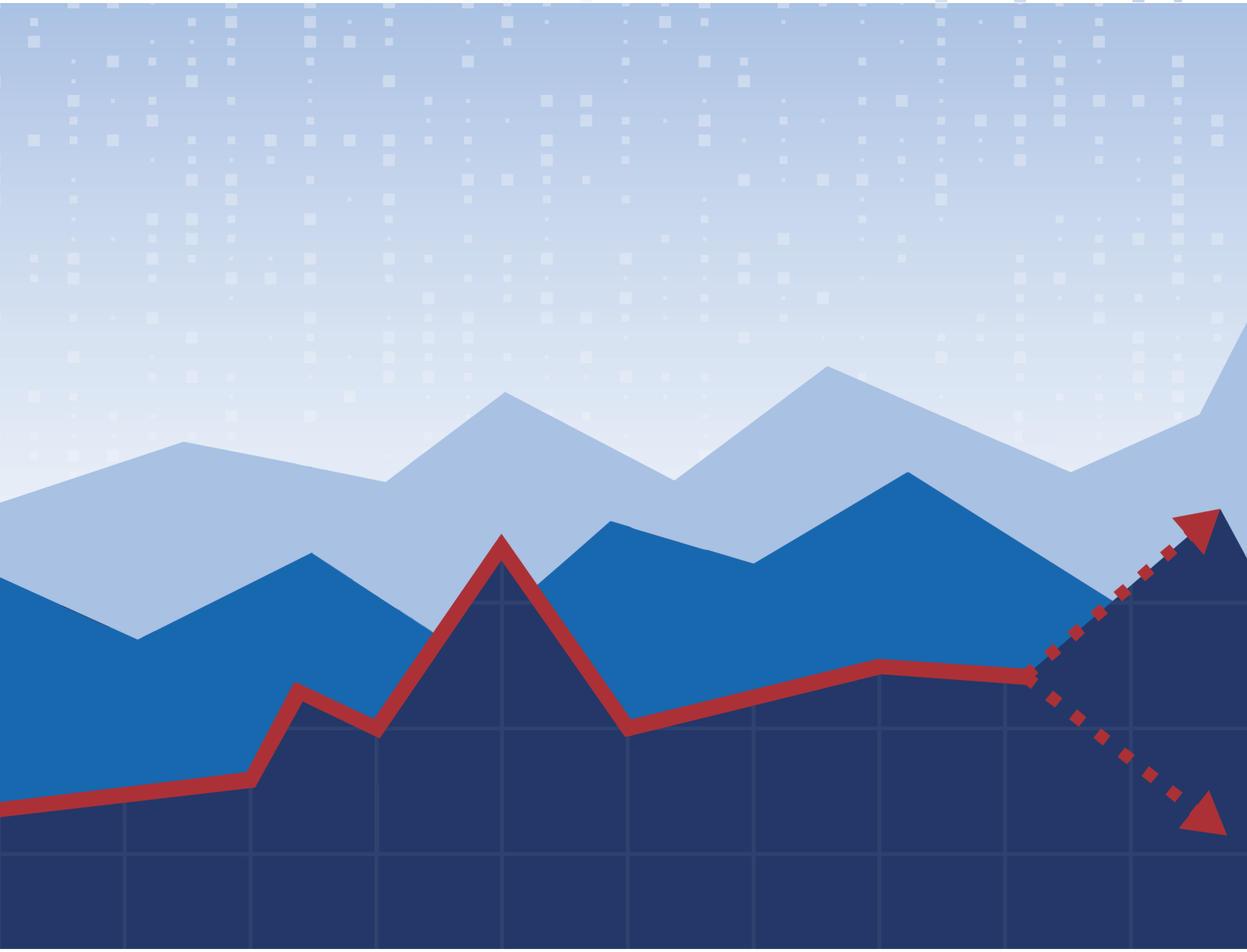
Our approach crowdsourced insights from leading funders, investors, and thought leaders that support product development for global health priorities, including USAID, BMGF, CIFF, Unitaid, UNICEF, Cross Border Ventures, Duke Global Health Innovation Center, and Institute for Transformative Technologies. We generated additional insights from over a dozen technical experts across the Global Health Bureau and 100 key informant interviews from global and country-based stakeholders to develop this publication and the accompanying Supplemental.

Boston Consulting Group (BCG) supported USAID's Center for Innovation and Impact in developing this publication. BCG brings extensive experience supporting private sector client work on critical issues related to new product introduction, including market acceleration in emerging economies and product launches for pharma and medical technology companies. BCG's clients in the healthcare space include 20 of the top 20 pharma companies and 19 of the top 20 MedTech companies, as well as smaller players across developed and emerging markets.

In addition, BCG has provided extensive support to innovators in low-resource settings to understand market dynamics and prepare for product launch and scale-up. This work includes direct innovator support through several USAID-funded Grand Challenges for health, acceleration of African healthcare ventures through the Home Grown Solutions (HGS) Accelerator for Pandemic Resilience, and longer-term tailored support to the leading climate-smart solutions through Green Ventures Africa.

1.2. Organizations Consulted for This Review

3rd Stone Design
ATscale Global Partnership
AVAC
Avenir Health
Baraka Impact Finance
Children's Investment Fund Foundation (CIFF)
Clinton Health Access Initiative (CHAI)
Consortium for Affordable Medical Technologies (CAMTech)
Cross-Border Impact Ventures
Dalberg Global Development Advisors
Duke Global Health Innovation
Every Breath Counts
Family Health International (FHI360)
GlaxoSmithKline (GSK)
Grand Challenges Canada (GCC)
Institute for Transformative Technologies (ITT)
Laerdal Foundation
LifeWrap
Linksbridge
Market Access Africa
Masimo
Medicines for Malaria Venture (MMV)
NEST360
PATH
U.S. President's Malaria Initiative (PMI)
Global Health Supply Chain-Procurement and Supply Management (GHSC-PSM)
PSI
Rice360
RTI International
SEMA Reproductive Health
Strides Pharma Science Limited
U.S. Agency for International Development (USAID)
UC San Francisco
UNICEF
UNICEF Supply Division
Unitaid
United Nations Population Fund (UNFPA)
USAID Global Health Supply Chain
VIA Global Health
Vissco Healthcare Private Limited
WHO Innovation hub
World Health Organization (WHO)



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